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# DECISIONS OF 97<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 28-08-2025 (PART-I MDL&R PORTAL AGENDA)

97<sup>th</sup> meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 28<sup>th</sup> August, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
5.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member (attended meeting through videolink)
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
7.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
8.	Prof Dr M Nadeen Ahmed, Department of radiology, Agha Khan Unicersity Hospital,	Member (attended meeting through videolink)
9.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)

10.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert
		(attended meeting through videolink)
11.	Asif Jalil, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Zia Ullah	Deputy Director-V
6.	Mr. Muhammad Ashfaq	Deputy Director-VI
7.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
8.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
9.	Mr. Muhammad Amin	Deputy Director-IX

The meeting commenced with the recitation of the Holy Quran. The Chairman, MDB welcomed all the participants. The Evaluators assisted the secretary in presenting the agenda of the meeting.

#### Item No. I. CONFIRMATION OF MINUTES OF 96th MEETINGS OF MEDICAL DEVICE BOARD.

Decision: The Board confirmed the minutes of 96th meeting of MDB.

**License Meeting Agenda** 

#### **Import License Agenda**

**Evaluator Name: Muhammad Amin (Evaluator-IX)** 

S.#	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	Name of Establishment: IUK SURGICALS  Office Address: 1ST FLOOR A-31 AND A-13 ,ALFATAH MEDICAL CENTRE G.T ROAD PESHAWAR	Name: ZIA UL ISLAMbright CNIC No: 2150227025257 Qualification: MASTER IN CHEMISTRY Experience: STORE INCHARGE (from	Destination: CEO Name: INAYAT ULLAH KHAN CNIC No: 1730187637673	Rejected. The firm failed to comply with the requirements of medical devices rules 2017 for appointment of technical staff as per aforesaid Rules.  The firm may apply a fresh

	Godown Address: A- 13,G.T ROAD AL-FATAH MEDICINE CENTRE ,PESHAWAR.KPK PAKISTAN Fee: Rs 25000/- Date of Submission: 01 August 2025 Tracking ID:MDMC- 250801-11728	May 2024 to June 2025)	(MIS)	once all the conditions are met.
2	Name of Establishment: Global Traders  Office Address: 1st floor Tehzeeb Furniture & Home Decor, Opposite Honda North University Road  Godown Address: 1st Floor Tehzeeb Furniture, Opposite Honda North University Road  Fee: Rs 25000 /- Date of Submission: 28 July 2025  Tracking ID:MDMC- 250728-11328	Name: Muhammad Wajid CNIC No: 1730186706067 Qualification: Master of Computer Science Experience: Technical Qualified Engineer (from January 2018 to N/A)	Destination: Owner Name: Haroon Ur Rashid CNIC No: 1730110421727	Deferred for appointment of qualified person as per requirements pf Medical Devices Rules, 2017.
3	Name of Establishment: Tokyo Electronics  Office Address: Shop 9,Block A,Awami Market Karkhanu Peshawar  Godown Address: Shope 9,Block A Awami Market Karkhanu Peshawar  Fee: Rs 26100/- Date of Submission: 05 August 2025  Tracking ID:MDMC- 250805-11890	Name: Raza Khan CNIC No: 1420175836571 Qualification: B Pharmacy Experience: Pharmacist Incharge (from January 20 to August 2023)	Destination: Owner Name: Sadam Hussain CNIC No: 2120303992779	Rejected. The board noticed that the applicant has applied for grant of license on a wrong address and inspector was unable to verify the facility/ godown.  The firm may apply afresh for grant of ELI with correct address.
4	Name of Establishment: S4S Emporium Pvt. Ltd	Name: Abdul Qudoos	Destination: CEO	Rejected as the inspector informed that the firm was

	Office Address: B-1 6th sunset lane, Extension Phase 2 ,DHA, KHI Godown Address: RB 3-19-1,G-1A,Strachen Road Near Daily Aman Newspaper,Pakistan Chowk Fee: Rs 25000/- Date of Submission: 23 July 2025 Tracking ID:MDMC-250723-10903	CNIC No: 4220166731661  Qualification: B.Pharmacy  Experience: Warehouse Incharge (from July 2025 to N/A)	Name: Muhammad Saleem  CNIC No: 4200004484957  Destination: Director  Name: MUHAMMAD SALMAN SALEEM  CNIC No: 4200094720601	not ready at the time of inspection.  The firm may apply afresh once ready for inspection.
5	Name of Establishment: RAD HEALTH SOLUTIONS (SMC- PRIVATE)  Office Address: House # B-131, Block03, Gulistan- e-Johar, Karachi, -, -, Pakistan  Godown Address: B-131, Ground Floor, Block 03 Gulistan-e-Jauhar Karachi.  Fee: Rs 25000/- Date of Submission: 19 July 2025  Tracking ID:MDMC- 250719-10160	Name: Sabbar Ahmed CNIC No: 4230107417885  Qualification: 17 March 2025  Experience: Manager - Business Development and Regulatory Affairs (from April 2025 to N/A)	Destination: Owner  Name: Kaleem Khan  CNIC No: 4200005058419	Approved
6	Name of Establishment: MEDSHOP  Office Address: H. No. 172-A, Shotar Mohallah Sadar Bazar Lahore Cantt  Godown Address: H. No. 172-A, Shotar Mohallah Sadar Bazar Lahore Cantt Lahore  Fee: Rs 25000 /-  Date of Submission: 07 August 2025	Name: Samia Habib CNIC No: 3520059660488 Qualification: Doctor of Pharmacy Experience: Pharmacist (from May 2024 to July 2025)	Destination: Partner Name: Abdur Rehman Jamil CNIC No: 5440047725087 Destination: Partner Name: Ashfaq Ahmad Awan CNIC No:	Rejected as the inspector informed that firm was not ready for inspection and technical staff was not available.  The firm may apply afresh once ready for inspection

	<b>Tracking ID:</b> MDMC-250807-12103		3520064592509	
7	Name of Establishment: Bright Health Care  Office Address: Millat Town, Ghona Road, Opp. Brain School System  Godown Address: House no. 80, Alnoor Town, Main Ghoona Road, Near Brain School System, Millat Road, Faisalabad  Fee: Rs 25000/- Date of Submission: 26 July 2025  Tracking ID:MDMC- 250726-11250	Name: Muhammad Arsal Rafiq CNIC No: 3310080803273 Qualification: 3 July 2024 Experience: Pharamcist (from December 2024 to N/A)	Destination: CEO Name: Muhammad Ali Ather CNIC No: 3310079601211 Destination: Partner Name: Abdullah Amjad CNIC No: 3310043812529	Rejected as the inspector informed that firm was not ready at the time of inspection.  The firm may apply afresh once ready for inspection.

#### Local Manufacturer Site Verification Agenda Evaluator Name: Muhammad Amin (Evaluator-IX)

S.#	Name of Establishment along with address	CEO/ Director /Proprietor (s) details	Minutes/Decision
1	Name of Establishment: MEDICARE MEDICAL DEVICES PVT. LTD.  Office Address: 32 KM, MULTAN ROAD, SHAMKEY BHATTIAN, LAHORE.  Factory Address: 32 KM, MULTAN ROAD, SHAMKEY BHATTIAN, LAHORE.  Fee: Rs 9000 /-  Date of Submission: 31 July 2025  Tracking ID:MDSV-20250801-01321	Destination: CEO Name: HAMZA SAJJAD CNIC No: 3520286084973 Destination: Director Name: SAJJAD AHMAD CNIC No: 3520229775921	Approved site.
2	Name of Establishment: SURGICARE  Office Address: Street 4, Office I-316, Malik Sher Ahmed Shadi Hall, Chittian Hattian, Near Committee Chowk  Factory Address: Office I-316, Street 4, Mohalla Qutab Ud Din, Malik Sher Ahmed Building, Near	Destination: CEO Name: Muhammad Tayyab CNIC No: 6110188897793	The Board Rejected the Site due to the reason that site is not suitable for establishment of medical device manufacturing facility.

committee Chowk Rawalpindi Punjab Pakistan

Fee: Rs 128500 /
Date of Submission: 11 August 2025

Tracking ID:MDMC-250811-12459

#### **Product Meeting Agenda**

#### AGENDA FOR CLASS A MEDICAL DEVICES

Evaluator Name: Waqar Ahmed (Evaluator-II)

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/ Decision
1	United Brothers Office # 301, Mehrab Market, Medicine Street No. 1, Marriot Road, Karachi., Karachi Fee: Rs 6000/- Challan No.: 4056557258 Date of submission: 30 July 2025 Tracking ID: MDMR-20250730-00031	Legal Manufacturer (as per FSC) WUXI MEDICAL INSTRUMENT FACTORY CO., LTD. Address: No: 43 Xixin Road, Zhangjing, Xibei town, Wuxi city, Jiangsu, 214194 China ISO 13485 Issue Date: 2024-03-20 Validity Date: 2027-03-18 Notarization Status: Yes, by CCPIT EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: 2024-05-23 Validity Date: 2028-12-31 Issuing Authority: TÜV Rheinland LGA Products GmbH • 51105 Köln Attestation Status: FSC Issue Date: 2025-06-20 Validity Date: 2027-06-20	Brand Name:  UB MERCURY FREE CLINICAL THERMOMETER Generic Name:  MERCURY FREE CLINICAL THERMOMETER Class A Shelf life/service life: 60 Months Codes/Sizes (if any): Mercury free thermometer CR.W00/Large size Specify grouping: Single Storage condition: Store in dry, cool and clean place. Protect from Moisture, heat and sun light	Approved

		Y . A		
		Issuing Authority: Jiangsu Medical Products Administration		
		Attestation Status: Apostille		
		Issue Date: 2025-06-20		
		Validity Date: 2027-06-20		
		Issuing Authority: Jiangsu Medical Products Administration	3) 25:11	
		Attestation Status: Apostille	4) 01:20	
		Issue Date:	001	
		Validity Date:	OF	
		Issuing Authority:		
		Attestation Status:		
		LOA		
		Issue Date: 2025-05-28		
	,	Validity Date: 2030-05-27		
		Notarization Status: Yes, CCPIT		
		Legal Manufacturer (as per FSC)		٠
		Jiangsu HXRT MD Co., Ltd		N
	Chohan & Company	Address: No.66 Xingyuan Road, the Modern Science and Technology Industrial Area, Jiangyan District, Taizhou City, 225300, Jiangsu, China	Brand Name: TUBER VAC MERUX NYCOTECH	•
	21 BAHADURABAD	ISO 13485	Generic Name:	
	BLOCK 2, Karachi,	Issue Date: 2023-09-06	LITHIUM HEPARIN	
	Karachi	Validity Date: 2026-08-12	Class A	
2	Fee: Rs 6000 /- Challan No.:	Notarization Status: PAKISTAN APOSTILLE	Shelf life/service life: 36 Months	Approved
	6928878317	FSC	Codes/Sizes (if any):	
	Date of submission: 23 July 2025	Issue Date: 2025-03-31	N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML,	
	Tracking ID: MDMR-	Validity Date: 2027-02-14	7ML, 8ML, 9ML, 10ML	
	20250723-00028	Issuing Authority: Jiangsu Medical Products Administration	Specify grouping: Single Storage condition:	
	4	Attestation Status: PAKISTAN APOSTILLE	ROOM TEMPERATURE	
	AC	Issue Date:		
	Meg	Validity Date:		

		Issuing Authority: Attestation Status: Issue Date: 2025-03-31 Validity Date: 2027-02-14 Issuing Authority: Jiangsu Medical Products Administration Attestation Status: PAKISTAN APOSTILLE LOA Issue Date: 2025-01-01	5) 5) 5) 5) 5) 5) 5)	
		Validity Date: 2031-12-31 Notarization Status: PAKISTAN APOSTILLE		
3	United Brothers Office # 301, Mehrab Market, Medicine Street No. 1, Marriot Road, Karachi., Karachi Fee: Rs 6000 /- Challan No.: 082457613556 Date of submission: 30 July 2025 Tracking ID: MDMR- 20250730-00028	Legal Manufacturer (as per FSC) WUXI MEDICAL INSTRUMENT FACTORY CO., LTD. Address: No: 43 Xixin Road, Zhangjing, Xibei town, Wuxi city, Jiangsu, 214194 China ISO 13485 Issue Date: 2024-03-20 Validity Date: 2027-03-18 Notarization Status: Yes, by CCPIT FSC Issue Date: 2025-05-20 Validity Date: 2027-05-19 Issuing Authority: China Chamber of Commerce for Import & Export of Medicines & Health Products Attestation Status: Apostille Issue Date: 2025-05-20 Validity Date: 2027-05-19 Issuing Authority: China Chamber of Commerce for Import & Export of Medicines & Health Products Attestation Status: Apostille	Brand Name:  UB ALCOHOL SWAB  Generic Name:  Alcohol Pads/Swab  Class A  Shelf life/service life: 60  Months  Codes/Sizes (if any): D- 010, D-012, D-013, D- 014, D- 016/65x30mm,65x56mm ,90x45mm,56x30mm, 150x110mm, 60x30mm and 58x30mm etc  Specify grouping: Single  Storage condition: Store in dry, cool and clean place. Protect from Moisture, heat and sun light	Deferred for submission of FSC from concerned regulatory authority of medical devices having applied product

		Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: 2025-05-28 Validity Date: 2030-05-27 Notarization Status: Yes, by CCPIT	31) 9:55:11 A	
37-0 Buk Com D.H Pak 4 Fee Cha 935 Date July	M. Distributors.pk C, 4th Floor, Lane-8, khari mmercial, Phase-VI, H.A. Karachi, kistan, Karachi e: Rs 6000 /- allan No.: 55381939 te of submission: 31 y 2025 acking ID: MDMR-250731-00010	Manufacturer M/s Anhui Tianrun Medical Packaging Material CO., LTD. Address: Located at No.29 Chaoyang Road, Yixiu District, 246003 Anqing City, Anhui Province, People's of Republic of China ISO 13485 Issue Date: 2024-08-24 Validity Date: 2027-08-23 Notarization Status: EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: 2025-02-28 Validity Date: 2027-02-27 Issuing Authority: Attestation Status: APOSTILLE Issue Date:	Brand Name: Gussetted Reel Generic Name: Heat Sealing Gussetted Reel Class A Shelf life/service life: 5 Years Codes/Sizes (if any): TRHGR075,TRHGR100, TRHGR150,TRHGR200, TRHGR250,TRHGR300, TRHGR350,TRHGR400, TRHGR450,TRHGR500/ 75mm X 100m,100mm X 100m,150mm X 100m,200mm X 100m,200mm X 100m,300mm X 100m,300mm X 100m,350mm X 100m,350mm X 100m,450mm X 100m,450mm X 100m,500mm X 100m Specify grouping: Single Storage condition: Room Temperature	Deferred for submission of FSC from concerned regulatory authority containing the applied product

		Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: 2024-06-21 Validity Date: Notarization Status: APOSTILLE	5025.9:55:17 A	
2 B K F S C S S D J I	Chohan & Company 21 BAHADURABAD BLOCK 2, Karachi, Karachi Fee: Rs 6000/- Challan No.: 5150960301 Date of submission: 23 fuly 2025 Fracking ID: MDMR-20250723-00027	Legal Manufacturer (as per FSC) Jiangsu HXRT MD Co., Ltd Address: No.66 Xingyuan Road, the Modern Science and Technology Industrial Area, Jiangyan District, Taizhou City, 225300, Jiangsu, China ISO 13485 Issue Date: 2023-09-06 Validity Date: 2026-08-12 Notarization Status: PAKISTAN APOSTILLE EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: 2025-03-31 Validity Date: 2027-02-14 Issuing Authority: Jiangsu Medical	Brand Name:  TUBER VAC MERUX SAS NYCOTECH GMBH  Generic Name:  BLOOD COLLECTION TUBE (Separation Gel + Coagulant)  Class A  Shelf life/service life: 36 Months  Codes/Sizes (if any): N/A/1ml, 1.6ml, 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml  Specify grouping: Single Storage condition: ROOM TEMPERATURE	Approved

		Products Administration		
		Attestation Status: PAKISTAN APOSTILLE		
		Issue Date:		
		Validity Date:		
		Issuing Authority:	6)(1)	
		Attestation Status:	(2)	
		Issue Date: 2025-03-31	(1) 9:3	
		Validity Date: 2027-02-14	JO,	
		Issuing Authority: Jiangsu Medical Products Administration	Or	
		Attestation Status: PAKISTAN APOSTILLE		
		LOA		
	,	Issue Date:		
		Validity Date:		
		Notarization Status:		
		Legal Manufacturer (as per FSC)		
	20	Jiangsu HXRT MD Co., Ltd	Brand Name:	
	Megr	Address: No.66 Xingyuan Road, the Modern Science and Technology	TUBER VAC MERUX NYCOTECH	
	Chohan & Company	Industrial Area, Jiangyan District, Taizhou City, 225300, Jiangsu, China	Generic Name:	
	21 BAHADURABAD	ISO 13485	Plain Tube (No Additive	
	BLOCK 2, Karachi,	Issue Date: 2023-09-06	Tube)	
	Karachi Fee: Rs 6000 /-	Validity Date: 2026-08-12	Class A	
6	Challan No.: 87051308	Notarization Status: PAKISTAN APOSTILLE	Shelf life/service life: 36 Months	Approved
	Date of submission: 23	EC Certificate	Codes/Sizes (if any): N/A/1ML, 1.6ML, 2ML,	
	July 2025 Tracking ID: MDMR-	Issue Date:	3ML, 4ML, 5ML, 6ML,	
	20250723-00025	Validity Date:	7ML, 8ML, 9ML, 10ML	
		Issuing Authority:	Specify grouping: Single	
		Attestation Status:	Storage condition: ROOM	
		Issue Date:	TEMPERATURE	
	di	Validity Date:		
			1	

		Issuing Authority		
		Issuing Authority:		
		Attestation Status:		
		FSC		
		Issue Date: 2025-03-31		
		Validity Date: 2027-02-14	1	
		Issuing Authority: Jiangsu Medical Products Administration	5)	
		Attestation Status: PAKISTAN APOSTILLE	3(1 9.	
		Issue Date:	OF	
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		
		Issue Date: 2025-03-31		
	1	Validity Date: 2027-02-14		
		Issuing Authority: Jiangsu Medical Products Administration		
		Attestation Status: PAKISTAN APOSTILLE		
		LOA		
	1001	Issue Date: 2025-01-01		
	No	Validity Date: 2031-12-31	3, 4,7,	
	·		y 0.22	
		Notarization Status: PAKISTAN APOSTILLE	3/1 3	
	ELECTRO-MEDICAL	Legal Manufacturer (as per FSC)	Brand Name:	
	EQUIPMENT	Instrumentation Laboratory, a Werfen	Werfen	
	SERVICES	Company	Generic Name:	
	H.No.4 Street No.3	Address: 180 Hartwell Road,	GEM Premier 3500	
	,Malik Park Punj Peer Mughalpura,Lahore,	Bedford, Massachusetts 01730-2443 (USA)	Class A	
7	Lahore	ISO 13485	Shelf life/service life: 6	Approved
	Fee: Rs 26100 /-	Issue Date:	Months	FF - 1.22
	Challan No.: 608928037102	Validity Date:	Codes/Sizes (if any): 00026000000/	
	Date of submission: 06	Notarization Status:	Specify grouping:	
	August 2025	EC Certificate	System System	
	Tracking ID: MDMR-	Issue Date:	Storage condition: 15°C -	
	-			

	20250806-00019	Validity Date:	25°C	
		Issuing Authority:		
		Attestation Status:		
		Issue Date: 2024-11-10		
		Validity Date: 2027-11-09	18	
		Issuing Authority:	5)	
		Attestation Status: Notarized		
		FSC	3(1, 0).	
		Issue Date: 2024-01-26	Jis,	
		Validity Date: 2026-01-25	O'	
		Issuing Authority: USFDA		
		Attestation Status: Legalized		
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		
		Issue Date:		<u> </u>
		Validity Date:		
		Issuing Authority:	18	
	Nes	Attestation Status:	5)	
		LOA	2.55	
		Issue Date: 2025-05-26	3(1, 0).	
		Validity Date: 2027-05-21	Jis,	
		Notarization Status: Notarized		
	Chohan & Company	Legal Manufacturer (as per FSC)	Brand Name:	
	21 BAHADURABAD	Jiangsu HXRT MD Co., Ltd	TUBER VAC MERUX	
	BLOCK 2, Karachi, Karachi	Address: No.66 Xingyuan Road, the	SAS NYCOTECH GMBH	
	Fee: Rs 6000 /-	Modern Science and Technology	Generic Name:	
8	Challan No.:	Industrial Area, Jiangyan District, Taizhou City, 225300, Jiangsu, China	BLOOD COLLECTION	Approved
	2191506129	ISO 13485	TUBE (Coagulant)	**
	Date of submission: 23	Issue Date: 2023-09-06	Class A	
	July 2025	Validity Date: 2026-08-12	Shelf life/service life: 36	
	Tracking ID: MDMR- 20250723-00026	Notarization Status: PAKISTAN	Months	
	sions of 07th Mo		Codes/Sizes (if any):	

	APOSTILLE EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: 2025-03-31 Validity Date: 2027-02-14 Issuing Authority: Jiangsu Medical Products Administration Attestation Status: PAKISTAN APOSTILLE Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: 2025-03-31 Validity Date: 2027-02-14 Issuing Authority: Attestation Status: Issue Date: 2025-03-31 Validity Date: 2027-02-14 Issuing Authority: Jiangsu Medical Products Administration Attestation Status: PAKISTAN APOSTILLE LOA Issue Date: 2025-01-01 Validity Date: 2031-12-31 Notarization Status: PAKISTAN APOSTILLE Manufacturer	9018.3981/1ml, 1.6ml, 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml Specify grouping: Single Storage condition: ROOM TEMPERATURE	
9 Quality Medical Services H-49 Gordon College	HEBEI ERYOU MEDICAL EQUIPMENT CO.Ltd	Hebei Eryou Medical Generic Name:	Approved

road, Rawalpindi

Fee: Rs 6000 /-

Challan No.: 50231683376

Date of submission: 25

July 2025

Tracking ID: MDMR-20250725-00012

Address: West Side of West Ring Road and North Side of Yongxing Road, Jizhou District, Hengshui City,

Hebei Province, China

ISO 13485

Issue Date: 22024-09-19

Validity Date: 2027-09-18

**Notarization Status: CCPIT** 

**EC** Certificate

Issue Date:

Validity Date:

Issuing Authority:

**Attestation Status:** 

Issue Date:

Validity Date:

**Issuing Authority:** 

**Attestation Status:** 

FSC

Issue Date: 2025-08-12

Validity Date: 2026-07-11

**Issuing Authority: CCPIT** 

Attestation Status: Apostille

Issue Date:

Validity Date:

Issuing Authority:

**Attestation Status:** 

Issue Date:

Validity Date:

**Issuing Authority:** 

**Attestation Status:** 

LOA

Issue Date:

Validity Date:

**Notarization Status:** 

Manual Hospital Bed

Class A

Shelf life/service life: 10

Years

Codes/Sizes (if any): SYC-A-(1~1284)/

Specify grouping: Single

Storage condition: Dry

Place

		Legal Manufacturer (as per FSC)		
		Jiangsu HXRT MD Co., Ltd		
		Address: No.66 Xingyuan Road, the Modern Science and Technology Industrial Area, Jiangyan District, Taizhou City, 225300, Jiangsu, China		<u>N</u>
		ISO 13485	5) (2)	
		Issue Date: 2023-09-06	2 0.55	
		Validity Date: 2026-08-12	31, 9.	
		Notarization Status: PAKISTAN APOSTILLE	D. A.N.	
		EC Certificate	Brand Name:	
		Issue Date:	TUBER VAC MERUX NYCOTECH	
	Chohan & Company	Validity Date:	Generic Name:	
	21 BAHADURABAD	Issuing Authority:	Blood collection tube	
	BLOCK 2, Karachi,	Attestation Status:	(SODIUM HEPARIN + Separation Gel)	
	Karachi	Issue Date:	Class A	
10	Fee: Rs 6000 /-	Validity Date:	Shelf life/service life: 36	Approved
10	Challan No.: 7771164790	Issuing Authority:	Months	ripproved
	Date of submission: 23	Attestation Status:	Codes/Sizes (if any):	
	July 2025	FSC	N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML,	
	Tracking ID: MDMR- 20250723-00029	Issue Date: 2025-03-31	7ML, 8ML, 9ML, 10ML	
	20230723-00029	Validity Date: 2027-02-14	Specify grouping: Single	
		Issuing Authority: Jiangsu Medical Products Administration	Storage condition: ROOM	
		Attestation Status: PAKISTAN APOSTILLE Issue Date: Validity Date:	TEMPERATURE	
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		
		Issue Date: 2025-03-31		
		Validity Date: 2027-02-14		
	40	Issuing Authority: Jiangsu Medical Products Administration		
	1180°	Attestation Status: PAKISTAN		

APOSTILLE		
LOA		
Issue Date: 2025-01-01		
Validity Date: 2031-12-31	.3	
Notarization Status: PAKISTAN APOSTILLE	3) (1)	

## AGENDA FORMAT FOR CLASS B, C & D MEDICAL DEVICES

Evaluator Name: Sadaf Ahmad (Evaluator-III)

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	Shams Enterprises  10 Medicine market kutchi gali no 1 mariot road karachi, Karachi Fee: Rs 31000/- Challan No.: 8387446772 Date of submission: 23 July 2025 Tracking ID: MDMR-20250723-00041 - Deferred	Manufacturer BONREE MEDICAL CO LTD Address: 1ST FLOOR OF BIULDING NO 2 BIULDING NO 4 LONGZHU VILLAGE ECONOMIC ESTATE, LONGZHU AVENUE NANTANG, 528451 ZHONGSHAN. GUANGDONG, CHINA ISO 13485 Issue Date: Validity Date: Notarization Status: EC Certificate Issue Date: 2023-10-25 Validity Date: 2025-10-24 Issuing Authority: guangdong medical product administration Attestation Status: 10978720 Issue Date: Validity Date: Issuing Authority: Attestation Status:	Brand Name: A1 SURGICS Generic Name: ENDOTRACHEAL TUBE Cuffed Type. Class B Shelf life/service life: 5 Years Codes/Sizes (if any): 4/I.D. 2.0, I.D. 2.5, I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0 Specify grouping: Single Storage condition: ROOM TEMPERATURE	Approved

		Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: 2025-06-16 Validity Date: 2030-06-15 Notarization Status: notarized	indisheri 9:55:11	
2	Benchmark Solutions Pakistan  28A, PCSIR, Phase 1, Canal Bank Road, Lahore, Lahore Fee: Rs 31000 /- Challan No.: 1049175868  Date of submission: 22 July 2025  Tracking ID: MDMR- 20250722-00008 - Deferred	Manufacturer SHANDONG AOSAITE MEDICAL DEVICES CO., LTD Address: No.3 North Ring Road, Chengwu Count, Heze,274200 Shandong, P.R. China ISO 13485 Issue Date: Validity Date: Notarization Status: EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date:	Brand Name: Aosaite Gold Generic Name: Disposable Blood Collection Needle Class B Shelf life/service life: 60 Months Codes/Sizes (if any): Plain type/ 20G×3/4, 21G×3/4, 22G×3/4, 23G×3/4, 24G×3/4, 25G×3/4, 26G×3/4" Specify grouping: Family Storage condition: 4-35 C	Approved

		Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: Validity Date: Notarization Status:	Internation of the second of t	
3	Shams Enterprises  10 Medicine market kutchi gali no 1 mariot road karachi, Karachi Fee: Rs 31000 /- Challan No.: 8950980560 Date of submission: 23 July 2025 Tracking ID: MDMR- 20250723-00042 - Deferred	Manufacturer BONREE MEDICAL CO LTD Address: 1ST FLOOR OF BIULDING NO 2 BIULDING NO 4 LONGZHU VILLAGE ECONOMIC ESTATE, LONGZHU AVENUE NANTANG, 528451 ZHONGSHAN. GUANGDONG, CHINA ISO 13485 Issue Date: 2025-08-01 Validity Date: 2028-07-31 Notarization Status: notarized EC Certificate	Brand Name: A1 SURGICS Generic Name: ENDOTRACHEAL TUBE UNCUFFED Class B Shelf life/service life: 5 Years Codes/Sizes (if any): N/A/I.D. 2.0, I.D. 2.5, I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0, I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0 Specify grouping: Single Storage condition: ROOM	Approved

		Issue Date: 2023-10-25	TEMPERATURE	
		Validity Date: 2025-10-24		
		Issuing Authority: guangdong medical product administration		14
		Attestation Status: 10978720		
		Issue Date:	(6)	
		Validity Date:	(M), (2).	
		Issuing Authority:	1 01 9.	
		Attestation Status:	"ielio"	
		FSC	Olio Joh	
		Issue Date:	O.S.	
		Validity Date:	100	
		Issuing Authority:	<b>,</b>	
		Attestation Status:		
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		1.
		Issue Date:	1	
	Ne	Validity Date:	(2)	
		Issuing Authority:	Will Po.	
		Attestation Status:	1, 61, 6:	
		LOA	1:00000	
		Issue Date: 2025-06-16	1011200	
		Validity Date: 2030-06-15		
		Notarization Status: notarized	100	
4	Abbott Laboratories	Legal Manufacturer (as per	Brand Name:	Approved
	Pakistan Limited	FSC)	ARCHITECT Pepsinogen II	
	Opposite Radio Pakistan Transmission	Abbott GmbH	Generic Name:	
	Centre, Hyderabad	Address: Max-Planck-Ring 2 65205, Wiesbaden, Germany	Pepsinogen II	
	Road, Landhi Karachi- 75120, Karachi	ISO 13485	Class B	
	Fee: Rs 31000 /-	Issue Date:	ARCHITECT Pepsinogen II	
	Challan No.:	Validity Date:	Reagent Kit	
		•	Shelf life/service life: 15	

	29556456686	Notarization Status:	Months	
	Date of submission: 29	EC Certificate	Codes/Sizes (if any): 9D65-28/	
	July 2025	Issue Date:	ARCHITECT Pepsinogen II	
	Tracking ID: MDMR- 20250729-00020 -	Validity Date:	Reagent Kit	W
	Deferred	Issuing Authority:	Shelf life/service life: 15 Months	
		Attestation Status:	Codes/Sizes (if any): 9D65-38/	
		Issue Date:	ARCHITECT Pepsinogen II	
		Validity Date:	Calibrators	
		Issuing Authority:	Shelf life/service life: 17	
		Attestation Status:	Months	
		FSC	Codes/Sizes (if any): 9D65-01/	
		Issue Date:	ARCHITECT Pepsinogen II Controls	
		Validity Date:	Shelf life/service life: 17	
		Issuing Authority:	Months	
		Attestation Status:	Codes/Sizes (if any): 9D65-10/	
		Issue Date:	Specify grouping: IVD Kit	
		Validity Date:	Storage condition: 2 to 8°C	<u> </u>
		Issuing Authority:		M
		Attestation Status:		
	Ne	Issue Date:	(19)	
		Validity Date:	(M), 0.22.	
		Issuing Authority:	7 6(1 0).	
		Attestation Status:	1181,019,	
		LOA	O., 50,	
		Issue Date:	O.C.	
		Validity Date:	100	
		Notarization Status:	•	
5	Clifton Enterprises	Manufacturer	Brand Name:	Approved
	Ground Floor, 166	Tianchang City Anrui Medical	Medi-Pro Plus	
	Shadman 1, Tehsil and District Lahore,	Equipments Co., Ltd.	Generic Name:	
	Lahore	Address: Renhe Industrial District 239331 Tianchang City,	Sterile Surgical Gloves for	
	Fee: Rs 31000 /-	Anhui Province, China	Single Use, Powdered	
	Challan No.:	ISO 13485	Class B	

	948494055	Issue Date:	Shelf life/service life: 5 Years	
	Date of submission: 29	Validity Date:	Codes/Sizes (if any): N/A/6, 6.5,	
	July 2025	Notarization Status:	7, 7.5, 8, 8.5, 9	
	Tracking ID: MDMR- 20250729-00005 -	EC Certificate	Specify grouping: Single	M
	Deferred	Issue Date:	Storage condition: Room Temperature Device	
		Validity Date: 2026-06-15	Temperature Device	
		Issuing Authority:	(W) 0.50	
		Attestation Status:	al Melling.	
		Issue Date:	1181,050,	
		Validity Date:	10. Jo.	
		Issuing Authority:	el,	
		Attestation Status:	P	
		FSC		
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		
		Issue Date:		RI
	10	Validity Date:	.1	
	Ne	Issuing Authority:	11/21	
		Attestation Status:	(6)	
		Issue Date:	The State of the S	
		Validity Date:	lier Oss.	
		Issuing Authority:	10. 50	
		Attestation Status:	el,	
		LOA		
		Attestation Status:  LOA  Issue Date:		
		validity Date.		
		Notarization Status:		
6	HOSPICARE	Legal Manufacturer (as per	Brand Name:	approved
	SYSTEMS	FSC)	F&P Flexitrunk Nasal Prong	
	Emarah Suites, 9th Floor, Plot# 8-B,	Fisher & Paykel Healthcare Limited	Generic Name:	
	Block-A, SMCHS, Shahrah-e-Faisal,	Address: 15 Maurice Paykel	Nasal Prong	

Karachi-75350, Place, East Tamaki, Auckland Class B Pakistan, Karachi 2013. New Zealand Shelf life/service life: 3 Years Fee: Rs 31000 /-ISO 13485 Codes/Sizes (if any): BC3020-Issue Date: Challan No.: 10/ 0492161601 Validity Date: Date of submission: 28 **Notarization Status:** Shelf life/service life: 3 Years July 2025 **EC** Certificate Codes/Sizes (if any): BC3520-Tracking ID: MDMR-10/ Issue Date: 20250728-00043 Validity Date: Shelf life/service life: 3 Years Issuing Authority: Codes/Sizes (if any): BC4030-**Attestation Status:** 10/ Issue Date: Validity Date: Shelf life/service life: 3 Years Issuing Authority: Codes/Sizes (if any): BC4540-**Attestation Status:** 10/ **FSC** Issue Date: Shelf life/service life: 3 Years Validity Date: Codes/Sizes (if any): BC5040-10/ **Issuing Authority: Attestation Status:** Shelf life/service life: 3 Years Issue Date: Codes/Sizes (if any): BC5050-Validity Date: 10/ Issuing Authority: **Attestation Status:** Shelf life/service life: 3 Years Issue Date: Codes/Sizes (if any): BC5550-Validity Date: 10/ Issuing Authority: **Attestation Status:** Shelf life/service life: 3 Years LOA Codes/Sizes (if any): BC5560-10/ Issue Date: Validity Date: Shelf life/service life: 3 Years **Notarization Status:** Codes/Sizes (if any): BC6060-10/

		adul Gadil	Shelf life/service life: 3 Years Codes/Sizes (if any): BC6070- 10/  Shelf life/service life: 3 Years Codes/Sizes (if any): BC6570- 10/ Specify grouping: Family Storage condition: -10 to 50 °C	
Plaza 6- Lahore Fee: Rs Challan 0419029 Date of August Trackin	or Hassan A Jail Road, 31000 /- No.: 99711 submission: 01	Legal Manufacturer (as per FSC)  Xuzhou Kaixin Electronic Instrument Co.Ltd  Address: Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China.  ISO 13485  Issue Date: 2023-04-01  Validity Date: 2026-03-31  Notarization Status: Notarized  EC Certificate  Issue Date: 2024-11-22  Validity Date: 2026-11-22  Attestation Status: Apostille  Issue Date:  Validity Date:  Issuing Authority:  Attestation Status:  FSC  Issue Date:  Validity Date:  Issue Date:	Brand Name: KAIXIN Generic Name: Ophthalmological A/B mode ultrasound scanner Class B Shelf life/service life: 10 Years Codes/Sizes (if any): ODU5 Specify grouping: Single Storage condition: Ambient temperature: -20°C-55°C Relative humidity: 30%-93% (without condensation) Atmospheric pressure: 700hPa- 1060hPa	Approved

	Validity Date: Issuing Authority: Attestation Status: Issue Date: 2024-11-22 Validity Date: 2026-11-22 Attestation Status: Apostille LOA Issue Date: 2025-04-11 Validity Date: 2030-08-11 Notarization Status: Notarized	Jolisher) 9:55:11	
8 JASANI SCIENTIFICS SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi Fee: Rs 31000 /- Challan No.: 2993696009 Date of submission: 0 August 2025 Tracking ID: MDMR- 20250804-00013	Address: 3222 Phoenixville Pike Malvern, PA 19355, USA  ISO 13485  Issue Date: Validity Date: Notarization Status:  EC Certificate  Issue Date:	Brand Name: A-Scan Plus Connect Generic Name: Ophthalmic ultrasound imaging system Class B A-Scan Plus Connect Ophthalmic ultrasound imaging system Shelf life/service life: 10 Years Codes/Sizes (if any): 24-4400 / A-Scan Probe Shelf life/service life: 10 Years Codes/Sizes (if any): 24-4001/ Immersion Shell Shelf life/service life: 10 Years Codes/Sizes (if any): 24-4100/ Specify grouping: System Storage condition: -20° to +60° C	Approved

	Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: Validity Date: Notarization Status:	oer, 2025, 9:55:11	
9 OPTI MED 2nd Floor Hassan Plaza 6-A Jail Road, Lahore Fee: Rs 32400 /- Challan No.: 547018005565 Date of submission: 0 August 2025 Tracking ID: MDMR 20250807-00013	Issue Date: 2023-03-24	Brand Name: Bandage Generic Name: Soft Contact Lens Class B Shelf life: 8 Years Codes/Sizes (if any): 32 x 35 x 60 mm Specify grouping: Single Storage condition: Below25°C (1~30°C)	Approved

10	JASANI	Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: 2024-09-02 Validity Date: 2029-08-14 Issuing Authority: Contact Lens Service GmbH Attestation Status: Apostille LOA Issue Date: 2025-07-15 Validity Date: 2028-07-14 Notarization Status: Notarized Legal Manufacturer (as per	Brand Name:	Approved
	SCIENTIFICS SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi Fee: Rs 31000/- Challan No.: 7913477061 Date of submission: 04 August 2025 Tracking ID: MDMR- 20250804-00016	FSC) Accutome, INC (Doing Business As) Keeler Ltd Address: 3222 Phoenixville Pike Malvern, PA 19355, USA	UBM Plus Guarded Generic Name: Ophthalmic ultrasound imaging system Class B Shelf life/service life: 10 Years UBM Plus Guarded Ophthalmic ultrasound imaging system 24-6300-G UBM Plus 24-6300 Immersion Scleral Shell, UBM 24-6301, 20mm Immersion Scleral Shell, UBM 24-6302, 18mm Immersion Scleral Shell, UBM 24-6303, 22mm	
	Me		Specify grouping: System	

Manufacturer (as per FSC)   Accutome, INC (Doing Business As) Keeler Ltd   Address: 3222 Phoenixville Pike Malvern, PA 19355, USA ISO 13485   Iso 13				Storage condition: -20° to -60° C (-4° to -140° F)	
	11	SCIENTIFICS SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi Fee: Rs 31000 /- Challan No.: 01845089 Date of submission: 04 August 2025 Tracking ID: MDMR-	Accutome, INC (Doing Buisness As) Keeler Ltd Address: 3222 Phoenixville Pike Malvern, PA 19355, USA ISO 13485 Issue Date: Validity Date: Notarization Status: EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority:	B-Scan Plus Generic Name: Ophthalmic ultrasound imaging system Class B Shelf life/service life: 10 Years Codes/Sizes (if any): 24-6100 Specify grouping: System Storage condition: -20° to +60° C	Approved

		LOA Issue Date: Validity Date:		
		Notarization Status:	. 1	M
12	Fresenius Medical Care Paksitan Pvt Ltd 27C/III, First Floor, TAMC Building M.M. Alam Road, Gulberg III, 54660 Lahore ,Pakistan, Lahore Fee: Rs 31000 /- Challan No.: 59243367517 Date of submission: 04 August 2025 Tracking ID: MDMR- 20250804-00012	Legal Manufacturer (as per FSC) Fresenius Medical Care AG Address: Else-Kröner-Str.1 61352 Bad Homburg Germany ISO 13485 Issue Date: Validity Date: Notarization Status: EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority:	Brand Name: Therapy Monitor Ver. 2.4 Generic Name: Monitoring software for the Therapy Data Management System Class B Shelf life/service life: 10 Years Codes/Sizes (if any): F988471 Specify grouping: Single Storage condition: As the software is only a DVD, there are no specific storage conditions.	Approved
			<u>.                                    </u>	1

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	LOA		
	Issue Date:		
	Validity Date:		M
	Notarization Status:	A .1	
	Manufacturing Site (as per FSC)	(MIS) 55:11	
	Fresenius Medical Care Deutschland GmbH Schweinfurt Plant	lighed 52, 8.2	
	Address: Hafenstr. 9 97424 Schweinfurt Germany	0. 20	
	ISO 13485	06	
	Issue Date:	) <sup>*</sup>	
	Validity Date:		
	Notarization Status:		
	EC Certificate		
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	Validity Date:		A.A.
	Issuing Authority:		
Ne	Attestation Status:	(6)	
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	Issuing Authority:		
	Attestation Status:		
10	Issue Date:		

13	The Searle Company Limited F-319, Sindh Industrial Trading Estate, Karachi, Karachi Fee: Rs 32400/- Challan No.: 9116395666 Date of submission: 11 August 2025 Tracking ID: MDMR- 20250811-00007	Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: Validity Date: Notarization Status:  Manufacturer M/s Abu Dhabi Medical Devices Co. L.L.C Address: Plot 124, M-43, Mussafah Industrial P.O. Box 30485, Abu Dhabi, United Arab Emirates. ISO 13485 Issue Date: 2025-04-03 Validity Date: 2026-03-09 Notarization Status: Notarized. EC Certificate Issue Date: 2024-10-31 Validity Date: 2028-12-31 Issuing Authority: Ministry of Health, Welfare and Sport, the Netherlands. Attestation Status: Embassy off Pakistan, The Hague. Attested. Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Issuing Authority: Attestation Status:	Brand Name: MEDECO Generic Name: I.V. CANNULA PEN TYPE Class B Shelf life/service life: 6 Years Codes/Sizes (if any): N/A/14G, 16G, 17G, 18G, 20G, 22G, 24G & 26G. Specify grouping: Single Storage condition: Temperature <35°C, Humidity <70% RH. Keep at dry place. Protect from direct sunlight.	Approved
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	Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: 2025-05-25 Validity Date: 2027-05-24 Notarization Status: Notarized.	in (MIS) 9:55:17	
JASANI SCIENTIFICS SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi Fee: Rs 31000/- Challan No.: 256726134 Date of submission: 04 August 2025 Tracking ID: MDMR- 20250804-00010	Manufacturer (as per FSC) Accutom, INC (Doing Business As) Keeler Ltd Address: 3222 Phoenixville Pike Malvern, PA 19355, USA ISO 13485 Issue Date: Validity Date: Notarization Status: EC Certificate Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Validity Date:	Brand Name:  4Sight Generic Name: Ophthalmic ultrasound imaging system Class B Shelf life/service life: 10 Years A-Scan Probe 4SIGHT 24-8000A  B-Scan Probe 4SIGHT 24-8000B  Pachymeter Probe 4SIGHT 24-8000P  UBM Probe 4SIGHT 24-8000U  4Sight Ophthalmic ultrasound imaging system 24-8000  Specify grouping: System Storage condition: -20° to -60° C (-4° to -140° F)	Approved

	Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: Validity Date: Notarization Status:	in (Mis), 9:55:17	
The Searle Company Limited F-319, Sindh Industrial Trading Estate, Karachi, Karachi Fee: Rs 32400/- Challan No.: 60548200163 Date of submission: 11 August 2025 Tracking ID: MDMR- 20250811-00020	Manufacturer M/s Abu Dhabi Medical Devices Co. L.L.C Address: Plot 124, M-43, Mussafah Industrial P.O. Box 30485, Abu Dhabi, United Arab Emirates.  ISO 13485 Issue Date: 2025-04-03 Validity Date: 2026-03-09 Notarization Status: Notarized. EC Certificate Issue Date: 2024-10-31 Validity Date: 2028-12-31 Issuing Authority: Ministry of Health, Welfare and Sport, the Netherlands. Attestation Status: Embassy off Pakistan, The Hague. Attested. Issue Date: Validity Date:	Brand Name: MEDECO Generic Name: I.V. CANNULA WITH INJECTION PORT AND STOPPER Class B Shelf life/service life: 6 Years Codes/Sizes (if any): N/A/14G, 16G, 17G, 18G, 20G, 22G, 24G & 26G. Specify grouping: Single Storage condition: Temperature < 35°C, Humidity < 70% RH. Keep at Dry place. Protect from Direct Sunlight	Approved

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		Attestation Status:	Col,	
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		
		LOA		
		Issue Date: 2025-05-25		
		Validity Date: 2027-05-24		M
		Notarization Status: Notarized.	.1	
16	The Searle Company	Manufacturer	Brand Name:	Approved
10	Limited	M/s Abu Dhabi Medical	MEDECO	ripproved
	F-319, Sindh	Devices Co. L.L.C	Generic Name:	
	Industrial Trading Estate, Karachi,	Address: Plot 124, M-43,	I.V. CANNULA WITHOUT	
	Karachi	Mussafah Industrial P.O. Box 30485, Abu Dhabi, United Arab	INJECTION PORT	
	Fee: Rs 32400 /-	Emirates.	Class B	
	Challan No.:	ISO 13485	Shelf life/service life: 6 Years	
	406971565352	Issue Date: 2025-04-03	Codes/Sizes (if any): N/A/14G,	
	Date of submission: 12 August 2025	Validity Date: 2026-03-09	16G, 17G, 18G, 20G, 22G, 24G & 26G.	
	Tracking ID: MDMR-	Notarization Status: Notarized.	Specify grouping: Single	
	20250812-00002	EC Certificate	Storage condition: Temperature	
		Issue Date: 2024-10-31	< 35°C, Humidity < 70% RH.	
		Validity Date: 2028-12-31	Keep at Dry place. Protect from Direct Sunlight.	
	Ne	Issuing Authority: Ministry of Health, Welfare and Sport, the	C	

		Netherlands.		
		Attestation Status: Embassy off Pakistan, The Hague. Attested.		
		Issue Date:		1.0
		Validity Date:	4	
		Issuing Authority:	1,5)(1)	
		Attestation Status:	Will Rose	
		FSC	1, 3(1) 9:	
		Issue Date:	"ielo"	
		Validity Date:	On Jon	
		Issuing Authority:		
		Attestation Status:	O	
		Issue Date:	<b>)</b> *	
		Validity Date:		
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		Validity Date:		Also
		Issuing Authority:		
	1/18	Attestation Status:	1,5)11	
		LOA	(M), (2)	
		Issue Date: 2025-05-25	1 6(1) 9.	
		Validity Date: 2027-05-24	, iego 50,5,	
		Notarization Status: Notarized.	1011-50h	
17	Imtiaz Brothers	Manufacturer	Brand Name:	Approved
	Suite No. 7B, 2nd	Guilin HBM Health Protections,	IB	
	Floor, Abrar Business Center, Wahdat Road,	Inc.	Generic Name:	
	Lahore., Lahore	Address: No. 1-2, Shuijing East Road, Economic and	DISPOSABLE LATEX	
	Fee: Rs 32400 /-	Technological Development	STERILE SURGICAL GLOVES	
	Challan No.:	Area, Guilin, Guangxi, China	Class B	
	921768475	ISO 13485	Shelf life/service life: 3 Years	
	Date of submission: 09 August 2025	Issue Date:	Codes/Sizes (if any): 6, 6.5, 7,	
	Tracking ID: MDMR-	Validity Date:	7.5, 8, 8.5, 9/	
	Ne	Notarization Status:		

	20250809-00025	EC Certificate	Specify grouping: Single	
	2020000 00020	Issue Date:	Storage condition: Store at room temperature. The environment should be non-corrosive, well – ventilated and clean and relative humidity not more than 80%.	
		Validity Date:		
		Issuing Authority:		N
		Attestation Status:		
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:	1181,019,	
		FSC	1011 JO	
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		Issuing Authority:		
		Attestation Status:		
		Issue Date:		
		Validity Date:		
		Issuing Authority:		
		Attestation Status:		M
		Issue Date:		
	Ne	Validity Date:	(19)	
		Issuing Authority:	(M), 2.22.	
		Attestation Status:	1, 10,	
		LOA	1121, 53,	
		Issue Date:	101. So.	
		Validity Date:	eli	
		Notarization Status:	lo-	
18	The Searle Company	Manufacturer	Brand Name:	Approved.
	Limited	M/s Abu Dhabi Medical	MEDECO	
	F-319, Sindh Industrial Trading Estate, Karachi, Karachi	Devices Co. L.L.C Address: Plot 124, M-43, Mussafah Industrial P.O. Box 30485, Abu Dhabi, United Arab	Generic Name:	
			IV Cannula without injection	
			port with stopper	
	Fee: Rs 32400 /-	Emirates.	Class B	
	Challan No.: 71408761126	ISO 13485	Shelf life/service life: 6 Years	
	,1100/01120		Codes/Sizes (if any): N/A/14G,	

Date of submission: 12 Issue Date: 2025-04-03 16G, 17G, 18G, 20G, 22G, 24G August 2025 & 26G. Validity Date: 2026-03-09 Tracking ID: MDMR-Specify grouping: Single Notarization Status: Notarized. 20250812-00003 Storage condition: Temperature **EC** Certificate < 35°C, Humidity < 70% RH. Issue Date: 2024-10-31 Keep at Dry place. Protect from Direct Sunlight. Validity Date: 2028-12-31 Issuing Authority: Ministry of Health, Welfare and Sport, the Netherlands. Attestation Status: Embassy off Pakistan, The Hague. Attested. Issue Date: Validity Date: Issuing Authority: **Attestation Status: FSC** Issue Date: Validity Date: **Issuing Authority: Attestation Status:** Issue Date: Validity Date: Issuing Authority: **Attestation Status:** Issue Date: Validity Date: Issuing Authority: **Attestation Status:** LOA Issue Date: 2025-05-25 Validity Date: 2027-05-24

Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)

Notarization Status: Notarized.

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	NI Healthcare products (Pvt) Ltd Office #A Unit 10 Survey No. 263 Damlotte Road, District Malir ,Karachi, Karachi Fee: Rs 62000 /- Challan No.: 4589103071 Date of submission: 29 July 2025 Tracking ID: MDMR-20250729- 00002	Manufacturer Günter Bissinger Medizintechnik GmbH Address: Hans-Theisen-Str. 01 79331 Teningen Germany ISO 13485 Issue Date: Validity Date: Notarization Status: EC Certificate Issue Date: Validity Date:	Brand Name: Bipolar Foreceps Generic Name: Bipolar Electrosurgical Forceps Class C Shelf life/service life: 7 Years Codes/Sizes (if any): 80520301/ Shelf life/service life: 7 Years	Deferred for justification/ clarification of grouping as family under MDR 2017 along with documentary proof and complete product catalogue . Furthermore, Applied brand is bipolar foreceps while attached brochure shows CLARIS REVERSE
		Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority: Attestation Status: Issue Date: Validity Date: Issuing Authority:	Codes/Sizes (if any): 80520306/  Shelf life/service life: 7 Years Codes/Sizes (if any): 80520331/  Shelf life/service life: 7 Years Codes/Sizes (if any): 80520397/  Shelf life/service life: 7 Years Codes/Sizes (if any): 80520398/  Shelf life/service life: 7 Years Codes/Sizes (if any): 80520398/	

	<u> </u>
Attestation Status:	80522236/
LOA	
Issue Date:	Shelf life/service life: 7
Validity Date:	Years
Notarization Status:	Codes/Sizes (if any): 80522237/
	16 (P) (2)
Q2S	Shelf life/service life: 7 Years
induling the state of the state	Codes/Sizes (if any): 80522301/
AD D	P of '
Elannel	Shelf life/service life: 7 Years
ASSIOIB SER	Codes/Sizes (if any): 80522306/
	Shelf life/service life: 7 Years
inesole	Codes/Sizes (if any): 80522333/
1801	(2)
	Shelf life/service life: 7 Years
, 02	Codes/Sizes (if any): 80522334/
duli re	1011300
Aloci Dillo	Shelf life/service life: 7 Years
esistali Ne	Codes/Sizes (if any): 80522348/
b2 01 201	Shelf life/service life: 7 Years
egay,	Codes/Sizes (if any): 80522349/
189Wez	Shelf life/service life: 7

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	Shelf life/service life: 7
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DO 011	Codes/Sizes (if any):
	80580220/
*31, 10,	
1510	831,
65, 10 00	Shelf life/service life: 7
10, Co.	Years
, (,1)	Codes/Sizes (if any):
	80580221/
1	
2000	
0.50	Shelf life/service life: 7
700	Years
1901	Codes/Sizes (if any):
	80620301/
	11 (19)
	Shelf life/service life: 7
, Q.	Years
100 sire	Codes/Sizes (if any):
Vo Ov	80620306/
	100
431 110	Shelf life/service life: 7
	Years
65,010-01	Codes/Sizes (if any):
P (0', 50')	80620331/
	00020331/
	Shelf life/service life: 7
600	Years
	Codes/Sizes (if any):
	80620397/

Alodul Oile	Shelf life/service life: 7 Years Codes/Sizes (if any): 80620398/  Shelf life/service life: 7 Years Codes/Sizes (if any): 80622301/  Shelf life/service life: 7 Years
Assistan Mer	Codes/Sizes (if any): 80622306/  Shelf life/service life: 7 Years
Mednesday	Codes/Sizes (if any): 80622315/  Shelf life/service life: 7 Years Codes/Sizes (if any):
Apoli Direct	Shelf life/service life: 7 Years Codes/Sizes (if any): 80622345/
regions sed	Shelf life/service life: 7 Years Codes/Sizes (if any): 80622348/
Mednest	Shelf life/service life: 7 Years Codes/Sizes (if any):

			80622349/	
			Shelf life/service life: 7 Years Codes/Sizes (if any): 80622351/	ANA TY.
		isolul Gali	Shelf life/service life: 7 Years Codes/Sizes (if any): 80680180/	) •
		esistant Neb	Shelf life/service life: 7 Years Codes/Sizes (if any):	
		437, J. 201, 201	80680181/ Shelf life/service life: 7 Years	A
	Ne	dnest	Codes/Sizes (if any): 80680200/ Shelf life/service life: 7 Years	:17 AM
		Voqri Oile	Codes/Sizes (if any): 80680201/ Shelf life/service life: 7	
		ssistant Neb	Years Codes/Sizes (if any): 81522352/	
		Huesgay, 12 Ser	Specify grouping: Family Storage condition: Sterilized instruments must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.	
2	HOSPICARE	Legal Manufacturer (as per	Brand Name:	Deferred for provision of

**SYSTEMS** FSC) F&P Neopuff T-Piece Free Sale certificate from resuscitator reference country having Emarah Suites, 9th Fisher & Paykel Healthcare applied product. Floor, Plot# 8-B, Limited Generic Name: Block-A, SMCHS, Address: 15 Maurice Paykel Automatic pneumatic Shahrah-e-Faisal, Place, East Tamaki, pulmonary resuscitator Karachi-75350, Auckland 2013, New Pakistan, Karachi Class C Zealand Shelf life/service life: 5 Fee: Rs 62000 /-**ISO 13485** Years Challan No.: Issue Date: 2024-11-11 07625927184 Codes/Sizes (if any): RD900AEU/NA, Validity Date: 2027-11-13 Date of submission: **Notarization Status:** Specify grouping: Single 27 July 2025 Notarized Storage condition: -10 to 50 Tracking ID: MDMR-20250727-**EC** Certificate 00001 Issue Date: 2025-04-15 Validity Date: 2030-04-15 Issuing Authority: Apostilled Attestation Status: Issue Date: Validity Date: Issuing Authority: **Attestation Status: FSC** Issue Date: Validity Date: Issuing Authority: **Attestation Status:** Issue Date: Validity Date: **Issuing Authority: Attestation Status:** 

Issue Date:

LOA

Validity Date: Issuing Authority: Attestation Status:

Issue Date: 2025-04-01 Validity Date: 2026-04-01	
Notarization Status: Notarized	

#### **Renewal of Import License Agenda**

**Evaluator Name: Muhammad Amin(Evaluator-IX)** 

S.#	Name of Establishment along with address	Details of Qualified Technical Person(s)	CEO/ Director /Proprietor (s) details	Minutes/Decision
5	Name of Establishment: Genix Pharma (Pvt) Ltd, Office Address: Plot No 44-45 B, Korangi Creek Road Karachi	Olb cebieup,	Destination: N/A Name: N/A CNIC No: N/A	Approved renewal of license.
	Godown Address: N/A	-11		
	<b>Fee:</b> Rs 12000 /-			
	<b>Date of Submission:</b> 11 August 2025	)		14.
	<b>Tracking ID:</b> MDMC-250811-12405		(e <sub>1</sub> ,	1 Air

#### RENEWAL OF PRODUCT CASES

# AGENDA FOR CLASS B, C & D MEDICAL DEVICES Evaluator Name C. 1 6 / 1

Evaluator Name: Sadaf Ahmad (Evaluator-III)

S#	Name & Address of Importer	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
1	HAJI S. AMEER DIN & SONS 305 A- UPPER MALL, Lahore Fee: Rs 15000 /- Challan No.: 652123075800 Date of submission: 07 August 2025 Tracking ID: MDMR-20250807-	Brand Name: Diagnostic Ophthalmic Ultrasound Generic Name: PacScan <sup>TM</sup> Plus Ophthalmic Ultrasound System Model 300AP + Class B Shelf life/service life: months	Deferred for submission of differential fee of Rs 10400 for system

	00016	Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: Not controlled	
2	HAJI S. AMEER DIN & SONS 305 A- UPPER MALL, Lahore Fee: Rs 15000/- Challan No.: 708297856424 Date of submission: 07 August 2025 Tracking ID: MDMR-20250807-00019	Brand Name:  Master-Vu-A Scan Generic Name: Diagnostic Ophthalmic Ultrasound System Class B Shelf life/service life: months Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: Not controlled	Deferred for submission of differential fee of Rs 10400 for system
3	F.W.DISTRIBUTORS  Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi  Fee: Rs 15000/-  Challan No.: 4345510117  Date of submission: 07 August 2025  Tracking ID: MDMR-20250807-00060	Brand Name: ANGIOGRAPHIC SYRINGES Generic Name: ANGIOGRAPHIC SYRINGE Class B Shelf life/service life: months Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: This product should be stored in a cool dry environment, avoid direct sunlight.	Approved
4	HAJI S. AMEER DIN & SONS 305 A- UPPER MALL, Lahore Fee: Rs 15000 /- Challan No.: 70383084124 Date of submission: 06 August 2025 Tracking ID: MDMR-20250806-00005	Brand Name: Diagnostic Ophthalmic Ultrasound Generic Name: VuPad <sup>TM</sup> A/B Ophthalmic Ultrasound and Corresponding components Class B Shelf life/service life: months Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: Not controlled	Deferred for submission of differential fee of Rs 10400 for system

5	HAJI S. AMEER DIN & SONS 305 A- UPPER MALL, Lahore Fee: Rs 15000/- Challan No.: 004483753586 Date of submission: 07 August 2025 Tracking ID: MDMR-20250807- 00017	Brand Name:  PacScan <sup>TM</sup> Plus Ophthalmic Ultrasound System Model 300A +  Generic Name:  Ophthalmic Ultrasound System  Class B  Shelf life/service life: months  Codes/Sizes (if any): N/A  Specify grouping: N/A  Storage condition: NOT CONTROLLED	Deferred for submission of differential fee of Rs 10400 for system
6	MEDEQUIPS SMC PVT. LTD  30-SHAHRAH E QUAID E AZAM, LAHORE PAKISTAN, Lahore Fee: Rs 15000 /- Challan No.: 74591116292  Date of submission: 05 August 2025  Tracking ID: MDMR-20250805- 00022	Brand Name: Salient Syringe 190ml Generic Name: Salient Syringe 190ml Class B Shelf life/service life: months Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: Specifically, it should be stored at room temperature, and prefilled syringes should be stored separately based on dose	Approved
7	The Searle Company Limited F-319, Sindh Industrial Trading Estate, Karachi, Karachi Fee: Rs 15000 /- Challan No.: 4827913081 Date of submission: 08 August 2025 Tracking ID: MDMR-20250808- 00055	Brand Name: Protiex Sterile Latex Surgical Gloves (Powdered) Generic Name: Sterile Latex Surgical Gloves (Powdered) Class B Shelf life/service life: months Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: Keep in cool and dry area and avoid direct sunlight	Approved
8	HAJI S. AMEER DIN & SONS	Brand Name:	Deferred for submission of differential fee of Rs

305 A- UPPER MALL, Lahore	Diagnostic Ophthalmic Ultrasound	10400 for system
Fee: Rs 15000 /-	Generic Name:	
Challan No.: 8919075149	VuPad™ U Ophthalmic Ultrasound system	
Date of submission: 07 August	and Corresponding components	
2025	Class B	1 1
Tracking ID: MDMR-20250807-	Shelf life/service life: months	
00014	Codes/Sizes (if any): N/A	0,
	Specify grouping: N/A	
	Storage condition: Not controlled	

## **Evaluator Name: Hafiz Asif Iqbal (Evaluator-VII)**

S#	Name & Address of Importer	Name & Address of Legal Manufacturer, Manufacturing Site, Contract Manufacturing	Name of Medical Device/ Shelf Life/ Codes/ Sizes (if any)	Minutes/Decision
8	MEDEQUIPS SMC PVT. LTD  30-SHAHRAH E QUAID E AZAM, LAHORE PAKISTAN, Lahore Fee: Rs 31000 /- Challan No.: 488740178597 Date of submission: 05 August 2025 Tracking ID: MDMR-20250805- 00021	nesday, h	Brand Name: Radixact Generic Name: Radixact Treatment Delivery System Class C Shelf life/service life: months Codes/Sizes (if any): N/A Specify grouping: N/A Storage condition: Environmental Storage Requirements Ambient Temperature: Maintain between 18 °C and 33 ° C	Deferred for last chance for submission of approved license details along with approval letter, if any, and applicable differential fee for system as per as per S.R.O. 1399(I)/2025 dated 1st August 2025

Generated by DRAP Product Management System

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# DECISIONS OF 97<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 28-08-2025 (PART-II MANUAL FILES)

97<sup>th</sup> meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 28<sup>th</sup> August, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
12.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
13.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
14.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
15.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
16.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member (attended meeting through videolink)
17.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
18.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
19.	Prof Dr M Nadeen Ahmed, Department of radiology, Agha Khan Unicersity Hospital,	Member (attended meeting through videolink)
20.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of	Member

	Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	(attended meeting through videolink)
21.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert
		(attended meeting through videolink)
22.	Asif Jalil, Additional Director (MD&MC), DRAP,	Member-cum-Secretary
	Islamabad.	(2)

SR.NO.	NAME OF EVALUATOR	DESIGNATION
10.	Mr. Saadat Ali Khan	Deputy Director-I
11.	Mr. Waqar Ahmad	Deputy Director-II
12.	Mst. Sadaf Ahmad	Deputy Director-III
13.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
14.	Mr. Zia Ullah	Deputy Director-V
15.	Mr. Muhammad Ashfaq	Deputy Director-VI
16.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
17.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
18.	Mr. Muhammad Amin	Deputy Director-IX

## Cases of Deputy Director-IX (Muhammad Amin)

# Item No. I(A): <u>APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.</u>

#### **FRESH CASES**

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s A V Hearing, Office no 120,	Waleed	Approved
	First Floor, Rafay Mall, Peshawar	DMLS 03161010	
	Road, Rawalpindi	1	
2.	M/s Home Land, House # 413-A,	Farrah Bashir	Approved
	Street# 1, Gulraiz II, Rawalpindi		
	707	CNIC82101-5852172-8	
3.	M/s Advance Medical Devices,	Mubashar Abbas	<b>Deferred</b> for appointment
	Apartment # 1 3rd floor Plaza 01		of qualified person in
	linear commercial phase 8 Bahria	CNIC37405-3758089-9	accordance with
	town Rawalpindi.		requirement of medical
		BS Computer Science	devices rules 2017.

4.	M/s Irtaza Health Services, House #B-235/C B-Block Satellite Town Commercial Market Rawalpindi	Syed Naeem Ullah Shah CNIC13202-4366006-9	Approved
5.	M/s Quick Start International, Plaza No. 19 1st Floor, Ali Commercial Phase -8 Behria Town Rawalpindi.	Regd. No. 9250-A/2024  Muhammad Irfan  CNIC17101-3761954-3	Approved
6.	M/s Allied Distributors, 1 <sup>st</sup> Floor, 103-K, Block-2, PECHS, Shahrah-e-Quaideen, Karachi	Syed Tanveer Haider Regd. No. 1567	Approved
7.	M/s S.J & G., Fazul Ellahie Private Limited, E-6, S.I.T.E, Karachi	Hafiza Uroosa Perviaz, CNIC No. 42101-5431443-2 Regd. No. 10030	Approved
8.	M/s Vision Technologies, 1 <sup>st</sup> Floor, 36-Kamran Block, Allama Iqbal Town, Lahore	Muhammad Asad Ullah, Biomedical Engineering Biomedical/002937	Approved
9.	M/s AL-Shoraim Technology, Room No. 4, 5 & 6, Plot No. 39, Habib Bank Plaza, 2 <sup>nd</sup> Floor, Jhelum Road, G-8/4, Islamabad	Niamat Ullah Khan  B.Sc. Medical Lab Technology	Approved
10.	M/s Clear Moyes Aligners, House No. 20, Raza Block, Allama Iqbal Town, Lahore	Shakeel Abid (CNIC-35202-7549616-3) Pharm-D Regd. No. 3825-A/06	Rejected. The board rejected the application for establishment of import license based upon the findings and recommendation of inspector.
	Assista Assista	A September, 2025	The Board further decided to direct Area FID to investigate the matter in detail and furnish complete information/report including list of accused persons along with violations and punishments under medical devices rules 2017 and DRAP Act, 2012.
11.	M/s Let's Outsource (SMC Private) Limited, Ground Floor,	Almas Khan (Quality Control Incharge)	<b>Rejected.</b> The Board decided to reject the
	,, 515 and 11001,	10-/	

	D720 Dlools D. Ambala Comer		omnlication C
	D739 Block D, Arbab Street, Commercial Market, Rawalpindi.	CNIC17301-9926932-1	application for establishment license to
			import of medical devices
			in light of findings and
			recommendations of
			inspector.
12.	M/s ADF International Pvt. Ltd.,		Dejected The Deard
12.	203-B, Gate No. 3, Sector F-10/3,		<b>Rejected.</b> The Board decided to reject the
	Islamabad		application for
	Islandoud		establishment license to
		10 101 che 02	import of medical devices
		"II "Crailes" Cha	in light of findings and
	<b>1</b> 00	10. Jo	recommendations of
		0, 60	inspector.
		11 10 100	
13.	M/s ASK Associates, 17/11-N,	W. SU.	Rejected. The Board
	Industrial Area, Opp Dawn News	3	decided to reject the
	Paper Office, Gulberg-II, Lahore	COY	application for
	1. 6	13	establishment license to import of medical devices
			in light of findings and
	-1-		recommendations of
	203		inspector.
14.	M/s Diazone, 14,16 Saith Center		<b>Rejected.</b> The Board
14.	M/s Diazone, 14,16 Saith Center Moj Darya Road, Lahore.		observed that the firm was
14.	Moj Darya Road, Lahore.	(8)	observed that the firm was not ready for inspection
14.	Moj Darya Road, Lahore.  Godown:	iii (MIS)	observed that the firm was not ready for inspection therefore decided to reject
14.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement,	odir (MIS)	observed that the firm was not ready for inspection therefore decided to reject the application for
14.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road,	Gadir (MIS)	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for
14.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement,	ogdir (Mis)	observed that the firm was not ready for inspection therefore decided to reject the application for
14.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery	oliector (Mis)	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board
	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street	Oile Publisher)	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is
	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1,	it Director (MIS)	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain
	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street	or Director in the Color of the	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for
	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1,	The bridge in the state of the	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices,
	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1,	at Director I (MIS)	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.	September, 2025	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.
	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.	A Sebiemper, 50%	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.	at Director lights 2025	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.  Rejected. The Board
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.  M/s Ethos Derma, 65-C, Punjab Small Industrial Estate II, Sundar-	A September 1 Sept	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.  Rejected. The Board observed that the firm is
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.  M/s Ethos Derma, 65-C, Punjab Small Industrial Estate II, Sundar-	The bring of the state of the s	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.  Rejected. The Board observed that the firm is not interested to obtain
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.  M/s Ethos Derma, 65-C, Punjab Small Industrial Estate II, Sundar-	A Director lights 2025	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.  M/s Ethos Derma, 65-C, Punjab Small Industrial Estate II, Sundar- Raiwind Road,	at Director Lights 225	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.
15.	Moj Darya Road, Lahore.  Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore  M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.  M/s Ethos Derma, 65-C, Punjab Small Industrial Estate II, Sundar-	A Georgian (MIS)	observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application.  Rejected. The Board observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject the application observed that the firm is not interested to obtain establishment license for import of medical devices, therefore decided to reject

	Kamboh Mosque Chung Multan		not ready for inspection
	Road, Lahore		therefore decided to reject
			the application for
			establishment license for
			import of medical devices.
18.	Noor Medicine Company,		<b>Rejected.</b> The Board
	Gulshan -e- Rehman, Street No.		observed that the firm is
	2, Tabindah Model High School	.61	not interested to obtain
	for Boys (Shaheen Campus)		establishment license for
	Tehsil Burewala, District Vehari.		import of medical devices,
			therefore decided to reject
		G of the	the application.

#### **DEFERRED CASES IMPORT MEDICAL DEVICES LICENSE**

S.#	Name of Establishment	Name of Qualified Technical	Decision of MDB
1.	M/s AF International, 3-Millat street, Near Millat Park, Lahore. <b>Godown Address:</b> H3B9, Street	Ms. Asma Rabail d/w/o Ghulam Abbas	Approved
	49, Millat Road, Paki Thati Samanabad, Lahore	Reg. No. 19338-A/18 CNIC:35202-4883859-0	

# Item No.I(B): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE/ADDITIAONAL SECTIONS TO MANUFACTURE MEDICAL DEVICES.

The below mentioned firm has applied for grant of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel was constituted for inspection of their establishment. The information about the firm/company and recommendations of the panel are submitted for consideration of MDB please: -

	Name and Address of Establishment	Decision
<b>S.</b> #		
1	M/s. Injection System (Pvt) Ltd., Plot No. 271, Main Road, Industrial Estate Gadoon Amazai, District Swabi, KPK	Decision: The board approved the following additional sections:  i. Disposable Blood Transfusion Set
	Medhese	Section (Packaging, Sterilization and Release only)  ii. Disposable Butterfly Scalp Vein Set Section

		iii. Disposable I.V Cannula Section (Packaging, Sterilization and Release) iv. Disposable Insulin Syringe Section
2.	M/s Faiz Surgical Medical Industries Pvt.Ltd., 540-Sunder Industrial Estate, Lahore	Decision: The board approved the following additional sections:
		<ul><li>I. Disposable Syringes Section</li><li>II. IV Cannula Section</li></ul>

### Item No. I(C): POST LICENSE VARIATION CASES.

#### A) Fresh Cases

Following firms have applied for post license variations as per detail mentioned below against each:-

S.#	Name of Firm	Detail of existing office address and Godown Address	Detail of New office address and Godown Address	Remarks	Decision of MDB
1.	M/s Hoora Pharma (Pvt) Ltd., WH-01- 20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037)	nominated for the ins	pection of proposed of ded the proposed office	Application on Form-2.  Fee of Rs. 9000/-for change of office and godown address.  Copy of ELI.  Rent Agreement  Declaration and  Undertaking from proprietor.  ector, CDL, Karachi was office and godown address.  ce and storage facility of	The Board approved the correction in the address of the godown as per following details;  Godown: Ground Floor, WH- 01-20-A7- A8, Korangi Creek Industrial Park, Karachi
2.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No, 806, 8th Floor Horizon Towers, Block 3, Scheme No 5,	Johnson Pakistan (Pvt) Ltd., Office No, 806, 8th Floor	Johnson Pakistan (Pvt) Ltd., Office No, 806, 8th Floor Horizon Towers, Block 3, Scheme No 5, Clifton, Karachi.	The firm has submitted application for the correction of additional godown addresss as it was mentioned WH-01, 20-A-7A, Korangi Creek Industrial Park, Karachi. Instead of Second Floor, WH-01, 20-A-7A,	The Board approved the correction in the address of the godown as per following details;

Clifton,			Korangi Creek Industrial	
Karachi.	Godown address:	Godown 1 address:	Park, Karachi.	Godown 2
	208 & 208/1,	208 & 208/1, Sector-		Address:
	Sector-23 Korangi	23 Korangi		Second
	Industrial Area,	Industrial Area,		Floor, WH-
	Karachi.	Karachi.		01, 20-A-7A,
			(2)	Korangi
				Creek
		Godown 2 Address:	W 2.	Industrial
		Second Floor, WH-	(1) 9:	Park,
		01, 20-A-7A,	Me ob:	Karachi.
		Korangi Creek	5, 2/2	
		Industrial Park,	02	
		Karachi.		
		Y A O		

#### Item No. II: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.

## **Evaluator: Muhammad Ashfaq, Deputy Director (DD-VI)**

S. No.	Name of Applicant(a)	Name of Manufacturer	Medical Device	Decision
5. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s. Sure Bio Diagnostics	Name of Manufacturer:	Brand name:	Deferred due to
	& Pharmaceutical, EE-10 Defence View Phase	M/s Thermo Electron LED GmbH, Zweigniederlassung	Thermo Scientific Multifuge X1 Pro-MD, Multifuge X1R	following deficiencies in application;
	11Near Iqra University Shaheed-e-Millat Express Way, Karachi.	Osterode Am Kalkberg D-37520 Osterode am Harz,	Pro-MD, Multifuge X4 Pro-MD, Multifuge X4R Pro-MD,	• Original FSC, LOA & ISO certificate,
	way, Karaciii.	Germany.	Megafuge ST1 Plus-MD	have not been
	(ETT 00004)	1110	Megafuge ST1R Plus-MD	<ul><li>submitted.</li><li>Multiple models of</li></ul>
	(ELI- 00084)	• LOA	Megafuge ST4 Plus-MD	centrifuge have
		<b>Type:</b> Copy of notarized	Megafuge ST4R Plus-MD	been applied as family.
	R&I detail	Notarization: Notarized	0810	• Service life
	21-05-2025	Validity: 05-03-2028	Generic Name:	information and data has not been
	Fee: 25,000/-	SIS B OTO	Centrifuge	submitted.
	<b>Slip:</b> 35740394	• FSC		
	•	Type: Copy of legalized	Applied on Family	
		Issued By: Govt. Body	Applied as: Family	
		Legalization: Legalized	Class: A	
		Issue Date: 11-11-2024		
	adine	Validity: Not mentioned.	Model/Codes/Sizes:	
	"VIO		1. Multifuge X1 Pro-MD-	

	• ISO Certificate Type: Copy of notarized Notarization: Notarzed Validity: 19-11-2026	75009210  2. Multifuge X1R Pro-MD- 75009250  3. Multifuge X4 Pro-MD- 75009500  4. Multifuge X4R Pro-MD- 75009515  5. Megafuge ST1 Plus-MD- 75009230  6. Megafuge ST1R Plus-MD- 75009270  7. Megafuge ST4 Plus-MD- 75009503  8. Megafuge ST4R Plus-MD- 75009518  Service life: Not mentioned	TAN
2. M/s. Technolinks, Office No. 30, Ground Floor, Jalal Centre, 59-A Mozang Road, Lahore.  (ELI- 01249)  R&I detail 22-05-2025 Fee: 6,000/- Slip: 91452477	Legal Manufacturer:  M/s Diamond Diagnostics Inc., 333 Fiske St Holliston, MA USA 01746.  Manufacturing Site: Diamond Diagnostics Inc., 6 Oradna Street Budapest, Budapest, Hungary 1044.  • LOA Type: Copy of notarized Notarization: Notarized Validity: 25-03-2030  • FSC Type: Copy of apostilled Issued By: UD FDA Legalization: Apostilled Validity: 24-03-2026  • ISO Certificate Type: Copy Notarization: Not Notarized	Brand name: Diamond Prolyte Electrolyte Analyzer  Generic Name: Electrolyte Analyzer  Applied as: Single  Class: A  Model/Codes/Sizes: 00-DD-Prolyte  Service life: Not mentioned	Deferred due to following deficiencies in application;  Original FSC, LOA & ISO certificate, have not been submitted. The applicant has applied analyzer with accessories and consumables as single. The accessories & consumables applied have not been mentioned in Form with codes. Challan & covering letter mentions the words accessories and consumables. Moreover, fee of single item has been submitted instead of system. Service life information and data has not been submitted.

		<b>Validity:</b> 06-11-2026		
3.	M/s. Sindh Medical Stores,	Name of Manufacturer:	Brand name:	The Board approved
	13-B, Block 6, PECHS, Shahrah-e-Faisal, Karachi.  (ELI- 00010)	M/s DiaSorin Italia S.p.A., Via Crescentino, snc 13040 Saluggia (VC), Itlay.	ETI-MAX 3000	the case.
			Generic Name:	
		• LOA	Microtiter plate analyzer	
	R&I detail	Type: Original	W/12 (2)	
	22-05-2025	Notarization: Notarized	Applied as: System	
		Validity: 02-04-2029	i cho ob:	
	Fee: 6,000/-	AUI CCL	Class: A	
	<b>Slip:</b> 45005876	• FSC		
	Fee: 20,000/-	Type: Original	Model/Codes/Sizes:	
	<b>Slip:</b> 525023829	Issued By: MoH	10020	
		Legalization: Apostilled	10020	
	D	Validity: 24-03-2026	Service life:	
	N. Carlotte	6,19	10 Years	
		ISO Certificate	TO Tears	
		Type: Original		
		Notarization: Notarized		
	4100	Validity: 06-02-2028		Dlu.
4.	M/s. Sindh Medical Stores,	Name of Manufacturer:	Brand name:	The Board approved
	13-B, Block 6, PECHS, Shahrah-e-Faisal, Karachi.	M/s DiaSorin Italia S.p.A.,	LIAISON® XS	the case.
	Shahan-e-i aisai, Karacin.	Via Crescentino, snc 13040 Saluggia (VC), Itlay.	16.49 01.50	
	(ELL 00010)	Saluggia (VC), Illay.	Generic Name:	
	(ELI- 00010)	TO AUI COLO	Chemiluminescence	
	· ·	• LOA Type: Original	Immunoassay analyzer	
	R&I detail	Notarization: Notarized	126/1	
	22-05-2025	Validity: 02-04-2029	Applied as: System	
	Fee: 6,000/-	Validaty: 02 01 202)		
	<b>Slip:</b> 2500742830	• FSC	Class: A	
	Fee: 20,000/-	Type: Original		
	<b>Slip:</b> 651384932857	Issued By: MoH	Model/Codes/Sizes:	
		Legalization: Apostilled	10090	
	_6	Validity: 24-03-2026		
	700.		Service life:	
	160,	ISO Certificate	10 Years	
		250 Col tilleate		

		Type: Original		
		Notarization: Notarized		
	16/ 6/ 11 16	Validity: 06-02-2028		
5.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS,	Name of Manufacturer:	Brand name:	The Board approved the case.
	Shahrah-e-Faisal, Karachi.	M/s DiaSorin Italia S.p.A., Via Crescentino, snc 13040 Saluggia (VC), Itlay.	LIAISON® XL	the case.
	(ELI- 00010)		Generic Name:	
	R&I detail	• LOA Type: Original	Chemiluminescence Immunoassay analyzer	
	22-05-2025	Notarization: Notarized	VIII OV	
	Fee: 6,000/-	Validity: 02-04-2029	Applied as: System	
	<b>Slip:</b> 667015673855	180 A	Class: A	
	Fee: 20,000/- Slip: 0132344965	• FSC Type: Original		
	51pt 0132311903	Issued By: MoH	Model/Codes/Sizes:	
	7	Legalization: Apostilled	10050	
		Validity: 24-03-2026		
		707,	Service life: 10 Years	
	408	• ISO Certificate Type: Original		AM
	160.	Notarization: Notarized	.6)	$\langle 1 \rangle$
	119	Validity: 06-02-2028	MIS 65	
6.	M/s Cabbot Surgicals, Ho.	Name of Manufacturer:	Brand name:	Deferred due to
	No. CB 6060 Rose Lane 3-A, New Lalazar,	M/s Joimax GmbH,	Cam Source® LED	following deficiencies in application;
	Rawalpindi	Amalienbadstrabe 41, RaumFabrik 61, 76227	Alla Oly	
		RaumFabrik 61, 76227 Karlsruhe, Germany.	Generic Name:	• Application has been submitted as
	ELI-00415	La Company	Camera & Light Source	single while it
	ELI-00413	LOA	System	should be submitted as system since
	Date of R& I	Type: Copy of Notarized		FSC mentions
	22-05-2025		Applied as: Single	different devices with unique codes
	<b>Fee:</b> PKR 6,000/-	Notarization: Notarized		that will be
	<b>Slip</b> # 14591733201	<b>Validity:</b> 17-03-2025	Class: A	combined to
		1	Cattors 11	perform function as system.
		• FSC	N 11/0 1 /0!	Accordingly, Fee of
		Type: Copy	Model/Codes/Sizes:	Rs. 25000/- should be deposited by the
		Issued By: Govt Body	1. CSFHD01-Camsource® LED Control Unit	applicant.
	Ne	Legalization: Not legalized	2. CSFHD01CC-Camera Head	• LOA is copy and has expired.

	Issue Date: 26-11-2024 Validity: Not mentioned  • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027	Combo for Cam Source® LED Joimax® single cable technology, with function buttons 3. CSFHD01CO-Camera Head Ocular for Cam Source® LED with function buttons. 4. CSFHD01COAS-Fiber Optic Cable Adapter.  Service life: Not mentioned	<ul> <li>Copy of FSC submitted has not been legalized.</li> <li>Copy of ISO certificate has not been notarized.</li> <li>Service life information and data has not been submitted.</li> </ul>
7. M/s Cabbot Surgicals, H No. CB 6060 Rose Lane 2 A, New Lalaza Rawalpindi	M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227	Brand name: Vitegra®	Deferred due to following deficiencies in application;  • Application has
ET 1 00415	Karlsruhe, Germany.	Generic Name:	been submitted as single while it
ELI-00415	LOA	Visual Integration System	should be submitted as system since
Date of R& I 22-05-2025	Type: Copy of Notarized  Notarization: Notarized	Applied as: Single	FSC mentions different devices with unique codes
Fee: PKR 6,000/- Slip # 452409000328	Validity: 17-03-2025	Class: A	that will be combined to perform function as
No. Calibra Sussiants III	• FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned  • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027	Model/Codes/Sizes:  1. ICS0401S-Joimax Vitegra Visual Integration System Fully integrated Full HD documentation system.  2. ICS0401-Joimax Vitegra Control Unit 3. ICS0401D-Joimax Vitegra DICOM Module 4. JECTTHS-Joimax Vitegra Tablet mount set joimax tablethalter set 5. JESTTH-Adapter plate. 6. JVFS0001- Joimax Vitegra Foot Switch.  Service life: Not mentioned	system. Accordingly, Fee of Rs. 25000/- should be deposited by the applicant.  • LOA is copy and has expired.  • Copy of FSC submitted has not been legalized.  • Copy of ISO certificate has not been notarized.  • Service life information and data has not been submitted.
8. M/s Cabbot Surgicals, H No. CB 6060 Rose Lane A, New Lalaza	B- M/s Ioimay GmbH	Brand name: Intralaminar Endoscopic Surgical System (ILESSYS)	Deferred due to following deficiencies in application;

	Rawalpindi	RaumFabrik 61, 76227 Karlsruhe, Germany.	Transforaminal Endoscopic Surgical System (TESSYS)	• The applicant has applied three
	ELI-00415	LOA	Cervical Endoscopic Surgical System (CESSYS)	different endoscopic surgical sysrtems in a single
	Date of R& I 22-05-2025	Type: Copy of Notarized  Notarization: Notarized	Generic Name:	application. One system should be selected by the
	Fee: PKR 6,000/- Slip # 2960963069	Validity: 17-03-2025	Intralaminar Endoscopic Surgical System (ILESSYS)	applicant. Fee of Rs. 25000/- should be deposited by the
		• FSC	Transforaminal Endoscopic Surgical System (TESSYS)	<ul><li>applicant.</li><li>The relevant</li></ul>
		Type: Copy  Issued By: Govt Body	Cervical Endoscopic Surgical System (CESSYS)	devices to be combined in selected sytem
		Legalization: Not legalized	eli	selected sytem along with their codes, should be
		Issue Date: 26-11-2024 Validity: Not mentioned	Applied as: Single	mentioned in the application.
		valuey. Not included	Class: A	• LOA is copy and has expired.
	Y	• ISO Certificate Type: Copy	Model/Codes/Sizes:	• Copy of FSC submitted has not
		Notarization: Not Notarized	Not mentioned in application.	<ul><li>been legalized.</li><li>Copy of ISO certificate has not</li></ul>
		Validity: 23-12-2027	Garage 199	been notarized.  • Service life
	Medine		Service life: Not mentioned	information and data has not been submitted.
9.	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3- A, New Lalazar,	M/s Joimax GmbH, Amalienbadstrabe 41,	Brand name: Intracs® EM Sytem	Deferred due to following deficiencies in application;
	Rawalpindi	RaumFabrik 61, 76227 Karlsruhe, Germany.	Generic Name:	• Evidence of payment of fee has
	ELI-00415	LOA	Integrated Navigation Tracking & Control System	<ul><li>not been submitted.</li><li>Application has been submitted as</li></ul>
	Date of R& I 22-05-2025	Type: Copy of Notarized  Notarization: Notarized	Applied as: Single	single while it should be submitted as system since
	Fee: Not submitted	Validity: 17-03-2025	Class: B	FSC mentions different devices with unique codes that will be
		• FSC Type: Copy	Model/Codes/Sizes:	combined to perform function as
	-01	Issued By: Govt Body	1. JINT01S-Intracs EM	system. Accordingly, Fee of
	18dhe	<b>Legalization:</b> Not legalized <b>Issue Date:</b> 26-11-2024	System. Integrated Navigation Track & Control. 2. JINTCU1115-Intracs EM	Rs. 50,000/- should be deposited by the
1	N	1550C Date: 20-11-2024	2.JINTCOTTIJ-IIII acs EM	applicant.

		<ul> <li>Validity: Not mentioned</li> <li>ISO Certificate Type: Copy</li> <li>Notarization: Not Notarized</li> <li>Validity: 23-12-2027</li> <li>EU QMS Certificate Type: Copy</li> <li>Notarization: Not Notarized</li> <li>Validity: 31-01-2029</li> </ul>	Control Unit 3. JINTFG1125-Intracs EM Field Generator. 4. JINTPM2245-AP-Intracs EM Patient Mapper-AP 5. JINTPM2245-LAT-Intracs EM Patient Mapper-LAT 6. JINTSC2205-Intracs EM Sensor Clip 7. JINTPT2235-Intracs EM Patient Tracker.  Service life: 3 Years	<ul> <li>LOA is copy and has expired.</li> <li>Copy of FSC submitted has not been legalized.</li> <li>Copy of ISO certificate has not been notarized.</li> <li>Copy of EU QMS certificate has not been notarized.</li> <li>Service life data has not been submitted.</li> </ul>
10.	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3- A, New Lalazar, Rawalpindi	Name of Manufacturer:  M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany.	Brand name: Versicon® Spine Pump  Generic Name:	Deferred due to following deficiencies in application;  • LOA is copy and has expired.
	ELI-00415	6,19	Irrigation Pump	• Copy of FSC submitted has not
	Date of R& I 22-05-2025	LOA Type: Copy of Notarized Notarization: Notarized	Applied as: Single	<ul><li>been legalized.</li><li>Copy of ISO certificate has not been notarized.</li></ul>
	<b>Fee:</b> PKR 31,000/- <b>Slip</b> # 4337260846	Validity: 17-03-2025	Class: B	• Copy of EU QMS certificate has not
	Megn	• FSC Type: Copy Issued By: Govt Body	Model/Codes/Sizes: JISP3000	<ul><li>been notarized.</li><li>Service life data has not been submitted.</li></ul>
		Legalization: Not legalized	Service life: 3 Years	
		Issue Date: 26-11-2024 Validity: Not mentioned	loel, re	
	D'	• ISO Certificate Type: Copy		
	The state of the s	Notarization: Not Notarized Validity: 23-12-2027		
	- CS	• EU QMS Certificate Type: Copy		
	18dhe	Notarization: Not Notarized		
		<b>Validity:</b> 31-01-2029		

11.	M/s Cabbot Surgicals, Ho.	Name of Manufacturer:	Brand name:	Deferred due to
	No. CB 6060 Rose Lane 3-	M/s Joimax GmbH,	Endovapor® 2	following deficiencies
	A, New Lalazar, Rawalpindi	Amalienbadstrabe 41,	Zindo (upor O Z	in application;
	Kawaipiliul	RaumFabrik 61, 76227		• Application has
		Karlsruhe, Germany.	Generic Name:	been submitted as single while it
	ELI-00415		Multi Radio Frequency System	should be submitted
	Data of D % I	LOA	(6)	as system since FSC mentions
	Date of R& I 22-05-2025	<b>Type:</b> Copy of Notarized	Applied as: Single	different devices
		Notarization: Notarized	1/20 0:2	with unique codes
	<b>Fee:</b> PKR 62,000/- <b>Slip</b> # 476366701	Validity: 17-03-2025	Class: C	that will be combined to
	Shp # 470300701	AUII COL		perform function as
		• FSC	Model/Codes/Sizes:	system. Accordingly, Fee of
		Type: Copy	1. JEVD0201-Endovapor 2	Rs. 100,000/-
		Issued By: Govt Body	Device (Power rating 220-	should be deposited
		<b>Legalization:</b> Not legalized	240V)	<ul><li>by the applicant.</li><li>LOA is copy and</li></ul>
		Issue Date: 26-11-2024	2. JEVD0202-Endovapor 2 Device (Power rating 100-	has expired.
	P		127V)	• Copy of FSC submitted has not
		Validity: Not mentioned	3. REFUSS01-Footswitch	been legalized.
		41	Endovapor 2	• Copy of ISO
		• ISO Certificate	Service life: 3 Years	certificate has not been notarized.
		Type: Copy		• Copy of EU QMS
	And	<b>Notarization</b> : Not Notarized		certificate has not been notarized.
	VISO	<b>Validity:</b> 23-12-2027	(6)	Service life data has
		244	ركي الله	not been submitted.
		• EU QMS Certificate	16.41 0:3	
		Type: Copy	in and	
		<b>Notarization</b> : Not Notarized	Alls O'	
		<b>Validity:</b> 31-01-2029		
12.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1 <sup>st</sup> Floor ABC, Plaza, Commercial	M/s Vircell, S.L., Parque	Vircell Mumps ELISA	the case.
	Center, Satellite Town,	Tecnologico de la Salud,	IgG/IgM Kit	
	Rawalpindi.	Avicena 8, 18016 Granada, Spain.		
	<b>P</b>	(0, 50,	Generic Name:	
	(ELI- 00056)	• LOA	Mumps ELISA IgG/IgM Kit	
		Type: Copy of notarized		
	R&I detail	Notarization: Notarized	Applied as: Kit	
	27-05-2025	Validity: 31-12-2025		
	Fee: 31,000/-	(Original has been submitted	Class: B	
	No	in Vircell Herpes Simples		

	<b>Slip:</b> 440352963	1+2 ELISA IgG/ IgM Kit Dossier)	Model/Codes/Sizes:	
			G/M1014	
		• FSC Type: Copy of legalized		M
		Issued By: Regulatory Body	Shelf life: 21 Months (2-8°C)	1
		Legalization: Legalized	(19)	
		<b>Issue Date:</b> 10-07-2020	(19)	
		Validity: Not mentioned	1, 6(1, 9.	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	olistis Sossi	
		• ISO Certificate Type: Copy of notarized		
		Notarization: Notarized		
		Validity: 06-02-2027		
	dines	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		AM
	Mes	• EU QMS Certificate Type: Copy of notarized	(MIS)	
		Notarization: Notarized	1 91 9.	
		Validity: 17-10-2027	, 18/1000	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	iper, Son	
13.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1 <sup>st</sup> Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Vircell Chikungunya ELISA IgM Kit	the case.
		1	Generic Name:	
	(ELI- 00056)	• LOA Type: Copy of notarized	Chikungunya ELISA IgM Kit	
		Type. Copy of flotalized		
	R&I detail	Notarization: Notarized	Applied as: Kit	
13.	Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)  Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Vircell Chikungunya ELISA IgM Kit  Generic Name:	The Board approve the case.

	Fee: 31,000/-	(Original has been submitted	Class: B	
	<b>Slip:</b> 23898265	in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit		
		Dossier)	Model/Codes/Sizes:	
			M1010	
		• FSC		VIII.
		Type: Copy of legalized	Shelf life: 21 Months (2-8°C)	$\mathcal{A}$
		Issued By: Regulatory Body		
		Legalization: Legalized	1/12/10:22	
		<b>Issue Date:</b> 10-07-2020	1, 40, 2	
		Validity: Not mentioned	Mis Ols	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	lost, lo	
		• ISO Certificate  Type: Copy of notarized		
		Notarization: Notarized		
		<b>Validity:</b> 06-02-2027		
	Mednes	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	,,(5)	17 AM
		• EU QMS Certificate Type: Copy of notarized	1 (Mil) 0:20	
		Notarization: Notarized	lie, Obs.	
		<b>Validity:</b> 17-10-2027	N. 12	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	loer,	
14.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Vircell Chikungunya ELISA IgG Kit	the case.
		O.	Generic Name:	
	(ELI- 00056)	• LOA	Chikungunya ELISA IgG Kit	
	710	<b>Type:</b> Copy of notarized		

	R&I detail	Notarization: Notarized	Applied as: Kit	
	27-05-2025	Validity: 31-12-2025		
	Fee: 31,000/-	(Original has been submitted	Class: B	
	<b>Slip:</b> 212563640183	in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit		
		Dossier)	Model/Codes/Sizes:	
			G1010	
		• FSC	(4)	
		<b>Type:</b> Copy of legalized	<b>Shelf life:</b> 21 Months (2-8°C)	
		<b>Issued By:</b> Regulatory Body	i cho ob	
		Legalization: Legalized	10/12 00 h	
		<b>Issue Date:</b> 10-07-2020		
		Validity: Not mentioned	Co.,	
	P	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
		ISO Certificate		
		Type: Copy of notarized		
		Notarization: Notarized		
	700	Validity: 06-02-2027		D.I.
	Medical	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	1 (MIS) 9:55	
		• EU QMS Certificate Type: Copy of notarized	lolis, 505;2	
		Notarization: Notarized	10st, 50,	
		Validity: 17-10-2027	100	
	P	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
15.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada,	Vircell Measles ELISA IgG/IgM Kit	the case.
	Medil	Spain.	Generic Name:	

	(ELI- 00056)	• LOA Type: Copy of notarized	Measles ELISA IgG/IgM Kit	
	R&I detail	Notarization: Notarized	Applied as: Kit	
	27-05-2025	Validity: 31-12-2025	rippiicu us. Itic	
	Fee: 31,000/- Slip: 9280427983	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	Class: B  Model/Codes/Sizes:  G/M1001	17 AM
		• FSC Type: Copy of legalized	ish op,	
		Issued By: Regulatory Body	<b>Shelf life:</b> 21 Months (2-8°C)	
		Legalization: Legalized	el.	
		<b>Issue Date:</b> 10-07-2020	100	
		Validity: Not mentioned		
	P	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
	All es	• ISO Certificate Type: Copy of notarized Notarization: Notarized		AM
	Nec	Validity: 06-02-2027	(6)	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	oet, 5052, 0:25	
		• EU QMS Certificate  Type: Copy of notarized	(OS),	
		Notarization: Notarized		
		<b>Validity:</b> 17-10-2027		
	P	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
16.	M/s. Med Lab Services, Office No. 1, 1 <sup>st</sup> Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada,	Brand name:  Vircell Cytomegalovirus  ELISA IgM Capture Kit	The Board approved the case.

	Spain.	Generic Name:	
(ELI- 00056)		Cytomegalovirus ELISA Kit	
R&I detail	• LOA Type: Copy of notarized	Applied as: Kit	
27-05-2025	<b>Notarization</b> : Notarized		VIII.
Fee: 62,000/-	<b>Validity:</b> 31-12-2025	Class: C	$\langle 1 \rangle$
Slip: 1333281656	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	Model/Codes/Sizes: M1004	
	• FSC Type: Copy of legalized	Shelf life: 21 Months (2-8°C)	
	Issued By: Regulatory Body	NO.	
	Legalization: Legalized		
	<b>Issue Date:</b> 10-07-2020		
Y	Validity: Not mentioned		
	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
Meglue	• ISO Certificate Type: Copy of notarized Notarization: Notarized	(19115)	T A
	Validity: 06-02-2027	11/10/15	
	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	ioel, 5052	
	• EU QMS Certificate Type: Copy of notarized		
Y	Notarization: Notarized		
	Validity: 17-10-2027		
108	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
17. M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
Office No. 1, 1st Floor	M/s Vircell, S.L., Parque	Vircell Cytomegalovirus	the case.

ABC, Plaza, Commercial Tecnologico de la Salud, ELISA IgG Kit Center, Satellite Town, Avicena 8, 18016 Granada, Spain. Rawalpindi. Generic Name: Cytomegalovirus ELISA Kit • LOA (ELI- 00056) Type: Copy of notarized Applied as: Kit Notarization: Notarized **R&I** detail Validity: 31-12-2025 27-05-2025 Class: C (Original has been submitted Fee: 62,000/in Vircell Herpes Simples Slip: 4228202157 1+2 ELISA IgG/ IgM Kit Model/Codes/Sizes: Dossier) G1004 • FSC Type: Copy of legalized **Shelf life:** 21 Months (2-8°C) Issued By: Regulatory Body Legalization: Legalized **Issue Date:** 10-07-2020 Validity: Not mentioned (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier) • ISO Certificate **Type:** Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier) • EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)

18.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada,	Vircell Syphilis ELISA IgG + IgM Kit  Generic Name:	the case.
		Spain.	Syphilis ELISA IgG + IgM Kit	CAN
	(ELI- 00056)	• LOA Type: Copy of notarized	Applied as: Kit	1
	R&I detail	Notarization: Notarized	1/1/2/ 0:22	
	27-05-2025	<b>Validity:</b> 31-12-2025	Class: C	
	Fee: 62,000/- Slip: 269130426	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	Model/Codes/Sizes: T1060	
	P	• FSC (Verified Via Website of Regulatory Body) Type: Copy	Shelf life: 21 Months (2-8°C)	
		Issued By: Regulatory Body		
		Legalization: Not Legalized		
	Cit Cit	Issue Date: 27-06-2022		No.
	Medine	Validity: Not mentioned	(9)	1 A.
		• ISO Certificate Type: Copy of notarized	1 (Mil) 0:20	
		Notarization: Notarized	1.000	
		Validity: 06-02-2027	1011200	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	loer,	
	P	• EU QMS Certificate		
		<b>Type:</b> Copy of notarized		
		Notarization: Notarized		
		Validity: 17-10-2027		
	Nednes	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		

19.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	-	the case.
	(ELI- 00056)	• LOA Type: Copy of notarized	Applied as: Kit	1
	R&I detail	Notarization: Notarized	1 (19, 9) 0:22	
	27-05-2025	Validity: 31-12-2025	Class: C	
	Fee: 62,000/- Slip: 9650841683	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	Model/Codes/Sizes: G1027	
	P	• FSC (Verified Via Website of Regulatory Body) Type: Copy	Shelf life: 21 Months (2-8°C)	
		Issued By: Regulatory Body		
		Legalization: Not Legalized		
		Issue Date: 27-06-2022		
	Medine	Validity: Not mentioned	(6)	1 R.
		• ISO Certificate Type: Copy of notarized	1 (4), 0:50	
		Notarization: Notarized	" che ob,	
		Validity: 06-02-2027	1011200	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	iper,	
	P	EU QMS Certificate		
	,	<b>Type:</b> Copy of notarized		
		<b>Notarization</b> : Notarized		
		Validity: 17-10-2027		
	Mednes	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		

20.	M/s. Med Lab Services,	Name of Manufacturer:	Brand name:	The Board approved
	Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Vircell Toxoplasma ELISA IgM Capture Kit  Generic Name:  Toxoplasma ELISA IgM Kit	the case.
	(ELI- 00056)	• LOA Type: Copy of notarized	Applied as: Kit	11
	R&I detail	Notarization: Notarized	1/1/2/ 0:22	
	27-05-2025	Validity: 31-12-2025	Class: C	
	Fee: 62,000/- Slip: 00774078	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	Model/Codes/Sizes: M1027	
	P	• FSC (Verified Via Website of Regulatory Body) Type: Copy	Shelf life: 21 Months (2-8°C)	
		Issued By: Regulatory Body		
		Legalization: Not Legalized		_
	Medines	Issue Date: 27-06-2022 Validity: Not mentioned	(5)	TARM
		• ISO Certificate  Type: Copy of notarized  Notarization: Notarized	1 (Mile) 9:55	
		Validity: 06-02-2027	lier Uso,	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	ioel, Te	
	P	EU QMS Certificate		
		<b>Type:</b> Copy of notarized		
		Notarization: Notarized		
		Validity: 17-10-2027		
	Medines	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		

21.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	Approved subject to
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial	M/s Vircell, S.L., Parque Tecnologico de la Salud,	Herpes Simplex 1+2 Virclia® IgM Monotest Kit	submission of Original Notarized LOA.
	Corporation, Punjab	Avicena 8, 18016 Granada, Spain.	Generic Name:	LOA.
	Industrial State, Taxila, Rawalpindi.	Spani.	Herpes Simplex IgM Monotest Kit	AM
	(ELI- 00496)	• LOA Type: Copy of notarized	Applied as: Kit	
		Notarization: Notarized	rippited us. Ist	
	<b>R&amp;I detail</b> 14-07-2025	Validity: 31-12-2025	Class: C	
	Fee: 62,000/- Slip: 183147898806	• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled	Model/Codes/Sizes: VCM036	
		<b>Issued By:</b> Regulatory Body	Shelf life: 15 Months (2-8oC)	
		Legalization: Apostilled		
		<b>Issue Date:</b> 14-03-2025		
		Validity: Not mentioned		
	18dhes	• ISO Certificate  Type: Copy of notarized		7 AM
	W	Notarization: Notarized		
		Validity: 06-02-2027	16,9 0.50	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	iolishen 2025,	
		• EU QMS Certificate Type: Copy of notarized		
		Notarization: Notarized		
	<b>Y</b>	Validity: 17-10-2027		
	_6	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		
22.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	Approved subject to
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial	M/s Vircell, S.L., Parque Tecnologico de la Salud,	Measles Virclia® IgG Monotest Kit	submission of Original Notarized

	Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Avicena 8, 18016 Granada, Spain.	Generic Name: Measles IgG Monotest Kit	LOA.
	(ELI- 00496)	• LOA Type: Copy of notarized	Applied as: Kit	MA
	R&I detail	Notarization: Notarized Validity: 31-12-2025	Class: B	1
	04-07-2025 Fee: 31,000/- Slip: 551120567	• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled	Model/Codes/Sizes: VCM054 Shelf life: 15 Months (2-8oC)	
		Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025	losi,	
		<ul><li>Validity: Not mentioned</li><li>ISO Certificate</li><li>Type: Copy of notarized</li></ul>		
	Meglues	Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	1 (MIS) 9:55	TAM
		• EU QMS Certificate Type: Copy of notarized	10st, 5052,	
		Notarization: Notarized  Validity: 17-10-2027	De	
	P	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		
23.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name:  Toxoplasma Virclia® IgM Monotest Kit  Generic Name:  Toxoplasma IgM Monotest Kit	Approved subject to submission of Original Notarized LOA.

		• LOA		
	(ELI- 00496)	<b>Type:</b> Copy of notarized	Applied as: Kit	
	(221 00 170)	Notarization: Notarized	rippiicu us. ixi	
	R&I detail	Validity: 31-12-2025	Class: C	ngh.
	04-07-2025 Fee: 62,000/- Slip: 816123169047	• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled	Model/Codes/Sizes: VCM088	
		Issued By: Regulatory Body	Shelf life: 15 Months (2-8oC)	
		Legalization: Apostilled	0, 00,	
		Issue Date: 14-03-2025		
		Validity: Not mentioned	100	
		isto Wiel		
	P	• ISO Certificate Type: Copy of notarized		
		Notarization: Notarized		
		Validity: 06-02-2027		
	Mednes	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	,(5)	TAM
		• EU QMS Certificate Type: Copy of notarized	1 (4) 9:50	
		Notarization: Notarized	1.60 00,	
		<b>Validity:</b> 17-10-2027	Ollador	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	iper,	
24.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	Approved subject to
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada,	Toxoplasma Virclia® IgG Monotest Kit Generic Name:	submission of Original Notarized LOA.
	Industrial State, Taxila, Rawalpindi.	Spain.	Toxoplasma IgG Monotest Kit	
	(ELI- 00496)	• LOA Type: Copy of notarized	Applied as: Kit	
		Notarization: Notarized		

		<b>Validity:</b> 31-12-2025	Class: C	
	R&I detail			
	04-07-2025	• FSC (Verified Via	Model/Codes/Sizes:	
	Fee: 62,000/-	Website of Regulatory Body)	VCM087	Also
	Slip: 4688828663	<b>Type:</b> Copy of apostilled		1 Die
		<b>Issued By:</b> Regulatory Body	Shelf life: 15 Months (2-8oC)	
		Legalization: Apostilled	1/12/1 01:22	
		<b>Issue Date:</b> 14-03-2025	in house	
		Validity: Not mentioned	lolis, 505;2	
		• ISO Certificate  Type: Copy of notarized	loer,	
		Notarization: Notarized		
		<b>Validity:</b> 06-02-2027		
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
	iedhe.	• EU QMS Certificate Type: Copy of notarized		1 AM
	No	Notarization: Notarized	1131	
	*	Validity: 17-10-2027	160.9 0.20	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	iolishen 2025, S	
25.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	Approved subject to
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	M/s Vircell, S.L., Parque	Cytomegalovirus Virclia® IgM	submission of Original Notarized
	Small Industrial	Tecnologico de la Salud, Avicena 8, 18016 Granada,	Monotest Kit	LOA.
	Corporation, Punjab Industrial State, Taxila,	Spain.	Generic Name: Cytomegalovirus IgM	
	Rawalpindi.		Monotest Kit	
		• LOA Type: Copy of notarized		
	(ELI- 00496)	Notarization: Notarized	Applied as: Kit	
	R&I detail	Validity: 31-12-2025	Class: C	
	04-07-2025	FCC (Voulge - 1 V):-		
	one of 07th Moot	• FSC (Verified Via	0.0.2025	22 9 9 74   327

	Fee: 62,000/-	Website of Regulatory	Model/Codes/Sizes:	
	Slip: 14172168	<b>Body</b> ) <b>Type:</b> Copy of apostilled	VCM022	
		<b>Issued By:</b> Regulatory Body	Shelf life: 15 Months (2-8oC)	M
		Legalization: Apostilled		
		<b>Issue Date:</b> 14-03-2025	.(6)	
		Validity: Not mentioned	(M), (2)	•
		030.	1, 6(1, 9,	
		• ISO Certificate  Type: Copy of notarized	1131	
		Notarization: Notarized	10112 JON	
		<b>Validity:</b> 06-02-2027	(1)	
	P	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		
		• EU QMS Certificate Type: Copy of notarized		
		Notarization: Notarized		
	Alle	Validity: 17-10-2027		
	Men	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	1 (MIS) 9:55	
26.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	Approved subject to
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada,	Parvovirus Virclia® IgG Monotest Kit	submission of Original Notarized LOA.
	Industrial State, Taxila, Rawalpindi.	Spain.	Generic Name:	
		• LOA	Parvovirus IgG Monotest Kit	
	(ELI- 00496)	Type: Copy of notarized  Notarization: Notarized	Applied as: Kit	
	R&I detail	Validity: 31-12-2025		
	14-07-2025	707,	Class: B	
	Fee: 31,000/-	• FSC (Verified Via		
	Slip: 511251287562	Website of Regulatory Body)	Model/Codes/Sizes:	
	Nev	Type: Copy of apostilled	VCM075	

		<b>Issued By:</b> Regulatory Body	Shelf life: 15 Months (2-8oC)	
		Legalization: Apostilled		
		Issue Date: 14-03-2025		
		Validity: Not mentioned		DU.
		• ISO Certificate	1115)	1
		<b>Type:</b> Copy of notarized	16,7 0.22	
		Notarization: Notarized	1, 10, 10, 10, 10, 10, 10, 10, 10, 10, 1	
		Validity: 06-02-2027	(18), J.S.	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	lost, So.	
	P	• EU QMS Certificate Type: Copy of notarized		
		Notarization: Notarized		
		Validity: 17-10-2027		
	1ednes	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		7 AM
27.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	• Approved subject
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	M/s Vircell, S.L., Parque	Diphtheria Virclia® IgG	to submission of Original Notarized
	Small Industrial	Tecnologico de la Salud, Avicena 8, 18016 Granada,	Monotest Kit	LOA.
	Corporation, Punjab Industrial State, Taxila,	Spain.	Generic Name:	
	Rawalpindi.	MODELL SOL	Diphtheria IgG Monotest Kit	
		• LOA	el'	
	(ELI- 00496)	Type: Copy of notarized	Applied as: Kit	
		Notarization: Notarized		
	R&I detail	<b>Validity:</b> 31-12-2025	Class: B	
	14-07-2025	6,12		
	Fee: 31,000/-	• FSC (Verified Via	Model/Codes/Sizes:	
	Slip: 086804456073	Website of Regulatory Body) Type: Copy of apostilled	VCM006	
	dhe	Issued By: Regulatory Body	Shelf life: 15 Months (2-8oC)	
	Ne	Legalization: Apostilled		

		<b>Issue Date:</b> 14-03-2025		
		Validity: Not mentioned		
		• ISO Certificate		An.
		<b>Type:</b> Copy of notarized		
		<b>Notarization:</b> Notarized	(6)	
		Validity: 06-02-2027	in the	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	plisher) 9:3	
		• EU QMS Certificate		
		<b>Type:</b> Copy of notarized	100	
		Notarization: Notarized	,	
		Validity: 17-10-2027		
	Y	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		
28.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	• Approved subject
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	M/s Vircell, S.L., Parque	Coxiella Burnetii Virclia® IgM	to submission of Original Notarized
	Small Industrial	Tecnologico de la Salud, Avicena 8, 18016 Granada,	Monotest Kit	LOA.
	Corporation, Punjab		~	
		Spain.	Generic Name:	
	Industrial State, Taxila, Rawalpindi.	Spain.	Generic Name:  Coxiella Burnetii IgM  Monotest Kit	
	Industrial State, Taxila,	• LOA	Coxiella Burnetii IgM	
	Industrial State, Taxila,	• LOA Type: Copy of notarized	Coxiella Burnetii IgM Monotest Kit	
	Industrial State, Taxila, Rawalpindi.	• LOA Type: Copy of notarized Notarization: Notarized	Coxiella Burnetii IgM	
	Industrial State, Taxila, Rawalpindi.	• LOA Type: Copy of notarized	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)	• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025	Coxiella Burnetii IgM Monotest Kit	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 </li> <li>FSC (Verified Via)</li> </ul>	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 14-07-2025	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 </li> <li>FSC (Verified Via Website of Regulatory Body)</li> </ul>	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit  Class: B  Model/Codes/Sizes:	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 14-07-2025 Fee: 31,000/-	<ul> <li>LOA         Type: Copy of notarized         Notarization: Notarized         Validity: 31-12-2025     </li> <li>FSC (Verified Via Website of Regulatory</li> </ul>	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit  Class: B	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 14-07-2025 Fee: 31,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 </li> <li>FSC (Verified Via Website of Regulatory Body)</li> </ul>	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit  Class: B  Model/Codes/Sizes:	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 14-07-2025 Fee: 31,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 </li> <li>FSC (Verified Via Website of Regulatory Body)</li> <li>Type: Copy of apostilled</li> <li>Issued By: Regulatory</li> </ul>	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit  Class: B  Model/Codes/Sizes:  VCM020	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 14-07-2025 Fee: 31,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</li> <li>FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body</li> </ul>	Coxiella Burnetii IgM Monotest Kit  Applied as: Kit  Class: B  Model/Codes/Sizes:  VCM020	

29.	M/s. Lab Diagnostic	• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)  • EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier) Name of Manufacturer:	Brand name:	Approved subject to submission of
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.  (ELI- 00496)	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.  • LOA Type: Copy of notarized Notarization: Notarized	Chagas Virclia® IgG + IgM Monotest Kit  Generic Name: Chagas IgG + IgM Monotest Kit  Applied as: Kit	submission of Original Notarized LOA.
	R&I detail 14-07-2025 Fee: 31,000/- Slip: 720406673367	<ul> <li>Validity: 31-12-2025</li> <li>FSC (Verified Via Website of Regulatory Body)</li> <li>Type: Copy of apostilled</li> </ul>	Class: B  Model/Codes/Sizes:  VCM008	
	Wednes	Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned  • ISO Certificate Type: Copy of notarized	Shelf life: 15 Months (2-8oC)	22 g 2 78   327

		Notarization: Notarized		
		Validity: 06-02-2027		
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		TAM
		• EU QMS Certificate Type: Copy of notarized Notarization: Notarized	11 (MI) 9:55	
		Validity: 17-10-2027	alie of	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	ipel, So	
30.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	Approved subject to
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial	M/s Vircell, S.L., Parque Tecnologico de la Salud,	Syphilis Virclia® IgG + IgM Monotest Kit	submission of Original Notarized LOA.
	Corporation, Punjab	Avicena 8, 18016 Granada, Spain.	Generic Name:	
	Industrial State, Taxila, Rawalpindi.	937,	Syphilis IgG + IgM Monotest Kit	
		• LOA Type: Copy of notarized		VPU
	(ELI- 00496)	Notarization: Notarized	Applied as: Kit	1
	R&I detail	Validity: 31-12-2025	Class: C	
	14-07-2025 Fee: 62,000/-	FSC (Verified Via Website of Regulatory	Model/Codes/Sizes:	
	Slip: 85900923742	Body) Type: Copy of apostilled	VCM086	
		Issued By: Regulatory Body	Shelf life: 15 Months (2-8oC)	
		Legalization: Apostilled		
	D	<b>Issue Date:</b> 14-03-2025		
		Validity: Not mentioned		
		• ISO Certificate  Type: Copy of notarized		
	0	Notarization: Notarized		
	10011	Validity: 06-02-2027		
	No	(Original has been		
		(511811101 1100 00011	L	

31.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 26-06-2025 Fee: 31,000/- Slip: 33354062711	submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)  • EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)  Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.  • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025  • FSC (Verified Via Website of Regulatory Body) Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Issue Date: 14-03-2025  Validity: Not mentioned  • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	Brand name: Chickengunya Virclia® IgG Monotest Kit Generic Name: Chickengunya IgG Monotest Kit Applied as: Kit Class: B Model/Codes/Sizes: VCM059 Shelf life: 15 Months (2-8°C)	Approved subject to submission of Original Notarized LOA.
	Mediles			

		• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	11(5)	TAM
32.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name: Hepatitis E Virclia® IgG Monotest Kit Generic Name: Hepatitis E IgG Monotest Kit	Approved subject to submission of Original Notarized LOA.
	(ELI- 00496)	• LOA Type: Copy of notarized Notarization: Notarized	Applied as: Kit	
	<b>R&amp;I detail</b> 26-06-2025	Validity: 31-12-2025	Class: B	
	Fee: 31,000/- Slip: 027670024181	<ul> <li>FSC (Verified Via Website of Regulatory Body)</li> <li>Type: Copy of apostilled</li> </ul>	Model/Codes/Sizes: VCM066	AM
	Meon	Issued By: Regulatory Body Legalization: Apostilled Issue Date: 06-02-2025 Validity: Not mentioned  • ISO Certificate	Shelf life: 15 Months (2-8°C)	
		Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027	ios.	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)  • EU QMS Certificate		
	"16qUe	Type: Copy of notarized  Notarization: Notarized		

		<b>Validity:</b> 17-10-2027		
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		Also.
33.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name: Hydatidosis Virclia® IgG Monotest Kit Generic Name: Hydatidosis IgG Monotest Kit	<ul> <li>Approved subject to submission of Original Notarized LOA.</li> </ul>
	(ELI- 00496)	• LOA Type: Copy of notarized Notarization: Notarized	Applied as: Kit	
	R&I detail 26-06-2025 Fee: 31,000/- Slip: 5380710965	Validity: 31-12-2025  • FSC (Verified Via Website of Regulatory Body)  Type: Copy of Apostilled	Class: B  Model/Codes/Sizes:  VCM040	
	Medines	Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned  • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted	Shelf life: 15 Months (2-8°C)	17 AM
	Nednes	in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)  • EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit		

		Dossier)		
34.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name:  Mumps Virclia® IgM Monotest Kit  Generic Name:  Mumps IgM Monotest Kit	Approved subject to submission of Original Notarized LOA.
	(ELI- 00496)	• LOA Type: Copy of notarized Notarization: Notarized	Applied as: Kit	•
	<b>R&amp;I detail</b> 26-06-2025	Validity: 31-12-2025	Class: B	
	Fee: 31,000/- Slip: 720989986	• FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled	Model/Codes/Sizes: VCM061	
	P	Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned	Shelf life: 15 Months (2-8°C)	
	Wednes	• ISO Certificate Type: Copy of notarized Notarization: Notarized	MIS) .55	TRIN
		Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	ioel, 5052, displaying	
		• EU QMS Certificate Type: Copy of notarized		
	P	Notarization: Notarized Validity: 17-10-2027		
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		
35.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud,	Brand name: Aspergillus Galactomannan	Approved subject to submission of Original Notarized

	Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Avicena 8, 18016 Granada, Spain.  • LOA	AG Virclia® Monotest Kit  Generic Name:  Aspergillus Galactomannan AG Monotest Kit	LOA.
	(ELI- 00496)  R&I detail	Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025	Applied as: Kit	17 AM
	26-06-2025 Fee: 62,000/- Slip: 83615382509	• FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled	Class: C  Model/Codes/Sizes:  VCM073	
	P.	<b>Issued By:</b> Regulatory Body <b>Legalization:</b> Apostilled <b>Issue Date:</b> 14-03-2025 <b>Validity:</b> Not mentioned	Shelf life: 15 Months (2-8°C)	
	Medines	• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	(MIS) 0:55	TAM
		• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	iper, 5052	
36.	M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	Name of Manufacturer:  M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name:  Mumps Virclia® IgG Monotest Kit  Generic Name:  Mumps IgG Monotest Kit	Approved subject to submission of Original Notarized LOA.
	0 0 7 4 4 7 7	• LOA		0.000 0.4   207

		Type: Copy of notarized	Applied as: Kit	
	(ELI- 00496)	Notarization: Notarized		
		<b>Validity:</b> 31-12-2025	Class: B	
	R&I detail			
	26-06-2025	• FSC (Verified Via	Model/Codes/Sizes:	
	Fee: 31,000/-	Website of Regulatory	VCM060	
	<b>Slip:</b> 218984870694	<b>Body</b> ) <b>Type:</b> Copy of Apostilled	ركي أأألي	
	_	Issued By: Regulatory Body	<b>Shelf life:</b> 15 Months (2-8°C)	
		Legalization: Apostilled	i cho chi	
		Issue Date: 14-03-2025	Alls Oly	
		Validity: Not mentioned	10. 10	
		variancy. From inclination	(G),	
		ISO Certificate		
		Type: Copy of notarized		
	D	Notarization: Notarized		
	•	Validity: 06-02-2027		
		(Original has been submitted		
		in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit		
		Dossier)		
	AUS			Alla
	1180	• EU QMS Certificate	.(6)	
		Type: Copy of notarized	WIII (5)	
		Notarization: Notarized	16.90 0:3	
		Validity: 17-10-2027	i cho ob	
		(Original has been submitted	Alls O'V	
		in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit		
		Dossier)	COI,	
37.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	• Approved subject
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	M/s Vircell, S.L., Parque	Measles Virclia® IgM	to submission of Original Notarized
	Small Industrial	Tecnologico de la Salud, Avicena 8, 18016 Granada,		LOA.
	Corporation, Punjab Industrial State, Taxila,	Spain.	Generic Name:	
	Rawalpindi.		Measles IgM Monotest Kit	
		• LOA		
	(ELI- 00496)	Type: Copy of notarized	Applied as: Kit	
	Ane	Notarization: Notarized		
	R&I detail	Validity: 31-12-2025	Class: B	

Fee: 31,000/-  Skin: 4257667081  • FSC (Verified Via Website of Regulatory VCM057	s·
Slip: 4357667981  Body)  Type: Copy of apostilled  VCM057	
Issued By: Regulatory Body Shelf life: 15 Month	ths (2-8°C)
Legalization: Apostilled	
Issue Date: 06-02-2025	(2)
Validity: Not mentioned	9.5
• ISO Certificate Type: Copy of notarized	
Notarization: Notarized	
Validity: 06-02-2027	
(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	
• EU QMS Certificate Type: Copy of notarized	
Notarization: Notarized	DIV.
Validity: 17-10-2027	
(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	0:22
38. M/s. Lab Diagnostic Name of Manufacturer: Brand name:	• Approved subject
Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Tecnologico de la Salud, Monotest Kit	rclia® IgM to submission of Original Notarized LOA.
Small Industrial Corporation, Punjab Spain.  Industrial Corporation, Punjab Spain.  Industrial Corporation, Punjab Spain.  Industrial Corporation, Punjab Spain.	LOA.
Rawalpindi Chickengunya IgM	M Monotest
• LOA Kit	
(ELI- 00496) Type: Copy of notarized Applied as: Kit	
Notarization: Notarized	
R&I detail Validity: 31-12-2025	
26-06-2025	
Fee: 31,000/- Slip: 36447614  • FSC (Verified Via Website of Regulatory Body)  Model/Codes/Sizes	s:

		Type: Copy of Apostilled	VCM063	
		Issued By: Regulatory Body		
		Legalization: Apostilled	<b>Shelf life:</b> 15 Months (2-8°C)	
		Issue Date: 14-03-2025		1.0
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			(6)	
		• ISO Certificate  Type: Copy of notarized	(M) .55	•
		Notarization: Notarized	1. O.	
		Validity: 06-02-2027	118/100	
		(Original has been submitted	10110 50	
		in Vircell Herpes Simples		
		1+2 ELISA IgG/ IgM Kit Dossier)	De	
		Bossiery		
		• EU QMS Certificate		
	Y	Type: Copy of notarized		
		Notarization: Notarized		
		Validity: 17-10-2027		
	0	(Original has been submitted		
	AU <sub>e</sub> ,	in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit		
	1180	Dossier)	(2)	
39.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	• Approved subject to submission of
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	M/s Vircell, S.L., Parque		Original Notarized
	Small Industrial	Tecnologico de la Salud, Avicena 8, 18016 Granada,		LOA.
	Corporation, Punjab Industrial State, Taxila,	Spain.	Generic Name:	
	Rawalpindi.	Plo Oll bi	Brucella IgM Monotest Kit	
		• LOA	Applied og Vit	
	(ELI- 00496)	Type: Copy of notarized	Applied as: Kit	
		Notarization: Notarized	Class D	
	R&I detail	<b>Validity:</b> 31-12-2025	Class: B	
	26-06-2025	TOO (A) 100 144	Model/Codes/Stress	
	Fee: 31,000/-	• FSC (Verified Via Website of Regulatory	Model/Codes/Sizes:	
	<b>Slip:</b> 59174230158	Body)	VCM007	
	200	<b>Type:</b> Copy of Apostilled	Cholf life: 15 Manufac (2.99C)	
	4.00/11/2	Issued By: Regulatory Body	<b>Shelf life:</b> 15 Months (2-8°C)	
	1/10	Legalization: Apostilled		

		<b>Issue Date:</b> 14-03-2025		
		Validity: Not mentioned		
		ISO Certificate		
		<b>Type:</b> Copy of notarized		
		<b>Notarization</b> : Notarized	(6)	
		Validity: 06-02-2027	Will Po	
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)	iolisher) 9:3	
		• EU QMS Certificate	vel,	
		<b>Type:</b> Copy of notarized		
		<b>Notarization</b> : Notarized		
		<b>Validity:</b> 17-10-2027		
		(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		
40.	M/s. Lab Diagnostic	Name of Manufacturer:	Brand name:	• Approved subject
	Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab	M/s Vircell, S.L., Parque Tecnologico de la Salud,	Herpes Simplex 1+2 Virclia® IgG Monotest Kit	to submission of Original Notarized
	Small Industrial		150 Monotest Rit	LOA.
	Corporation. Puniab	Avicena 8, 18016 Granada,	Generic Name:	LOTI.
	Corporation, Punjab Industrial State, Taxila,	Avicena 8, 18016 Granada, Spain.	Generic Name: Herpes Simplex IgG Monotest	DOM:
		Spain.	Generic Name: Herpes Simplex IgG Monotest Kit	LOTE
	Industrial State, Taxila, Rawalpindi.	Spain.  • LOA	Herpes Simplex IgG Monotest	LOTE
	Industrial State, Taxila,	Spain.	Herpes Simplex IgG Monotest	LOTE.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)	<ul><li>Spain.</li><li>LOA</li><li>Type: Copy of notarized</li></ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit	LOTE.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail	<ul><li>• LOA</li><li>Type: Copy of notarized</li><li>Notarization: Notarized</li></ul>	Herpes Simplex IgG Monotest Kit	LOTE.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)	<ul> <li>LOA</li> <li>Type: Copy of notarized</li> <li>Notarization: Notarized</li> <li>Validity: 31-12-2025</li> <li>FSC (Verified Via)</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C	LOTE.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 04-07-2025	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</li> <li>FSC (Verified Via Website of Regulatory</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C  Model/Codes/Sizes:	EOT.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 04-07-2025  Fee: 62,000/-	<ul> <li>LOA</li> <li>Type: Copy of notarized</li> <li>Notarization: Notarized</li> <li>Validity: 31-12-2025</li> <li>FSC (Verified Via)</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C	LOTE.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 04-07-2025  Fee: 62,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 </li> <li>FSC (Verified Via Website of Regulatory Body)</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C  Model/Codes/Sizes:  VCM034	BOTT.
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 04-07-2025  Fee: 62,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</li> <li>FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C  Model/Codes/Sizes:	
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 04-07-2025  Fee: 62,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</li> <li>FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled Issued By: Regulatory Body</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C  Model/Codes/Sizes:  VCM034	DOTE
	Industrial State, Taxila, Rawalpindi.  (ELI- 00496)  R&I detail 04-07-2025  Fee: 62,000/-	<ul> <li>LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</li> <li>FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled Issued By: Regulatory Body Legalization: Apostilled</li> </ul>	Herpes Simplex IgG Monotest Kit  Applied as: Kit  Class: C  Model/Codes/Sizes:  VCM034	DOT.

	• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)  • EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	interiors, 9:55	T ANN
Systems (SMC) Pvt Plot No. 36-A, Small Inc Corporation,		Brand name: Virclia® Lotus  Generic Name: In Vitro Chemiluminescent Immunoassay Analyzer.  Applied as: Kit  Class: A  Model/Codes/Sizes: VCLTS-CL  Service life: Not Mentioned	Deferred due to following deficiencies in application;  Original notarized LOA has not been submitted. Data and information pertaining to Service life has not been submitted. System has been applied as single. Differential fee is required.

	Validity: 06-02-2027		
	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)		AM
	• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)	oer, 2025, 9:55	
42. M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.	M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name: Virclia® Auxiliary Reagents  Generic Name: Auxiliary Reagents for washing, decontamination and	Approved subject to submission of Original Notarized LOA.
(ELI- 00496) R&I detail	• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025	dilution steps of Virclia Kits.  Applied as: Family	T AM
26-06-2025  Fee: 25,000/- Slip: 7996184219	• FSC (Verified Via Website of Regulatory Body)	Class: A  Model/Codes/Sizes:	
	Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 06-02-2025 Validity: Not mentioned	1. VCMAR (Virclia Auxiliary Reagent) 2. VCMAR-DS (Virclia Auxiliary Reagent-DS)-30 Months 3. VCMAR-EDB (Virclia	
P	• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027	Auxiliary Reagent-EDB) 4. VCMAR-EDP (Virclia Auxiliary Reagent-EDP) 5. VCMAR-W1 (Virclia Auxiliary Reagent-W1)	
Meque	(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit	Shelf life: 1. VCMAR (Virclia Auxiliary)	

		D	Decemb 20 Manufacture	
43.	M/s. A.M. Sales & Services, A.M house 82-L,	• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)  Name of Manufacturer:	Reagent)-30 Months  2. VCMAR-DS (Virclia Auxiliary Reagent-DS)-30 Months  3. VCMAR-EDB (Virclia Auxiliary Reagent-EDB) -30 Months  4. VCMAR-EDP (Virclia Auxiliary Reagent-EDP) -18 Months  5. VCMAR-W1 (Virclia Auxiliary Reagent-W1) -30 Months  Brand name:	Deferred due to following deficiencies
	Block-02, PECHS, Karachi.  (ELI- 00244)  R&I detail 16-06-2025 Fee: 6,000/- Slip: 6294763510	M/s Intrumentation Laboratory Company, 180 Hartwell Road, Bedford Massachusetts, USA 01730.  • LOA Type: Original Notarization: Notarized Validity: 31-12-2026  • FSC Type: Original Issued By: US FDA Legalization: Apostilled Validity: 18-03-2026  • ISO Certificate Type: Original Notarization: Notarized Validity: 09-11-2027	ACL Elite Pro & Its Reagents  Generic Name: Blood Coagulation Analyzer & its reagents  Applied as: Cluster  Class: A  Model/Codes/Sizes: Not clear  Service life: Not clear	in application;  Coagulation analyzer and its reagents have been applied in single application as cluster. The analyzer should be applied separately as system with a fee of Rs. 25000/- while reagents should be applied separately as cluster with a fee of Rs. 25000/  Codes applied have not been specified. Service life data has not been submitted.
44.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  (ELI- 00244)  R&I detail 16-06-2025	Name of Manufacturer:  M/s Intrumentation Laboratory Company, 180 Hartwell Road, Bedford Massachusetts, USA 01730.  • LOA Type: Original	Brand name:  ACL Top 550 CTS & Its Reagents  Generic Name:  Blood Coagulation Analyzer & its reagents	Deferred due to following deficiencies in application;  • Coagulation analyzer and its reagents have been applied in single application as cluster. The analyzer should be
	10 00 2025			applied separately

	Fee: 6,000/-	Notarization: Notarized	Applied as: Cluster	as system with a fee
	Slip: 495960806824	Validity: 31-12-2026		of Rs. 25000/- while reagents
			Class: A	should be applied
		• FSC		separately as cluster
		Type: Original	M - 1-1/C - 1/C	with a fee of Rs. 25000/
		Issued By: US FDA	Model/Codes/Sizes:	• Codes applied have
		·	Not clear	not been specified.
		<b>Legalization:</b> Apostilled	W	• Service life data has not been submitted.
		<b>Validity</b> : 18-03-2026	Service life:	not been submitted.
		( Q- 40	Not clear	
		• ISO Certificate Type: Original	10112 50, ra	
		Notarization: Notarized		
		Validity: 09-11-2027	100	
45.	M/s. A.M. Sales &	Name of Manufacturer:	Brand name:	Deferred due to
	Services, A.M house 82-L,	M/s Rapid Labs Ltd., Unit		following deficiencies
	Block-02, PECHS, Karachi.	2& 2a Hall Farm, Church		in application;
	·	Road, Little Bentley,	C N	• Valid legalized FSC from
	(ELI- 00244)	Colchester, Essex, CO7 8SD., UK.		FSC from regulatory body of
			Blood Grouping Reagent Kit	country of origin,
	R&I detail	101		has not been submitted.
	16-06-2025	• LOA Type: Original	Applied as: Kit	• Shelf life data has
	Fee: 62,000/-	Notarization: Notarize	(6)	not been submitted.
	Slip: 031845124		Class: C	
	Sup: 031643124	<b>Issue Date:</b> 23-04-2025	16, 4 4,5	
		Validity: Not mentioned	Model/Codes/Sizes:	
			BG-A10 (as per DOC)	
		• FSC	BG-A10 (as per BOC)	
		Not aubmitted.		
		00, 00	Shelf life:	
		• ISO Certificate Type: Original	Not mentioned	
		Notarization: Notarized		
	P			
		<b>Validity:</b> 15-10-2027		
		• CE Certificate		
		Type: Original		
	1,0	Notarization: Notarized		
	"16 <sub>01</sub>	Validity: 27-05-2025		

46.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.	Name of Manufacturer:  M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley,	Brand name: Anti-D Monoclonal (IgG + IgM)	Deferred due to following deficiencies in application;  • Valid legalized FSC from
	(ELI- 00244)	Colchester, Essex, CO7 8SD., UK.	Generic Name:	FSC from regulatory body of country of origin,
	R&I detail	101	Blood Grouping Reagent Kit	has not been submitted.
	16-06-2025	• LOA Type: Original	Angle 1 Civi	• Shelf life data has
	Fee: 62,000/-	Notarization: Notarize	Applied as: Kit	not been submitted.
	<b>Slip:</b> 416173331	<b>Issue Date:</b> 23-04-2025	Class: C	
		Validity: Not mentioned	Class: C	
		001180	Model/Codes/Sizes:	
		• FSC Not aubmitted.	BG-D10 (as per DOC)	
	P	• ISO Certificate	Shelf life:	
		Type: Original	Not mentioned	
		Notarization: Notarized		
	Ane.	<b>Validity:</b> 15-10-2027		AM
	Men	• CE Certificate  Type: Original	MIS) 65	
		Notarization: Notarized	1/20 0:5	
		Validity: 27-05-2025	115/1025	
47.	M/c AM Solos &	Name of Manufacturer:	Drand name	Deferred due to
7/.	M/s. A.M. Sales & Services, A.M house 82-L,	M/s Rapid Labs Ltd., Unit	Brand name: ABOD Blood Grouping Kit	Deferred due to following deficiencies
	Block-02, PECHS, Karachi.	2& 2a Hall Farm, Church	ADOD Blood Grouping Kit	in application;
		Road, Little Bentley, Colchester, Essex, CO7	Generic Name:	• Valid legalized FSC from
	(ELI- 00244)	8SD., UK.	Blood Grouping Reagent Kit	regulatory body of country of origin,
	R&I detail	• LOA		has not been submitted.
	16-06-2025	Type: Original	Applied as: Kit	• Shelf life data has
	Fee: 62,000/-	Notarization: Notarize		not been submitted.
	<b>Slip:</b> 70654835	<b>Issue Date:</b> 23-04-2025	Class: C	
	Medi	Validity: Not mentioned	Model/Codes/Sizes:	

			BG-ABOD10 (as per DOC)	
		• FSC Not aubmitted.	Shelf life:	
		<ul> <li>ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027</li> <li>CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025</li> </ul>	Not mentioned	17 AM
		ista, No "eu		
48.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.	Name of Manufacturer:  M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church	Brand name: Anti-B Monoclonal	Deferred due to following deficiencies in application;
	(ELI- 00244)	Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.	Generic Name: Blood Grouping Reagent Kit	Valid legalized     FSC from     regulatory body of     country of origin,
	R&I detail 16-06-2025 Fee: 62,000/-	• LOA Type: Original Notarization: Notarize	Applied as: Kit	has not been submitted.  • Shelf life data has not been submitted.
	<b>Slip:</b> 3695108471	Issue Date: 23-04-2025 Validity: Not mentioned	Class: C	
		induling City	Model/Codes/Sizes: BG-B10 (as per DOC)	
		• FSC Not aubmitted.	Shelf life:	
	D'	• ISO Certificate Type: Original	Not mentioned	
		Notarization: Notarized Validity: 15-10-2027  • CE Certificate		
	Meque	Type: Original Notarization: Notarized Validity: 27-05-2025	-08-2025) B	22 g a 94   327

49.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.  (ELI- 00109)  R&I detail 02-06-2025 Fee: 6,000/- Slip: 55009983465	Legal Manufacturer:  M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.  Manufacturing Site:  M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2, 3A, 4A and 6, Building T20- 1 & Room 301, Building T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China.	Brand name: HistoCore Water Bath M  Generic Name: Tissue Flotation Bath  Applied as: Single  Class: A  Model/Codes/Sizes:	Deferred due to following deficiencies in application;  • LOA is copy and not notarized.  • FSC submitted, has not been legalized.  • Service life has not been mentioned in application.  • ISO certificate of manufacturing site is copy and not notarized.
	P	• LOA Type: Copy Notarization: Not Notarized	140607020C1 (as per DOC letter)  Service life:	
	1ednes	Validity: 31-05-2026  • FSC Type: Original Issued By: Govt. Body	Not mentioned	T AM
		Legalization: Not legalized Issue Date: 02-05-2023 Validity: Not mentioned  • ISO Certificate Type: Copy	olisher) 9:55	
		Notarization: Not Notarized Validity: 31-01-2027	100	
50.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Legal Manufacturer:  M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19,	Brand name: HistoCore Pegasus Plus	Deferred due to following deficiencies in application;
	(ELI- 00109)	69226 Nussloch, Germany.	Generic Name: Tissue Processor	<ul> <li>LOA is copy and not notarized.</li> <li>Valid legalized FSC, has not been when the desired in the company in in the comp</li></ul>
	<b>R&amp;I detail</b> 02-06-2025	Manufacturing Site:  M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2,	Applied as: Single	submitted.  • Service life has not been mentioned in application.

	Fee: 6,000/-	3A, 4A and 6, Building T20- 1 & Room 301, Building	Class: A	• ISO certificate of manufacturing site
	<b>Slip:</b> 617643639	T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China.		is copy and not notarized.  • Codes have not
		, and the second	Model/Codes/Sizes: Not mentioned	been mentioned.
		• LOA Type: Copy Notarization: Not Notarized	Service life:	
		Validity: 31-05-2026	Not mentioned	
		• FSC Not submitted	10112 50, re	
		• ISO Certificate Type: Copy		
	P	Notarization: Not Notarized Validity: 31-01-2027		
51.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Legal Manufacturer: M/s Leica Biosystems	Brand name: HistoCore Biocut	Deferred due to following deficiencies in application;
	(ELI- 00109)	Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name:	<ul><li>LOA is copy and not notarized.</li><li>Valid legalized</li></ul>
	R&I detail	Manufacturing Site:	Rotary Microtome	FSC, has not been submitted.  • Service life has not
	02-06-2025 Fee: 6,000/-	M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2, 3A, 4A and 6, Building T20-	Applied as: Single	been mentioned in application.  • ISO certificate of
	Slip: 7887774539	1 & Room 301, Building T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade	eli	manufacturing site is copy and not notarized.
		Zone, Shanghai, China.	Model/Codes/Sizes: Not mentioned	Codes have not been mentioned.
	P.	• LOA Type: Copy Notarization: Not Notarized	Service life:	
		Validity: 31-05-2026	Not mentioned	
	1ednes	• FSC Not submitted		

		ISO Certificate		
		Type: Copy		
		Notarization: Not Notarized		
		Validity: 31-01-2027		
52.	M/s. Global Marketing	Legal Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19,	Leica RM2125 RTS	following deficiencies in application;  • LOA is copy and
	(ELI- 00109)	69226 Nussloch, Germany.	Generic Name: Rotary Microtome	not notarized.  • FSC submitted, has not been legalized.
	R&I detail	Manufacturing Site:	die Oss,	• Service life has not
	02-06-2025	M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2,	Applied as: Single	been mentioned in application.  • ISO certificate of
	Fee: 6,000/-	3A, 4A and 6, Building T20- 1 & Room 301, Building	Class: A	manufacturing site
	<b>Slip:</b> 7887774539	T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade		is copy and not notarized.  • Codes have not
	P	Zone, Shanghai, China.	Model/Codes/Sizes:	been mentioned.
	*	• LOA	Not mentioned	
		Type: Copy	Service life:	
		Notarization: Not Notarized	Not mentioned	
	"Meque.	Validity: 31-05-2026	(9)	17 All
		• FSC Not submitted	1 (Mil) 0:20	
		• ISO Certificate Type: Copy	101121505p	
		Notarization: Not Notarized	el'	
		<b>Validity:</b> 31-01-2027		
53.	M/s. Global Marketing Services, 111-B, Hali Road,	Legal Manufacturer:	Brand name:	Deferred due to following deficiencies
	Westridge 1, Rawalpindi.	M/s Leica Biosystems Nussloch GmbH,	HistoCore Pegasus	in application;
	(ELI- 00109)	Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name:	LOA is copy and not notarized.
	(ELLI- 00107)	201,	Tissue Processor	• FSC submitted, has not been legalized.
	R&I detail	Manufacturing Site:		• Service life has not been mentioned in
	02-06-2025	M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2,	Applied as: Single	application.
	Fee: 6,000/-	3A, 4A and 6, Building T20- 1 & Room 301, Building		• ISO certificate of manufacturing site

	Slip: 45180735953	T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China.  • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026  • FSC Not submitted	Class: A  Model/Codes/Sizes:  Not mentioned  Service life:  Not mentioned	is copy and not notarized.  • Codes have not been mentioned.
		• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027	loer,	
54.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.  (ELI- 00109)  R&I detail 02-06-2025 Fee: 6,000/- Slip: 02704225	Legal Manufacturer:  M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.  Manufacturing Site:  M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2, 3A, 4A and 6, Building T20- 1 & Room 301, Building T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China.	Brand name: Leica ST4020  Generic Name: Automated Slide Stainer  Applied as: Single  Class: A  Model/Codes/Sizes: Not mentioned	Deferred due to following deficiencies in application;  • LOA is copy and not notarized.  • Valid legalized FSC, has not been submitted.  • Service life has not been mentioned in application.  • ISO certificate of manufacturing site is copy and not notarized.  • Codes have not been mentioned.
	Nednes	Type: Copy Notarization: Not Notarized Validity: 31-05-2026  • FSC Not submitted  • ISO Certificate Type: Copy	Service life:  Not mentioned	

		Notarization: Not Notarized		
		<b>Validity:</b> 31-01-2027		
		•		
55.	M/s. Global Marketing	Legal Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems	Leica TP1020	following deficiencies in application;
	westrage 1, rawarpman	Nussloch GmbH,		
		Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name:	• LOA is copy and not notarized.
	(ELI- 00109)	0)220 Itassioon, Germany.		Valid legalized
			Tissue Processor	FSC, has not been
	R&I detail	Manufacturing Site:	11 011 0.	submitted.
	02-06-2025	M/s Leica Microsystems	Applied as: Single	• Service life has not been mentioned in
		Ltd., Shanghai, Floor 1, 2,	Alls O'V	application.
	Fee: 6,000/-	3A, 4A and 6, Building T20- 1 & Room 301, Building	Class: A	• ISO certificate of
	<b>Slip:</b> 99149517	T20-5, 258 Jinzang Road	Class. A	manufacturing site
		(Shanghai) Pilot Free Trade	100	is copy and not notarized.
		Zone, Shanghai, China.	Model/Codes/Sizes:	• Codes have not
		SI IS OIL	Not mentioned	been mentioned.
		• LOA		
	•	Type: Copy	Service life:	
		Notarization: Not Notarized		
			Not mentioned	
		<b>Validity:</b> 31-05-2026		
		• FSC		
	Nec	Not submitted	1151	
		700 G 1100 1	(6),	
		• ISO Certificate	31 31 9.	
		Type: Copy	1 600 001	
		<b>Notarization</b> : Not Notarized	Alls O'V	
		Validity: 31-01-2027	10. 10	
56.	M/s. Global Marketing	Legal Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road,	M/s Leica Biosystems	Leica CV5030	following deficiencies
	Westridge 1, Rawalpindi.	Nussloch GmbH,		in application;
		Heidelberger Str. 17-19,		• LOA is copy and
	(ELI- 00109)	69226 Nussloch, Germany.	Generic Name:	not notarized.  • Valid legalized
		(1)	Automated Coverslipper	• Valid legalized FSC, has not been
	D 0 I Jo4o !I	Manufacturing Site:		submitted.
	R&I detail	M/s Leica Microsystems	Applied as: Single	• Service life has not
	10-06-2025	Ltd., Shanghai, Floor 1, 2,	Thbuca an nuite	been mentioned in
	Fee: 6,000/-	3A, 4A and 6, Building T20-		<ul><li>application.</li><li>ISO certificate of</li></ul>
	<b>Slip:</b> 19921913067	1 & Room 301, Building	Class: A	manufacturing site
	7180	T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade		is copy and not
	'M'	(Shanghai) Filot Free Trade		notarized.

		Zone, Shanghai, China.	Model/Codes/Sizes:	• Codes have not
			Not mentioned	been mentioned.
		<ul> <li>LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026</li> <li>FSC Not submitted</li> </ul>	Service life: Not mentioned	17 AM
		• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027	ipel, 505p,	
57.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Legal Manufacturer:  M/s Leica Biosystems Nussloch GmbH,	Brand name: Leica CM3050S	Deferred due to following deficiencies in application;
	(ELI- 00109)	Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name: Crystat Microtom	<ul> <li>LOA is copy and not notarized.</li> <li>Valid legalized FSC, has not been</li> </ul>
	R&I detail 10-06-2025 Fee: 6,000/- Slip: 0443243367	Manufacturing Site:  M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2, 3A, 4A and 6, Building T20- 1 & Room 301, Building T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China.  • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026  • FSC Not submitted  • ISO Certificate Type: Copy Notarization: Not Notarized	Applied as: Single  Class: A  Model/Codes/Sizes:  Not mentioned  Service life:  Not mentioned	FSC, has not been submitted.  Service life has not been mentioned in application.  ISO certificate of manufacturing site is copy and not notarized.  Codes have not been mentioned.

		Validity: 31-01-2027		
58.	M/s. Global Marketing Services, 111-B, Hali Road,	Legal Manufacturer: M/s Leica Biosystems	Brand name: Leica CM1950	Deferred due to following deficiencies
	Westridge 1, Rawalpindi. (ELI- 00109)	Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name:	<ul><li>in application;</li><li>LOA is copy and not notarized.</li></ul>
	(EEI- 00107)	Manufacturing Site:	Crystat Microtom	• Valid legalized FSC, has not been submitted.
	<b>R&amp;I detail</b> 10-06-2025	M/s Leica Microsystems	Applied as: Single	• Service life has not been mentioned in
	Fee: 6,000/-	Ltd., Shanghai, Floor 1, 2, 3A, 4A and 6, Building T20-1 & Room 301, Building	Class: A	<ul><li>application.</li><li>ISO certificate of manufacturing site</li></ul>
	<b>Slip:</b> 00840557577	T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade		manufacturing site is copy and not notarized.
		Zone, Shanghai, China.	Model/Codes/Sizes: Not mentioned	• Codes have not been mentioned.
		• LOA Type: Copy	Service life:	
		<b>Notarization</b> : Not Notarized <b>Validity:</b> 31-05-2026	Not mentioned	
		937,		
	18que	• FSC Not submitted		1 AM
	Me	• ISO Certificate Type: Copy	(MIS) 0.55	
		Notarization: Not Notarized Validity: 31-01-2027	inchell 2	
59.	M/s. Global Marketing	Legal Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Nussloch GmbH,	HistoCore Pearl	following deficiencies in application;
	(ELI- 00109)	Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name:	<ul><li>LOA is copy and not notarized.</li><li>Valid legalized</li></ul>
	R&I detail	Manufacturing Site:	Tissue Processor	FSC, has not been submitted.  • Service life has not
	02-06-2025 Fee: 6,000/-	M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2, 3A, 4A and 6, Building T20-	Applied as: Single	been mentioned in application.
	Slip: 8129682709	1 & Room 301, Building T20-5, 258 Jinzang Road	Class: A	• ISO certificate of manufacturing site is copy and not
	Megli	(Shanghai) Pilot Free Trade Zone, Shanghai, China.	Model/Codes/Sizes:	notarized.  • Codes have not been mentioned.

			Not mentioned	
		• LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026	Service life: Not mentioned	AN
		• FSC Not submitted	1 (MIS) 9:55	
		• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027	iolisius 5052	
60.	M/s. Global Marketing	Legal Manufacturer:	Brand name:	Deferred due to
00.	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Nussloch GmbH,	HistoCore Multicut	following deficiencies in application;
	(ETT 00100)	Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name:	• LOA is copy and not notarized.
	(ELI- 00109)	. 41	Rotary Microtome	• Valid legalized FSC, has not been
	R&I detail	Manufacturing Site:		submitted.
	02-06-2025	M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2,	Applied as: Single	• Service life has not been mentioned in
	Fee: 6,000/-	3A, 4A and 6, Building T20-	(2)	<ul><li>application.</li><li>ISO certificate of</li></ul>
	Slip: 14560793704	1 & Room 301, Building T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade	Class: A	manufacturing site is copy and not notarized.
		Zone, Shanghai, China.	Model/Codes/Sizes:	Codes have not been mentioned.
		TOTAL SOLUTION OF THE COLUMN O	Not mentioned	been mentioned.
		• LOA Type: Copy	Service life:	
		Notarization: Not Notarized	Not mentioned	
		Validity: 31-05-2026		
	P	• FSC Not submitted		
		110t Submitted		
		• ISO Certificate		
		Type: Copy		
	adine	Notarization: Not Notarized		
	Ne	<b>Validity:</b> 31-01-2027		

61.	M/s. Global Marketing	Name of Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Nussloch GmbH,		following deficiencies in application;
	(ELI- 00109)	Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name: Automated Coverslipper	<ul><li>LOA is copy and not notarized.</li><li>FSC has not been</li></ul>
	<b>R&amp;I detail</b> 02-06-2025 <b>Fee: 6,000/- Slip:</b> 955889808830	• LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026	Applied as: Single Class: A	<ul> <li>legalized.</li> <li>Service life has not been mentioned in application.</li> <li>ISO certificate is copy.</li> <li>Codes have not been mentioned.</li> </ul>
		• FSC Type: Original Legalization: Not legalized	Model/Codes/Sizes: Not mentioned	
	P	Issue Date: 16-01-2025 Validity: Not mentioned	Service life: Not mentioned	
	05	• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 23-12-2026		Man
62.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Name of Manufacturer:  M/s Leica Biosystems Nussloch GmbH,	Brand name: HistoCore Chromax ST	Deferred due to following deficiencies in application;
	(ELI- 00109)	Heidelberger Str. 17-19, 69226 Nussloch, Germany.	Generic Name: Automated Slide Stainer	<ul><li>LOA is copy and not notarized.</li><li>FSC has not been legalized.</li></ul>
	R&I detail 02-06-2025 Fee: 6,000/- Slip: 427259757	• LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026	Applied as: Single Class: A	<ul> <li>Service life has not been mentioned in application.</li> <li>ISO certificate is copy.</li> <li>Codes have not</li> </ul>
	P	• FSC Type: Original Legalization: Not legalized	Model/Codes/Sizes: Not mentioned	been mentioned.
	adnes	Issue Date: 16-01-2025 Validity: Not mentioned	Service life: Not mentioned	
	Ne	ISO Certificate		

		<b>Type:</b> Copy of notarized		
		Notarization: Notarized		
		Validity: 23-12-2026		_
63.	M/s. Global Marketing	Name of Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19,	Leica CM1860 UV	following deficiencies in application;  • LOA is copy and
	(ELI- 00109)	69226 Nussloch, Germany.	Generic Name: Crystat Microtom	not notarized.  • Valid legalized
	R&I detail 10-06-2025 Fee: 6,000/- Slip: 5376278944	<ul> <li>LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026</li> <li>FSC Not submitted</li> <li>ISO Certificate Type: Copy</li> </ul>	Applied as: Single  Class: A  Model/Codes/Sizes:  Not mentioned  Service life:	<ul> <li>FSC, has not been submitted.</li> <li>Service life has not been mentioned in application.</li> <li>ISO certificate of manufacturing site is copy and not notarized.</li> <li>Codes have not been mentioned.</li> </ul>
		Notarization: Not Notarized	Not mentioned	
	C	<b>Validity:</b> 31-01-2027		A.
		-		
64.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Melbourne Pty Ltd., 495 Blackburn Road, Mount	Brand name: HistoCore Peloris 3	Deferred due to following deficiencies in application;  • Copy of LOA
	(ELI- 00109)	Waverley, Victoria 3149,		submitted is from
	,	Australia.	Tissue processor	M/s Leica Biosystems Nussloch GmbH,
	<b>R&amp;I detail</b> 12-06-2025	• LOA Not submitted.	Applied as: System	Heidelberger Str. 17-19, 69226 Nussloch, Germany
	Fee: 25,000/- Slip: 8052760298	• FSC	Class: A	while FSC mentions M/s Leica Biosystems
		Type: Copy of legalized		Melbourne Pty
	,	Issue By: TGA	Model/Codes/Sizes:	Ltd., 495 Blackburn
		Legalization: legalized	45.0001	Road, Mount Waverley, Victoria
		<b>Issue Date:</b> 20-06-2022		3149, Australia as
	_0	Validity: Not mentioned.	Service life:	MAH. • Original FSC has
	100		Not mentioned	not been submitted.
	Megi	• ISO Certificate		Original ISO certificate has not been submitted.

		Type: Copy of notarized		Service life has not
		Notarization: Notarized		been mentioned in
		<b>Validity:</b> 30-11-2027		application.
65.	M/s. Global Marketing	Name of Manufacturer:	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	M/s Leica Biosystems Imaging Inc., 1360 Park Center Drive Vista, CA		following deficiencies in application;  • Copy of LOA
	(ELI- 00109)	92081, USA.	Generic Name: Web-based digital slide	submitted is from M/s Leica
	<b>R&amp;I detail</b> 02-06-2025	• LOA Not submitted.	viewing software  Applied as: Single	Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany
	Fee: 6,000/-	• FSC (Netherlands)		while FSC
	<b>Slip:</b> 820555297385	Type: Copy of legalized	Class: A	mentions M/s Leica Biosystems
	. lednes	Issued By: MOH Netherlands Legalization: legalized Validity: 30-05-2027  • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 27-03-2028	Model/Codes/Sizes: 23WVROWIVD  Service life: Not mentioned	Imaging Inc., 1360 Park Center Drive Vista, CA 92081, USA as MAH.  Original FSC has not been submitted. Original notarized ISO certificate has not been submitted. Service life has not been mentioned in application.
66.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Name of Manufacturer:  M/s Leica Biosystems Imaging Inc., 1360 Park	Brand name: Aperio GT450 DX	Deferred due to following deficiencies in application;
	(ELI- 00109)	Center Drive Vista, CA 92081, USA.	Generic Name: Digital Pathology Scanner	• Copy of LOA submitted is from M/s Leica Biosystems
	<b>R&amp;I detail</b> 02-06-2025	• LOA Not submitted.	Applied as: Single	Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany
	Fee: 6,000/- Slip: 714441074718	• FSC (Netherlands) Type: Copy of legalized	Class: A	while FSC mentions M/s Leica Biosystems
		Issued By: MOH Netherlands	Model/Codes/Sizes: 23GT450DXIVD	Imaging Inc., 1360 Park Center Drive Vista, CA 92081,
	9	Legalization: legalized	2301430DAIYD	USA as MAH.
	Meglue	Validity: 30-05-2027  • ISO Certificate	Service life:	<ul><li> Original FSC has not been submitted.</li><li> Original notarized ISO certificate has</li></ul>

		Type: Copy	Not mentioned	not been submitted.
		Notarization: Not Notarized		• Service life has not been mentioned in
		Validity: 27-03-2028		application.
67.	M/s. Global Marketing Services, 111-B, Hali Road,	Name of Authorized Representative:	Brand name:	Deferred due to following deficiencies
	Westridge 1, Rawalpindi.	M/s bioMerieux SA, 376 Chemin de I'Orme, 69280	BacT/ALERT® FA Plus	in application; • Original LOA has
	(ELI- 00109)	Marcy I'Etoile, France.  Legal Manufacturer:	Generic Name: Culture Bottles	not been submitted.  • Original FSC has
	<b>R&amp;I detail</b> 02-06-2025	M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA.	Applied as: Single	not been submitted.  Original notarized ISO certificate has not been submitted
	Fee: 62,000/- Slip: 367485449521	Manufacturing Site:  M/s bioMerieux Inc., 100 Rodolphe Street, Durham,	Class: C	and has expired.
		North Carolina 27712, USA.	Model/Codes/Sizes:	
		• LOA Type: Copy of Notarized	410851 (as per FSC)  Shelf life: 12 Months	
		Notarization: Notarized Validity: 31-03-2026	Shear me. 12 iviolidis	Ala.
	Medine	• FSC Type: Copy of legalized	MIS)	1 Air
		Issued By: CCI Legalization: legalized	1/18/1 0:50	
		Issue Date: 22-12-2016	dielioss,	
		Validity: Not mentioned	iosi, So.	
		• ISO Certificate  Type: Copy of Notarized	No.	
		<b>Notarization</b> : Notarized		
	Y	Validity: 17-12-2021		
68.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Name of Authorized Representative: M/s bioMerieux SA, 376	Brand name: BacT/ALERT® SA	Deferred due to following deficiencies in application;
	(ELI- 00109)	Chemin de l'Orme, 69280 Marcy l'Etoile, France.	Generic Name:	<ul><li> Original LOA has not been submitted.</li><li> Original FSC has</li></ul>
	Medi	Legal Manufacturer: M/s bioMerieux Inc., 100	Culture Bottles	not been submitted.  • Original notarized

	R&I detail 02-06-2025 Fee: 62,000/-	Rodolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site:	Applied as: Single	ISO certificate has not been submitted and has expired.
	Slip: 7807289208	M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA.	Class: C	AN
			Model/Codes/Sizes:	
		• LOA Type: Copy of Notarized	259789 (as per FSC)	
		Notarization: Notarized	Shelf life: 12 Months	
		Validity: 31-03-2026	10/18,50/5	
		• FSC Type: Copy of legalized	Poli,	
		Issued By: CCI		
		Legalization: legalized		
		<b>Issue Date:</b> 22-12-2016		
		Validity: Not mentioned		
		·91,		
		• ISO Certificate		
	7/08.	Type: Copy of Notarized		VIII.
	16 <sub>01</sub>	<b>Notarization</b> : Notarized	(6)	$\langle 1 \rangle$
		Validity: 17-12-2021	ركبي اللهر	
69.	M/s. Global Marketing Services, 111-B, Hali Road,	Name of Authorized Representative:	Brand name:	Deferred due to following deficiencies
	Westridge 1, Rawalpindi.	M/s bioMerieux SA, 376	BacT/ALERT® SN	in application;
		Chemin de l'Orme, 69280	Conorio Nomo	• Original LOA has not been submitted.
	(ELI- 00109)	Marcy I'Etoile, France.  Legal Manufacturer:	Generic Name: Culture Bottles	• Original FSC has
		M/s bioMerieux Inc., 100	Culture Bottles	<ul><li>not been submitted.</li><li>Original notarized</li></ul>
	R&I detail	Rodolphe Street, Durham,	Applied as: Single	ISO certificate has
	02-06-2025	North Carolina 27712, USA.		not been submitted and has expired.
	Fee: 62,000/-	Manufacturing Site:	Class: C	
	<b>Slip:</b> 973342622	M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA.	Model/Codes/Sizes:	
		000	259790 (as per FSC)	
	1eque.	• LOA Type: Copy of Notarized	Shelf life: 12 Months	
		<b>Notarization</b> : Notarized		

		Validity: 31-03-2026		
		• FSC Type: Copy of legalized Issued By: CCI Legalization: legalized Issue Date: 22-12-2016 Validity: Not mentioned • ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 17-12-2021	olisher) 9:55	AM AM
70.	M/s. Global Marketing	Name of Authorized	Brand name:	Deferred due to
	Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Representative: M/s bioMerieux SA, 376	BacT/ALERT® FN Plus	following deficiencies in application;
		Chemin de l'Orme, 69280	Generic Name:	Original LOA has not been submitted.
	(ELI- 00109)	Marcy I'Etoile, France.  Legal Manufacturer:	Culture Bottles	• Original FSC has
	<b>R&amp;I detail</b> 02-06-2025	M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA.	Applied as: Single	not been submitted.  Original notarized ISO certificate has not been submitted and has expired.
	Fee: 62,000/- Slip: 6031378879	Manufacturing Site:  M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA.	Class: C  Model/Codes/Sizes:	
		• LOA Type: Copy of Notarized Notarization: Notarized Validity: 31-03-2026	410852 (as per FSC)  Shelf life: 12 Months	
	P	• FSC Type: Copy of legalized Issued By: CCI		
		Legalization: legalized		
	Medines	Issue Date: 22-12-2016 Validity: Not mentioned		
		<u> </u>	<u> </u>	<u> </u>

		• ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 17-12-2021		
71.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.	Name of Authorized Representative: M/s bioMerieux SA, 376 Chemin de I'Orme, 69280	Brand name: BacT/ALERT® PF Plus	Deferred due to following deficiencies in application;  • Original LOA has
	(ELI- 00109)	Marcy I'Etoile, France.  Legal Manufacturer:	Generic Name: Culture Bottles	not been submitted.  Original FSC has not been submitted.
	<b>R&amp;I detail</b> 02-06-2025	M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA.	Applied as: Single	• Original notarized ISO certificate has not been submitted
	Fee: 62,000/- Slip: 2822532428	Manufacturing Site:  M/s bioMerieux Inc., 100 Rodolphe Street, Durham,	Class: C	and has expired.
	P	North Carolina 27712, USA.  • LOA	Model/Codes/Sizes: 410853 (as per FSC)	
		Type: Copy of Notarized Notarization: Notarized	Shelf life: 12 Months	
	Meglue	• FSC Type: Copy of legalized Issued By: CCI Legalization: legalized Issue Date: 22-12-2016 Validity: Not mentioned	iolisher), 9:55	T All
	P	• ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 17-12-2021		
72.	M/s. Total Technologies (Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.	Name of Manufacturer:  M/s MMM Munchener Medizin Mechanik GmbH,	Brand name: Hyper LTS 150	Deferred due to following deficiencies in application;
	(ELI- 00129)	Semmelweisstrabe 6 82152 Planegg Deutschland, Germany.	Generic Name:  Medical Low temperature	• The model applied by the applicant is Hyper LTS 150 while FSC

			Sterilizer	mentions Hyper
	D &I doto!	. 1.04	Stermizer	LTS (all models).
	R&I detail	• LOA Type: Copy of Notarized		Moreover, there are
	03-06-2025	Notarization: Notarized	Applied as: Single	two variants mentioned in
	Fee: 31,000/-			documents i.e.,
	<b>Slip:</b> 707293557906	Validity: 18-02-2030	Class: B	Single Door & Double Door. The
			.(5)	applied variant
		• FSC	Model/Codes/Sizes:	should be specified by the applicant.
		<b>Type:</b> Copy of legalized	Hyper LTS 150-1 (Single	• Original LOA has
		Issued By: Govt. Body	Door)	not been submitted.
		Legalization: Legalized	Hyper LTS 150-2 (Double	• Original FSC has not been submitted.
		<b>Issue Date:</b> 19-02-2025	Door)	Original notarized
		Validity: Not mentioned	(as per technical documents)	ISO certificate has not been submitted.
		ISO Certificate	Service life: 10 Years	
		Type: Copy of Notarized		
	P	Notarization: Notarized		
		Validity: 30-11-2027		
		. 21		
		• EU QMS/CE Certificate		
	09	Type: Copy of Notarized		'UI
		Notarization: Notarized		1
	Ne	Validity: 24-04-2027	1191	
73.	M/s. Total Technologies	Name of Manufacturer:	Brand name:	Deferred due to
	(Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.	M/s MMM Munchener	Selectomat PL CL 6612	following deficiencies in application;
	Town, District Lanoic.	Medizin Mechanik GmbH, Semmelweisstrabe 6 82152	, 18, 10,	• The model applied
	(ET 1 00140)		Generic Name:	by the applicant is
	(ELI- 00129)	Germany.	Steam Sterilizer	Selectomat PL CL
		06, 10	108,	6612 while FSC mentions
	R&I detail	• LOA	Applied as: Single	Selectomat PL (all
	03-06-2025	<b>Type:</b> Copy of Notarized	Applied as: Single	models). Moreover, there model applied
	Fee: 31,000/-	Notarization: Notarized	Clause D	by the applicant has
	<b>Slip:</b> 6981381120	Validity: 18-02-2030	Class: B	not been mentioned in technical
				documents
		• FSC	Model/Codes/Sizes:	submitted.
	_6	Type: Copy of legalized	Not mentioned in FSC or other	• Original LOA has not been submitted.
	100	Issued By: Govt. Body	documents	• Original FSC has
	001	Legalization: Legalized		not been submitted.
		Deganzation. Deganzed	Service life: 10 Years	Original notarized

		<b>Issue Date:</b> 19-02-2025		not been submitted.
		Validity: Not mentioned		
		• ISO Certificate Type: Copy of Notarized		anh
		Notarization: Notarized		
		Validity: 30-11-2027	(1) 0:55	
		• EU QMS/CE Certificate	1, 20, 20	
		Type: Copy of Notarized	1181, 500	
		Notarization: Notarized	101. Jo.	
		Validity: 24-04-2027	011	
74.	M/s. Total Technologies	Name of Manufacturer:	Brand name:	Deferred due to
	(Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.	M/s MMM Munchener Medizin Mechanik GmbH,	Unisteri SL 336	following deficiencies in application;
	<b>P</b>	Semmelweisstrabe 6 82152 Planegg Deutschland,	Generic Name:	• The device applied by the applicant has
	(ELI- 00129)	Germany.	Steam Sterilizer	not been mentioned
		11	Steam Stermzer	<ul><li>in FSC submitted.</li><li>Original LOA has</li></ul>
	R&I detail	• LOA		not been submitted.
	03-06-2025	Type: Copy of Notarized	Applied as: Single	Original FSC has
	Fee: 31,000/-	Notarization: Notarized		<ul><li>not been submitted.</li><li>Original notarized</li></ul>
	<b>Slip:</b> 11309961462	Validity: 18-02-2030	Class: B	ISO certificate has not been submitted.
		• FSC Type: Copy of legalized	Model/Codes/Sizes:  Not mentioned in FSC	
		Issued By: Govt. Body	Service life: 10 Years	
		Legalization: Legalized	oct vice inc. 10 Teats	
		<b>Issue Date:</b> 19-02-2025	100	
		Validity: Not mentioned	*	
		ISO Certificate		
	*	Type: Copy of Notarized		
		Notarization: Notarized		
		Validity: 30-11-2027		
	AUS	EU QMS/CE Certificate		
	1180	Type: Copy of Notarized		

		Notarization: Notarized		
		Validity: 24-04-2027		
75.	M/s. Total Technologies	Name of Manufacturer:	Brand name:	Deferred due to
	(Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.	M/s MMM Munchener Medizin Mechanik GmbH, Semmelweisstrabe 6 82152	Unisteri SL 636	following deficiencies in application;  • The device applied
	(ELI- 00129)	Planegg Deutschland, Germany.	Generic Name: Steam Sterilizer	by the applicant has not been mentioned in FSC submitted.
	<b>R&amp;I detail</b> 03-06-2025	• LOA Type: Copy of Notarized	Applied as: Single	<ul><li> Original LOA has not been submitted.</li><li> Original FSC has</li></ul>
	Fee: 31,000/- Slip: 00626251946	Notarization: Notarized Validity: 18-02-2030	Class: B	not been submitted.  Original notarized ISO certificate has not been submitted.
		- AND NOTES	Model/Codes/Sizes:	
		• FSC Type: Copy of legalized	Not mentioned in FSC	
	P	Issued By: Govt. Body		
	,	Legalization: Legalized	Service life: 10 Years	
		Issue Date: 19-02-2025		
		Validity: Not mentioned		
	Medines	• ISO Certificate  Type: Copy of Notarized  Notarization: Notarized	MIS)	TAM
		Validity: 30-11-2027	"I (Jeil 0:20	
		• EU QMS/CE Certificate Type: Copy of Notarized	Jolie, 5052	
		Notarization: Notarized	100,	
		Validity: 24-04-2027		
76.	M/s. Total Technologies	Name of Manufacturer:	Brand name:	Deferred due to
	(Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.	M/s MELAF Medizintechnik GmbH & Co. KG Geneststr.	Vacuclave 105	following deficiencies in application;
	(ELI- 00129)	6-10 10829 Berlin, Germany.	Generic Name: Steam Sterilizer	<ul> <li>Original notarized ISO certificate has not been submitted.</li> <li>Service life and data has not been</li> </ul>
	<b>R&amp;I detail</b> 03-06-2025	• LOA Type: Original Notarization: Notarized	Applied as: Single	data has not been submitted

	Fee: 31,000/-	Validity: 25-02-2030	Class: B	
	<b>Slip:</b> 273039579			
		• FSC	Model/Codes/Sizes:	
		Type: Original	ME10105 (as per FSC)	
		Issued By: Govt. Body		
		<b>Legalization</b> : Legalized	Service life: Not submitted	
		<b>Issue Date:</b> 19-02-2025	Will as	
		Validity: Not mentioned	16.90 0:3	
		, Q <sup>2</sup> , x0	i cho ob	
		• ISO Certificate Type: Copy	10112 50, re	
		Notarization: Not Notarized		
		Validity: 03-12-2027	100	
		isla Wiell		
	P	• EU QMS/CE Certificate Type: Copy		
		Notarization: Not Notarized		
		Validity: 23-12-2026		
77.	M/s. Opti Med, 2 <sup>nd</sup> Floor	Name of Manufacturer:	Brand name:	The Board approved
	Hassan Plaza 6-A Jail Road, Lahore.	M/s AJL Ophthalmic SA.,	AJL Ring	the case.
	1601	Parque Technologico de Alava, Ferdinand Zeppelin,		1
	(ELI- 00501)	1, 01510 Minano (Alava),	Generic Name:	
		Spain.	Intrastromal Ring	
	R&I detail	TO 1	1110015	
	25-06-2025	• LOA Type: Original	Applied as: Family	
	Fee: 100,000/-	Notarization: Notarized	10. 10	
	<b>Slip:</b> 2375554809 (62,000/-	Validity: 13-05-2030	Class: C	
	)	431,118,		
	38576998363 (38,000/-)	• FSC	Codes (Sizes): Are mentioned	
	D	Type: Original	in FSC and same are applied by the applicant.	
	,	Issued By: Spanish Agency	AFR15140	
		Legalization: Apostilled	AFR15180	
		Issue Date: 14-07-2023	AFR20120	
	e c	Validity: Not mentioned	AFR20150	
	AUR		AFR20180	
	Ner	• ISO Certificate	AFR20210	

		Type: Original	AFR25120	
		Notarization: Notarized	AFR25140	
		Validity: 20-08-2027	AFR25160	
			AFR25180	
			AFR25210	Alla
			AFR25300	
			AFR30120	•
		agoli.	AFR30160	
		Q <sup>o</sup> xo	AFR620090	
		All Co.	AFR620120	
		Plo Oll bi	AFR620160	
		Ob. in	AFR620320	
		icia, Moi el	AFR630150	
		SIS IS SOLO	AFR630210	
		6 (0), 86,		
	·		Shelf life: 4.5 Years	
78.	M/s. Opti Med, 2 <sup>nd</sup> Floor	Name of Manufacturer:	Brand name:	The Board approved
	Hassan Plaza 6-A Jail Road, Lahore.	M/s Iromed Group S.R.L.,	Ribofast	the case.
	170	Via Tempio del Cielo, 3/5-00144 Roma (RM), Italy.		USU.
	(ELI- 00501)		Generic Name:	1
	No	• LOA	Dextran -Free Ophthalmic	
		LOA	Colution for Corneal Cross	
	R&I detail	Type: Copy of Notarized	Solution for Corneal Cross- Linking	
	<b>R&amp;I detail</b> 04-03-2024			
		<b>Type:</b> Copy of Notarized		
	04-03-2024	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker	Linking	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028	Linking	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker Device)	Linking  Applied as: Kit	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker	Linking  Applied as: Kit	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized  Notarization: Notarized  Validity: 14-04-2028  (Original in CFX Linker Device)  • FSC	Applied as: Kit  Class: B  Model as per FSC & Label:  1.5ml Single Use Sterile	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker Device)  • FSC Type: Copy of Legalized	Applied as: Kit  Class: B  Model as per FSC & Label:	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker Device)  • FSC Type: Copy of Legalized Issued By: MOH	Applied as: Kit  Class: B  Model as per FSC & Label:  1.5ml Single Use Sterile Syringe	
	04-03-2024 Fee: 25,000/-	Type: Copy of Notarized Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker Device)  • FSC Type: Copy of Legalized Issued By: MOH Legalization: Apostilled	Applied as: Kit  Class: B  Model as per FSC & Label:  1.5ml Single Use Sterile	
	04-03-2024 Fee: 25,000/-	Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker Device)  • FSC Type: Copy of Legalized Issued By: MOH Legalization: Apostilled Issue Date: 20-01-2023 Validity: Not mentioned (Original in CFX Linker	Applied as: Kit  Class: B  Model as per FSC & Label:  1.5ml Single Use Sterile Syringe	
	04-03-2024 Fee: 25,000/-	Notarization: Notarized Validity: 14-04-2028 (Original in CFX Linker Device)  • FSC Type: Copy of Legalized Issued By: MOH Legalization: Apostilled Issue Date: 20-01-2023 Validity: Not mentioned	Applied as: Kit  Class: B  Model as per FSC & Label:  1.5ml Single Use Sterile Syringe	

		• ISO Certificate Type: Original		
		Notarization: Notarized		
		Validity: 28-05-2028		
79.	M/s. Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi.	Legal Manufacturer:  VSY Biotechnology GmbH, Esslinger Strabe 7, 70771 Leinfelden-Echterdingen, Germany.	Brand name: Acrijet®  Generic Name:	The Board approved the case.
	(ELI- 00091)	Manufacturing Site:	Cartridge & Injection for insersion of IOLs	
	<b>R&amp;I detail</b> 26-06-2025 <b>Fee: 31,000/- Slip:</b> 294767238	VSY Biyoteknoloji ve Ilac San. A.S, Tepeoren Mevkii Istanbul Tuzla Organize Sanayi Bolgesi 3.Cadde No:3 Tuzla/Istanbul, Turkey	Applied as: Kit Class: B	
	P	• LOA Type: Original	Model/Codes/Sizes (as per FSC):	
		Notarization: Notarized	Acrijetfly 1.8	
		<b>Issue Date:</b> 03-04-2025	Acrijetfly 2.2	
	18dhes	Validity: Not mentioned	Shelf life: 3 Years	7 AM
	W	• FSC Type: Original	(19/13) 0.55	
		Issued By: Govt. Body	" (B) (B)	
		<b>Legalization</b> : Legalized	118, 50,	
		<b>Issue Date:</b> 24-04-2025	10. Jo.	
		Validity: Not mentioned  • ISO Certificate	loel,	
		Type: Original		
	D	Notarization: Notarized		
		Validity: 25-07-2026		
80.	M/s. Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 &	Legal Manufacturer:  VSY Biotechnology GmbH, Esslinger Strabe 7, 70771	Brand name: Protectalon	The Board approved the case.
	8, KMCHS, Karachi.	Leinfelden-Echterdingen, Germany.	Generic Name:	
	(ELI- 00091)		Ophthalmic Viscosurgical	

		Manufacturing Site:	Device	
	R&I detail 26-06-2025 Fee: 62,000/- Slip: 5213163189	VSY Biyoteknoloji ve Ilac San. A.S, Tepeoren Mevkii Istanbul Tuzla Organize Sanayi Bolgesi 3.Cadde No:3 Tuzla/Istanbul, Turkey	Applied as: Kit Class: C	AN
		<ul> <li>LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned</li> <li>FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 24-04-2025 Validity: Not mentioned</li> </ul>	Model/Codes/Sizes (as per FSC):  Protectalon 1%  Protectalon 1.2%  Protectalon 1.4%  Protectalon 1.6%  Protectalon 1.8%  Protectalon 2%  Protectalon 3%  Protectalon Duo  Shelf life: 3 Years	
	Medines	• ISO Certificate Type: Original Notarization: Notarized Validity: 25-07-2026	MIS)	TAN
81.	M/s. Bombay Optical Corporation, Shop No. A-1, Ground Floor, Plot No. Z- 103, Block-3, Dehli Cooperative Housing Society, Karachi.	Name of Manufacturer:  SBO Hearing A/S, Kongebakken 9, 2765 Smorum, Denmark.  Manufacturing Site:	Brand name: Bernafont®  Generic Name: Hearing Aid Devices	Deferred due to following deficiencies in application;  • FSC has been expired and is apostilled not legalized by embassy.
	(ELI- 00565)  R&I detail 01-07-2025	1.Demant Enterprise A/S, Tempovej 15, 2750 Ballerup, Denmark.	Applied as: Family  Class: B	The model(s) applied have not been specified since multiple models and types have been mentioned in FSC
	Fee: 31,000/- Slip: 2848019373	Sp. Z.o.o. ul Lubieszyriska 59, 42, 72-006 Mierzyn, Poland • LOA	Model/Codes/Sizes (as per FSC & Application): As per FSC.	under Bernafon Family.  DOC has not been submitted.  Service life & data has not been

		Type: Original		submitted.
		Notarization: Notarized	Service life: Not mentioned	
		Validity: 30-06-2029		
		• FSC Type: Original Issued By: Danish Medicine Agency Legalization: Apostilled Validity: 12-08-2025 • ISO Certificate	Jolisher) 9:55	TAN
		Type: Original	100, 1	
		Notarization: Notarized		
		Validity: 12-08-2026		
82.	M/s. Varitron, First Floor	Legal Manufacturer:	Brand name:	Deferred due to
02.	60-D, F.C.C. Zahoor Elahi Road, Gulberg-IV, Lahore.	Blue Belt Technologies, Inc., 2875 Railroad Street,	CORI Real Intelligence Surgical System	following deficiencies in application;
		Pittsburgh, PA USA 15222.		• LOA/Agnecy Agreement has
	(ELI- 00510)		Generic Name:	been issued by
	dno	<b>Manufacturing Sites:</b>	Ophthalmic Viscosurgical	Smith & Nephew Inc., UAE, while
	R&I detail	1. Smith & Nephew Inc., Endocscopy, 76 S.	Device	the legal
	24-06-2025	Meridian Ave., Oklahoma	Will Ro	manufacturer as per FSC is Blue Belt
	Fee: 240,000/-	City, OK USA 73107. 2. Smith & Nephew Inc.,	Applied as: System	Technologies, Inc., 2875 Railroad
	<b>Slip:</b> 9646735025	Endocscopy, 120 Forbes	" che up	Street, Pittsburgh,
		Blvd., Suite 150/130	Class: B	PA USA 15222.
		Forbes Blvd., Mansfield, MA USA 02048.		• ISO certificate is not notarized.
		06, 100	Model/Codes/Sizes (as per	• Justification of applying articles as
		• LOA	FSC & Application):  i. ROB10024-Real	systems is required.
		Type: Copy of Notarized	Intelligence CORI	• The codes
	P	Notarization: Notarized	ii. ROB10025-Real	ROB10102, ROB10100 &
	•	<b>Issue Date:</b> 03-04-2025	Intelligence Tracking Camera	ROB10101 applied in application, have
		Validity: Not mentioned	iii. ROB10027-Real	not been mentioned
		• FSC	Intelligence Tablet iv. ROB10001-Real	in FSC. • Service life of
	0	Type: Original	Intelligence Robotics	• Service life of complete system is
	1edne	Issued By: US FDA Legalization: Apostilled	Instruments v. ROB10026-Real	required.
			Intelligence Foot Pedal	

T	' DOD10010 D 1
Validity: 18-11-202	
	Intelligence Robotics
	Drill
• ISO Certificate	vii. ROB10014-Real
Type: Copy	Intelligence Robotics
Notarization: Not 1	Notarized Drill Tracker
Validity: 08-08-202	viii. ROB10010-Real Intelligence Robotics
Valuaty: 00 00 202	Bone Pins 4.0mm x
	127mm
	ix. ROB10011-Real
	Intelligence Robotics
, ,	Bone Pins 4.0mm x
	152mm
100001	x. ROB00032-Navio Bone
DO . O	Pin 3.5mm x 127mm
	xi. ROB10002-Real
~211°-1	Intelligence Robotics
1610 W	Cart Column.
510	xii. ROB10003-Real
DP OV G	Intelligence 24" Touch
1 6/2	Screen.
	xiii. ROB10031-Real
	Intelligence Tubing Set.
1037	xiv. ROB10024S-Real
	Intelligence CORI.
21	xv. ROB10025S-Real
	Intelligence Tracking
180	Camera.
	xvi. ROB10027S-Real
	Intelligence Tablet.
	xvii. ROB10013S-Real
	Intelligence Robotic
	Drill. xviii. ROB10003S-Real
70,	Intelligence 24" Touch
70,01	Screen.
	viv ROB10028-Real
	Intelligence
i ctor N	Intelligence Transportation Case. xx. ROB10015-Real Intelligence Robotics
GIP 10	xx. ROB10015-Real
6 0 0	Intelligence Robotics
Y (0', 5	Drill Attachment.
	xxi. ROB10017-Real
	Intelligence Point Probe.
1 2/3	xxii. ROB10086-Real
80-3	Intelligence Plane
9	Visualizer.
700	xxiii. ROB10020-Real
160)	Intelligence Tracker
No	Clamp.

	' DOD10010 D. 1
	xxiv. ROB10018-Real
	Intelligence Femur
	Tracker.
	xxv. ROB10019-Real
	Intelligence Tibbia
	Tracker.
	xxvi. ROB10021-Real
	Intelligence Drill Guide.
	xxvii. ROB10022-Real
	Intelligence Check Point
	Tool.
Qu', c	xviii. ROB10012-Real
	Intelligence Check Point
70, 60	Pins Qty:4.
	xxix. ROB10023-Real
DA D. S.	Intelligence Z-Retractor.
	xxx. ROB10050-Real
-al'-10 <sup>2</sup>	Intelligence Robotics
igit Wigi	Intrument Tray.
clo ich alle	xxxi. ROB10016-Real
	Intelligence Robotics
N° (0', 50')	Drill Guard.
	xxxii. ROB10000-CORI Starter
	Kit.
	xxiii. ROB10051-Real
	Intelligence Robotics Pin
01	Caddy.
100	xxiv. ROB10052-Real
180"	Intelligence Robotics Pin
No	Caddy Lid.
	xxxv. ROB10053-JOURNEY II
	Uni Robotics Finishing
	Insert(F).
Q- "C	xxvi. ROB10054-Universal
	Insert Lid(F)
70. 100	
	kxvii. ROB10055-Real
	Intelligence Shipping
0, 7, 0	Inser(A).
10, 10, 4	xviii. ROB10056-Real
16" V" "61	Intelligence Shipping
65° (8) -01°	Inser(B).
D2.01.064	xxix. ROB10057-Real
	Intelligence Shipping
	Inser(C).
	xl. ROB10058-Real
	Intelligence Shipping
(20-)	Inser(F).
-90	xli. ROB10087-Universal
100	Base Tray Lid.
All 1	xlii. ROB100022-Real
160	Intelligence Robotics
	mongenee Robotics

83.	M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.	Name of Manufacturer: Micro Medical Devices Inc., 23945 Calabasas Rd., Suit 110 Calabasas, CA USA 91302.	Intelligence Implant Database V2.88.  xlvi. ROB00025-TKA Left Tibbia Twin Peg Cut Guide.  xlvii. ROB00026-KA Right Tibbia Twin Peg Cut Guide  klviii. ROB00060-TKA Distal FMR Punches-38mm  xlix. ROB00061-TKA Distal FMR Punches-45mm  1. ROB10300-Welcome Box 1  1i. PFSDV0016-Navio Flat Markers (Case of 18)  1ii. ROB10033-Real Intelligence 6mm Bullet Bur.  1iii. ROB10035-Real Intelligence 5mm Cylinderical Bur.  1iv. ROB10036-Real Intelligence 6mm Cylinderical Bur.  1v. ROB10034-Real Intelligence 6mm Chip Breaker Bullet Bur.  Service life: Not mentioned  Brand name:  PalmScan K2000  Generic Name:	Deferred due to following deficiencies in application;  • Application form submitted is
	(ELI-00416)	• LOA Type: Original (PalmScan	Portable Keratometer  Applied as: Single	unfilled & unsigned.  • FSC submitted has expired.
	Date of R& I 02-07-2025 Fee: PKR 6,000/-	K2000) Notarization: Notarized	* F Smg-	Notarized ISO     Certificate of the manufacturer, has not been submitted.

• Service of the substitution of the substitut	been submitted. vice life and
• FSC  Model/Codes/Sizes (as per data substitution of the code substitu	vice life and
Type: Original (Palsacn P 2000 File)  Issued By: US FDA Legalization: Legalized Validity: 12-06-2025  • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 25-07-2026	n has not been mitted.
Marium Square, Chandni Chowk, Stadium Road, Karachi Road,	red due to ving deficiencies dication; olication form mitted is
Ophthalmic Ultrasound unfi	illed &
• LOA Type: Original (PalmScan K2000)  Notarization: Notarized Fee: PKR 31,000/-Slip # 1273281242  • LOA Type: Original (PalmScan K2000)  Notarization: Notarized Issue Date: 03-04-2025  Validity: May-2027  • FSC Type: Original (Palsacn P  PalmScan A2000 PalmScan P2000  • Just appli mode as: Single  • Just appli mode a	igned. ification of ying multiple lels in single lication, is ired. C submitted has ired. arized ISO tificate of the nufacturer, has been submitted. arized DOC has
Issued By: US FDA  PalmScan AP2000 PalmScan P2000FP  data	been submitted. vice life and has not been mitted.
Validity: 12-06-2025  • ISO Certificate Type: Copy of notarized  Notarization: Notarized  Validity: 25-07-2026	
	red due to

	Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.  (ELI-00416)  Date of R& I 03-06-2025  Fee: PKR 6,000/-Slip # 78303720086	Good-Lite Co., 1155 Jansen Farm Dr. Elgin, IL USA 60123.  • LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2025  • FSC Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 06-03-2026	Grey Generic Name: Adjustable Ophthalmic Trial Frame  Applied as: Single  Class: A  Model/Codes/Sizes (as per FSC): 469900	following deficiencies in application;  • Application form submitted is unfilled & unsigned.  • LOA is copy and not notarized.  • FSC is copy and not legalized.  • ISO certificate is copy & not notarized.  • Undertaking has not been submitted.  • Stability Data has not been submitted.
	P	• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 17-11-2025	Shelf/Service life: 5 Years	
86.	M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.  (ELI-00416)  Date of R& I	Name of Manufacturer: Good-Lite Co., 1155 Jansen Farm Dr. Elgin, IL USA 60123.  • LOA Type: Copy Notarization: Not Notarized	Brand name: GL Ophthalmology Full Trial Lense Set (Red & Black Rims) Generic Name: Ophthalmology Trial Lense Set Applied as: Set	Deferred due to following deficiencies in application;  • Application form submitted is unfilled & unsigned.  • LOA is copy and not notarized.
	03-06-2025	Validity: 31-12-2025	Class: A	<ul><li>FSC is copy and not legalized.</li><li>ISO certificate is</li></ul>

		Validity: 17-11-2025		
87.	M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.	Name of Manufacturer: Good-Lite Co., 1155 Jansen Farm Dr. Elgin, IL USA 60123.		Deferred due to following deficiencies in application;  • Application form submitted is
	(ELI-00416)  Date of R& I 03-06-2025  Fee: PKR 6,000/- Slip # 247122682	<ul> <li>LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2025</li> <li>FSC Type: Copy Issued By: US FDA Legalization: Not Legalized</li> </ul>	Visual alignment & Binocular Vision Diagnostic Device.  Applied as: Kit  Class: A  Model/Codes/Sizes (as per FSC): 671000	unfilled & unsigned.  • LOA is copy and not notarized.  • FSC is copy and not legalized.  • ISO certificate is copy & not notarized.  • Undertaking has not been submitted.  • Stability Data has not been submitted.
	Anes	Validity: 06-03-2026  • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 17-11-2025	Shelf/Service life: 5 Years	AN
88.	M/s. Roche Pakistan Limited, 1 <sup>st</sup> Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009)	Legal Manufacturer:  M/s Roche Molecular Systems Inc., 1080 US Highway 202 South Branchburg, NJ 08876 USA.	Brand name: Cobas® 6800  Generic Name: PCR based molecular	Deferred due to following deficiencies in application;  • Justification of applying system as single, is required.  • LOA is copy, not
	<b>R&amp;I detail</b> 19-06-2025 <b>Fee: 6,000/- Slip:</b> 761959153215	Manufacturing Site:  M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany.	Applied as: Single  Class: A	original. • FSC mentions manufacturing site of Germany while Form-6A mentioned manufacturing site of Swotzerland.
	i ednes	• LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination	Model/Codes/Sizes: 09575154001  Shelf life:	<ul> <li>Valid notarized ISO certificate of manufacturing site has not been submitted.</li> <li>Copy of ISO certificate of legal manufacturer is not</li> </ul>
	Meo.	• FSC (Germany)	Not mentioned.	manufacturer is notarized.

		Type: Original		• Service life has not
		Issued By: Govt Body		been mentioned.
		Legalization: Legalized		
		<b>Issue Date:</b> 26-03-2025		Ala.
		Validity: Not mentioned		V VIII
		• ISO Certificate Type: Copy	(MIS) 0:55	
		Notarization: Not Notarized	1, 10, 2	
		Validity: 30-06-2027	lier Uso,	
89.	M/s Roche Pakistan	Name of Manufacturer:	Brand Name:	The Board approved
	Limited, 1st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.	Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive	Ventana anti-AREG (SP272) Rabit Monoclonal Primary Antibody	the case.
	(ELI-00009)	Tucson, AZ 85755, USA.	Generic Name: Monoclonal Primary Antibody for qualitative	
	Date of R& I 19-06-2025	• LOA Type: Copy of Notarized Notarization: Notarized	immunohistochemical detection of amphiregulin (AREG) protein.	
	Fee: PKR 62,000/-	Validity: Till termination	Applied as: Single	
	Slip # 3594129287	(Original in Ventana DP 200 Slide Scanner File)	Class: C	1 AM
	No	• FSC Type: Copy of apostilled	Code/sizes: 09858725001	
		Issued By: US FDA	Shelf Life: 24 Months (2-8°C)	
		Legalization: Legalized		
		Validity: 20-08-2026		
		(Original in SSR Solution File)	10e	
	P	5 Old Septe		
		• ISO – Certificate:		
		Type: Copy of notarized		
	6	Notarization: Notarized Validity: 19-08-2027		
	adhe	(Original in BenchMark GX File)		
90.	M/s Roche Pakistan	Name of Manufacturer:	Brand Name:	The Board approved

Limited, 1st Floor, Block-6, P.E.C Karachi East 75400.  (ELI-00009)  Date of R& I 19-06-2025  Fee: PKR 62,000/-Slip # 04408415613	37-B, C.H.S., Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  • LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  • FSC Type: Copy of apostilled	Ventana anti-EREG (SP326) Rabit Monoclonal Primary Antibody  Generic Name: Monoclonal Primary Antibody for qualitative immunohistochemical detection of epiregulin (EREG) protein.  Applied as: Single  Class: C  Code/sizes: 09858715001	the case.
	Issued By: US FDA Legalization: Legalized Validity: 20-08-2026 (Original in SSR Solution File)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 19-08-2027 (Original in BenchMark GX File)  • EU QMS Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-11-2026 (Original in Anti-p40 (SP225) File)	Shelf Life: 24 Months (2-8°C)	T AM
Limited, 1st Floor,	Akistan 37-B, C.H.S., Roche Diabetes Care GmbH, Sandhofer Strasse 116 68305 Mannheim, Germany.  Manufacturing Site:	Brand Name: Accu-Chek SmartGuide App Generic Name: Software for real-time glucose monitoring device. Applied as: Family	The Board approved the case subject to submission of separate fee for each type of app and confirmation of class before issuance of
Date of R& I	Roche Diabetes Care Inc., 9115 Hague Road	Class: C	registration letter.

	19-06-2025	Indianapolis, Indiana 46250		
	Fee: PKR 62,000/-	USA.	Code/sizes:	
	<b>Slip</b> # 095007001010	• LOA	09872272001-Accu-Chek	
		Type: Copy of Notarized	SmartGuide App (iOS) 09873597001- Accu-Chek	
		Notarization: Notarized	SmartGuide App (Android)	
		Validity: Till termination	(5)	
		(Original in Ventana DP 200	Service Life: Not mentioned	•
		Slide Scanner File)	1 01 9:3	
		il Granio	118/2019,	
		• FSC	Olio Joh	
		Type: Copy of legalized	O(1)	
		Issued By: Govt. Body	100	
		Legalization: Legalized		
		Issue Date: 03-02-2025		
		Validity: Not mentioned		
		(Original in Accu-Chek SmartGuide Predict App		
		File)		
		900		
	09	• ISO – Certificate:		VIII
		<b>Type:</b> Copy of notarized		1
	Ne	Notarization: Notarized Validity: 31-10-2027	MIS) SS	
		(Original in AccuChek	16,91 0:0	
		Active device File)	"e/\"05"	
		• EU QMS Certificate:	1011200	
		Not submitted.		
92.	M/s Roche Pakistan	Legal Manufacturer:	Brand Name:	The Board approved
	Limited, 1 <sup>st</sup> Floor, 37-B, Block-6, P.E.C.H.S.,	Roche Diabetes Care GmbH,	Accu-Chek SmartGuide Predict App	the case subject to submission of
	Karachi East 75400.	Sandhofer Strasse 116 68305 Mannheim, Germany.		separate fee for each
		Talinioni, Comuny.	Generic Name: Software for real-time glucose	type of app and confirmation of class
	(ELI-00009)	Manufacturing Site:	monitoring device.	before issuance of
		Roche Diabetes Care Spain	Applied as: Family	registration letter.
	Date of R& I 03-06-2025	SL, AV., de la Generalitat	Class: B	
		171-173, 08174 Sant Cugat de Valles, Barcelona, Spain.	Ciuos. D	
	<b>Fee:</b> PKR 31,000/- <b>Slip</b> # 8326581370	de Tanes, Barcelona, Spani.	Code/sizes:	
	. We		Couci Sizes.	

	Ī	104	00402620001 A Cl1-	T
		• LOA Type: Copy of Notorized	09493620001-Accu-Chek SmartGuide Predict App (iOS)	
		Type: Copy of Notarized	09873627001- Accu-Chek	
		<b>Notarization</b> : Notarized	SmartGuide Predict App	
		Validity: Till termination	(Android)	1/2
		(Original in Ventana DP 200 Slide Scanner File)	Service Life: Not mentioned	1 All
		• FSC Type: Original	1 (1) 9:55	
		Issued By: Govt. Body	, 18/100,	
		Legalization: Legalized	10/100	
		<b>Issue Date:</b> 03-02-2025		
		Validity: Not mentioned	100,	
		• ISO – Certificate: Type: Copy of notarized		
		Notarization: Notarized Validity: 31-10-2027		
	-0	(Original in AccuChek Active device File)		
93.	M/s Roche Pakistan Limited, 1 <sup>st</sup> Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400.	Legal Manufacturer:  Roche Diabetes Care GmbH, Sandhofer Strasse 116 68305 Mannheim, Germany.	Brand Name: Serum DAT Control Set  Generic Name: Serum DAT Control Set	The Board approved the case.
	(ELI-00009)	Manufacturing Site:	Applied as: Set	
	Date of R& I 03-06-2025	ACQ Science GmbH, Etzwiesenstrabe 37, 72108	Class: B	
	Fee: PKR 31,000/- Slip # 7701136010	Rottenburg-Hailfingen, Deutschland, Germany.	Code/sizes: 09543112190	
	<b>Σπρ</b> π 7701130010	• LOA Type: Copy of Notarized	Shelf Life: 24 Months (2-8oC)	
	<b>V</b>	Notarization: Notarized		
		Validity: Till termination		
	_6	(Original in Ventana DP 200 Slide Scanner File)		
	Meque	• FSC Type: Copy of legalized		

	Issued By: Govt. Body		
	Legalization: Legalized		
	<b>Issue Date:</b> 12-02-2025		
	Validity: Not mentioned		e la
	(Original in Cobas ISE Neo 900 file)	(19)	1 12
	• ISO – Certificate: Type: Original Notarization: Notarized	"I (M. 1) 0:22	
	Validity: 27-02-2028	10. Un.	
94. M/s Roche Pakistar Limited, 1st Floor, 37-B Block-6, P.E.C.H.S. Karachi East 75400.	COPANITALIA S n A Via	Brand Name: FLOQSwab Self-Vaginal Swab, Marked Breakpoint Generic Name: Self-Vaginal Swab, Marked	The Board approved the case.
(ELI-00009)	• LOA	Breakpoint Breakpoint	
D . CDO I	Type: Orginal	Applied as: Single	
Date of R& I 03-06-2025	Notarization: Notarized	Class: B	
Fee: PKR 31,000/-	Validity: 05-09-2029		1/2
Slip # 5978741448		Code/sizes:	
Medi	• FSC Type: Original	552C.80	(1)
	Issued By: Govt. Body	Shelf Life: 36 Months	
	Legalization: MOH	1 01 0	
	Issue Date: 02-01-2024	1.000	
	Validity: Not mentioned	10112 50r	
	• ISO – Certificate: Type: Original	Posi,	
	Notarization: Notarized Validity: 01-09-2027		
95. M/s. Roche Pakistan	8	Brand name:	The Board approved
Limited, 1 <sup>st</sup> Floor, 37-B Block-6, PECHS, Karachi.	M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim	Cobas Magnesium Gen.2 MG2	the case.
(ELI- 00009)	Deutschland/Germany.	Generic Name:	
R&I detail	Manufacturing Site:	In-vitro test kit fot quantitative determination of magnesium in human serum, plasma & urine	

	19-06-2025	Roche Diagnostics (Suzhou)		
	Fee: 31,000/-	Ltd., No. 259 Zhongyuan Road 215028 Suzhou,	Applied as: Kit	
	<b>Slip:</b> 0097293027	Jiangsu, China.		
			Class: B	
		• LOA		Alla
		<b>Type:</b> Copy of Notarized	Model/Codes/Sizes:	
		<b>Notarization</b> : Notarized	08058016214	•
		Validity: Till termination	16.90 0:3	
		Original in Ventana DP 200 Slide Scanner File)	Shelf life: 24 Months	
		MODELL SOL	101. Jo.	
		• FSC	O.C.	
		<b>Type:</b> Copy of legalized	D	
		Issued By: Govt Body		
		Legalization: Legalized		
	Y	<b>Issue Date:</b> 12-02-2025		
		Validity: Not mentioned		
		(Original in Cobas ISR neo 900 File)		<u> </u>
	16glue	• ISO Certificate Type: Copy of notarized		7 12
	No	<b>Notarization</b> : Notarized		
	· ·	Validity: 29-06-2027	160.9 0:22	
		(Original in Elecsys AFP	I'I VOI S	
		File)	lie Oss.	
96.	M/s. Roche Pakistan	Legal Manufacturer:	Brand name:	The Board approved
	Limited, 1 <sup>st</sup> Floor, 37-B, Block-6, PECHS, Karachi.	M/s Roche Diagnostics	Cluster of Liver Enzymes	the case subject to submission of
	, ,	GmbH, Sandhofer Strasse 116 68305 Mannheim	P	differential fee.
	(ELI- 00009)	Deutschland/Germany.	Generic Name:	
		5 OF COX	Cluster of Liver Enzymes	
	R&I detail	Manufacturing Site:		
	03-06-2025	Roche Diagnostics (Suzhou)	Applied as: Cluster	
	Fee: 31,000/-	Ltd., No. 259 Zhongyuan Road 215028 Suzhou,		
	Slip: 642838916	Jiangsu, China.	Class: B	
	AUR			
	162	• LOA	Model/Codes/Sizes (as per SC	

	Type: Copy of Notarized	& application):	
	Notarization: Notarized	05166888214 (ALP-2)	
	Validity: Till termination	08056757214 (ALP-2)	
	Original in Ventana DP 200	05168775214 (GGT-2)	1/4
	Slide Scanner File)	08057796214 (GGT-2)	D.I.
		(8)	
	• FSC1 Type: Copy of legalized		
	Issued By: Govt Body	<b>Shelf life:</b> 12 Months (2-8 oC)	
	Legalization: Legalized	(18), 52,	
	Issue Date: 06-11-2024	10, Jn	
	Validity: Not mentioned	ON 1	
	(Original in Elecsys CA 72-	De	
	4)		
	• FSC2 Type: Copy of legalized		
Y	Issued By: Govt Body		
	Legalization: Legalized		
	Issue Date: 12-02-2025		
	(0)		. 1
10	Validity: Not mentioned		O.N.
1601	(Original in Cobas ISR neo 900 File)		1
No.		"Was "Ri	
		16, 9 0.22	
	• ISO Certificate 1	1, 18, 2	
	<b>Type:</b> Copy of notarized	112, 33,	
	Notarization: Notarized	10. 30	
	Validity: 20-10-2025	Poli, So,	
	(Original in Elecsys Cyfra		
	21-1 Test Kit)		
D.	5,017,08		
Y.	• ISO Certificate 2  Type: Copy of notarized		
	Notarization: Notarized		
	Validity: 29-06-2027		
400	(Original in Elecsys AFP File)		
97. M/s. Roche Pakistan Limited, 1 <sup>st</sup> Floor, 37-B,	Legal Manufacturer:	Brand name:	The Board approved

Block-6, PECHS, Karachi.	M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim	Ureal	the case.
(ELI- 00009)	Deutschland/Germany.	Generic Name:	
		In vitro diagnostic reagent	
R&I detail	Manufacturing Site:		VIII
03-06-2025	Roche Diagnostics (Suzhou)	Applied as: Kit	
Fee: 31,000/-	Ltd., No. 259 Zhongyuan Road 215028 Suzhou,	10/11/25	
<b>Slip:</b> 73479993956	Jiangsu, China.	Class: B	
	• LOA	Model/Codes/Sizes (as per SC	
	Type: Copy of Notarized	& application):	
	Notarization: Notarized	08058806214	
	Validity: Till termination	05171873214	
P	Original in Ventana DP 200 Slide Scanner File)	Shelf life: 12 Months (2-8 oC)	
, and the second	• FSC1 Type: Copy of legalized		
	Issued By: Govt Body		
-6	Legalization: Legalized		
dillo	Issue Date: 06-11-2024		1 AM
Ne	Validity: Not mentioned	(19)	
	(Original in Elecsys CA 72-4)	1 (MII) 0:20	
	• FSC2 Type: Copy of legalized	dieyoss,	
	Issued By: Govt Body		
	Legalization: Legalized	10 <sub>0</sub> ,	
	<b>Issue Date:</b> 12-02-2025		
	Validity: Not mentioned		
P	(Original in Cobas ISR neo 900 File)		
	• ISO Certificate 1		
	Type: Copy of notarized		
	Notarization: Notarized		

		Validity: 20-10-2025		
		(Original in Elecsys Cyfra		
		21-1 Test Kit)		
		,		
		IGO G A'C A A		
		• ISO Certificate 2  Type: Copy of notarized		
		Notarization: Notarized	(6)	
			ركي الله	
		Validity: 29-06-2027	16,9 0.5	
		(Original in Elecsys AFP	1, 20, 2	
		File)	(18), (13),	
98.	M/s. Roche Pakistan	Legal Manufacturer:	Brand name:	The Board approved
	Limited, 1 <sup>st</sup> Floor, 37-B, Block-6, PECHS, Karachi.	M/s Roche Diagnostics	Cobas Iron2	the case.
		GmbH, Sandhofer Strasse 116 68305 Mannheim	100.	
	(E) I 00000)	Deutschland/Germany.	Generic Name:	
	(ELI- 00009)	SIS B SIS	in vitro diagnostic reagent	
		Manufacturing Site:		
	R&I detail		A 10 1 YZ'.	
	03-06-2025	1.Roche Diagnostics GmbH, Sandhofer Strasse 116 68305	Applied as: Kit	
	Fee: 31,000/-	Mannheim		
	<b>Slip:</b> 369952667	Deutschland/Germany	Class: B	
	1			
		2.Roche Diagnostics	Model/Codes/Sizes (as per SC	1
	"VIO	(Suzhou) Ltd., No. 259	& application):	
		Zhongyuan Road 215028 Suzhou, Jiangsu, China.	10059605190	
		Suzilou, Hangsu, Cilila.	08057931214	
		, Q- , o	05169291214	
		• LOA	03103231211	
		Type: Copy of Notarized	G. 1010 1534 1 (2.0 G)	
		<b>Notarization</b> : Notarized	Shelf life: 15 Months (2-8 oC)	
		Validity: Till termination	100	
		Original in Ventana DP 200		
		Slide Scanner File)		
		, (O, 'So,		
		• FSC1		
		Type: Original		
		Issued By: Govt Body		
		Legalization: Legalized		
	700.	<b>Issue Date:</b> 01-04-2025		
	160,	Validity: Not mentioned		

		• FSC2 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 12-02-2025 Validity: Not mentioned	(5)	T AM
		<ul> <li>FSC3 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 31-01-2024 Validity: Not mentioned</li> <li>ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)</li> </ul>	in and the state of the state o	
99.	M/s. Roche Pakistan Limited, 1 <sup>st</sup> Floor, 37-B, Block-6, PECHS, Karachi.	Name of Manufacturer:  M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany.	Brand name: Cobas HypoCleaner  Generic Name: ISE Deproteinizer	The Board approved the case.
	<b>R&amp;I detail</b> 02-07-2025 <b>Fee: 6,000/- Slip:</b> 7765423415	• LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination Original in Ventana DP 200	Applied as: Single Class: A	
	P.	• FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized	Model/Codes/Sizes (as per FSC & Application): 10166274001 (500ml)  Shelf life: 25 Months (2-8°C)	
	"Iequi	Issue Date: 01-04-2025		

Indicate   Indicate			Validity: Not mentioned		
- ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)  100. M/s. Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi.  (ELI-00009)  R&I detail 02-07-2025 Fee: 62,000/- Slip: 13889480643  R&I detail 02-07-2025  Fee: 62,000/- Slip: 13889480643  Deutschland/Germany.  Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tusson, AZ 85755, USA.  Class: C  LOA Type: Copy of Notarized Notarization: Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  FSC. Type: Copy of legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate					
Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)  100.  M/s. Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi. (ELI-00009)  R&I detail 02-07-2025 Fee: 62,000/- Slip: 13889480643  Deutschland/Germany.  Notarization: Notarized Notarization: Notarized Notarization: Notarized Notarization: Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  PSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  Inc. (Tuzson)  Park Drive Class: C  Model/Codes/Sizes: 10070323001  Shelf life: 24 Months (2-8oC)			(Original in IRON2 File)		
Validity: 29-06-2027 (Original in Elecsys AFP File)			Type: Copy of notarized		AM
Coriginal in Elecsys AFP   File				(5)	
File			<b>Validity:</b> 29-06-2027	(6)	•
Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi.  (ELI- 00009)  R&I detail  02-07-2025  Fee: 62,000/- Slip: 13889480643  Deutschland/Germany.    Cape				1 heil 9:3	
Block-6, PECHS, Karachi.  MS Roche Diagnostics (BmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany.  Manufacturing Site: Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  • FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate	100.		Legal Manufacturer:	Brand name:	The Board approved
R&I detail  02-07-2025 Fee: 62,000/- Slip: 13889480643  Deutschland/Germany.  Manufacturing Site:  Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  FISO Certificate  Generic Name: Epstein-Barr virus-encoded RNA (EBER) Reagent  Applied as: Single  Class: C  Wodel/Codes/Sizes: 10070323001  Shelf life: 24 Months (2-8oC)				Ventana Eber Probe	the case.
R&I detail  02-07-2025  Fee: 62,000/- Slip: 13889480643  Manufacturing Site:  Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  PFSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  PEpstein-Barr virus-encoded RNA (EBER) Reagent  Applied as: Single  Model/Codes/Sizes: 10070323001  Shelf life: 24 Months (2-8oC)				(0),	
R&I detail  02-07-2025  Fee: 62,000/- Slip: 13889480643  Manufacturing Site: Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  FISO Certificate		(ELI- 00009)	Deutschland/Germany.		
Ventana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  IVentana Medical Systems Inc. (Tuzson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA.  Class: C  Model/Codes/Sizes: 10070323001  Shelf life: 24 Months (2-8oC) Shelf life: 24 Months (2-8oC)  Shelf life: 24 Months (2-8oC)		D&I dotoil	Manufacturing Site:		
• LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  • FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate		02-07-2025 Fee: 62,000/-	Inc. (Tuzson) 1910 E. Innovation Park Drive	Applied as: Single	
Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  • FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate		<b>Slip:</b> 13889480643	Tueson, AZ 65755, CSA.	Class: C	
Validity: Till termination (Original in Ventana DP 200 Slide Scanner File)  • FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate		1ednes		Model/Codes/Sizes:	1 AM
(Original in Ventana DP 200 Slide Scanner File)  • FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate		Mo	Notarization: Notarized	10070323001	
• FSC Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File) • ISO Certificate		_	Validity: Till termination	(10, 7 5.2)	
Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate				Shelf life: 24 Months (2-8oC)	
Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate			1200 1100	10, Jn	
Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate			A		
Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate				100	
Issue Date: 26-03-2025 Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate			167		
Validity: Not mentioned (Original in PAS Stain Core Kit File)  • ISO Certificate					
(Original in PAS Stain Core Kit File)  • ISO Certificate		P	<b>Issue Date:</b> 26-03-2025		
Kit File)  • ISO Certificate			Validity: Not mentioned		
		_0			
Type: copy of notarized		"leque.	• ISO Certificate Type: Copy of notarized		

		Notarization: Notarized		
		Validity: 29-06-2027		
		(Original in Elecsys AFP		
		File)		
101.	M/s. Roche Pakistan	Legal Manufacturer:	Brand name:	The Board approved
	Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi.	M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim	PAS Stain Core Kit	the case.
	(======================================	116 68305 Mannheim Deutschland/Germany.	Generic Name:	
	(ELI- 00009)	Ogo	Qualitative Histologic stain	
		Manufacturing Site:	Quantariye mistorogio stam	
	R&I detail	Ventana Medical Systems	Applied as: Single	
	02-07-2025	Inc. (Tuzson) 1910 E.	Applied as. Single	
	Fee: 6,000/-	Innovation Park Drive		
	<b>Slip:</b> 990836279434	Tucson, AZ 85755, USA.	Class: A	
		SIN BOIL		
	P	• LOA Type: Copy of Notarized	Model/Codes/Sizes:	
	· ·	Notarization: Notarized	09328823001	
		Validity: Till termination	Shelf life: 12 Months	_
	1108	(Original in Ventana DP 200 Slide Scanner File)		TAN
	Meor	• FSC Type: Original	MIS) .55	
		Issued By: Govt Body	1 01 9.	
		Legalization: Legalized	1:00	
		Issue Date: 26-03-2025	1011200	
		Validity: Not mentioned	lost, Son	
		06, 10	108,	
		ISO Certificate		
		Type: Copy of notarized		
	P	Notarization: Notarized		
		Validity: 29-06-2027		
		(Original in Elecsys AFP File)		
102.	M/s Ferozsons Laboratories	Legal Manufacturer:	Brand Name:	Deferred due to
	Limited, P.O. Ferozsons, Amangarh, Nowshera-	Boston Scientific	Easy-Mate SureLink	following deficiencies in application;
	KPK, Pakistan.	Corporation, 300, Boston		
	· N	Scientific Way,	Generic Name:	• Justification of

## Marlborough, MA 01752 Sterile Electrode Cables. applying two types of cables as family, USA. (ELI-00120)Applied as: Family is required. Original ISO Class: A Date of R& I certificate has not **Manufacturing Site:** been submitted. 16-06-2025 Philips-Medisize Costa Models/Code/sizes: • LOA is copy and Mesa, LLC, 3545 Harbor Fee: PKR 25,000/has expired. M0042000088P0 Blvd, Suite 150 Costa Mesa, Slip # 99055424 Moreover, LOA has Cable. Easy-Mate, CA 92626, USA. been issued 125cm/4ft, 4-Pin Boston Scientific ii. M0042000089P0 International B.V. Cable, Easy-Mate, Packaged and labelled at: Netherlands. 125cm/4ft, 6-Pin **Boston Scientific** M004200774P0 iii. Corporation, 302 Parkway, Cable, Easy-Mate, Global Park, Heredia Costa 125cm/4ft, 8-Pin Rice M004560001A0 iv. Cable. SureLink. 210cm/7ft, 10-Pin • LOA M004560001P0 Type: Copy of Notarized Cable, SureLink, Notarization: Notarized 210cm/7ft, 10-Pin M004560002A0 vi. Validity: 30-06-2025 Cable, SureLink, 125cm/4ft, 4-Pin M004560002BA0 vii. • FSC Cable, SureLink, Type: Original 125cm/4ft, 4-Pin **Issued By:** US FDA M004560002BP0 viii. Cable, SureLink Legalization: Apostilled 125cm/4ft, 4-Pin Validity: 10-06-2026 M004560002P0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002RA0 Cable. SureLink. • ISO - Certificate: 125cm/4ft, 4-Pin Type: Copy of notarized M004560002RP0 Notarization: Notarized Cable, SureLink, Validity: 01-09-2026 125cm/4ft, 4-Pin xii. M004560002YA0 SureLink, Cable, 125cm/4ft, 4-Pin xiii. M004560002YP0 Cable, SureLink, 125cm/4ft, 4-Pin M004560003A0 xiv. Cable, SureLink, 210cm/7ft, 4-Pin M004560003P0 XV.

Cable,

210cm/7ft, 4-Pin

SureLink,

			xvi. M004560004A0 Cable, SureLink, 125cm/4ft, 10-Pin xvii. M004560004P0 Cable, SureLink, 125cm/4ft, 10-Pin	AM
			Service Life: Easy-mate-3 Years SureLink-2 Years	
Li An Kl (E Da 24	imited, P.O. Ferozsons, mangarh, Nowshera-PK, Pakistan.  ELI-00120)	Nihon Kohden Corporation, 1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161- 8560, Japan.  Manufacturing Site: Nihon Kohden Tomioka Corporation, Tomioka Production Center 1-1 Tajino Tomioka-shi, Gunma, Japan.  • LOA Type: Copy Notarization: Not Notarized	Brand Name: Bedside Monitor Life Scope TR  Generic Name: Bedside Monitor.  Applied as: Family  Class: C  Models/Code/Sizes: BSM-6301K BSM-6501K BSM-6701K  Service Life: Not mentioned	Deferred due to following deficiencies in application;  • LOA is copy and is not notarized.  • Service life has not been mentioned.
	A	<ul> <li>Validity: 31-03-2026</li> <li>FSC Type: Original Issued By: Ministry of Health Legalization: Apostilled Validity: 10-06-2026</li> <li>ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 05-04-2027</li> </ul>	in Which of Sold in the Sold i	
Li	1/s Ferozsons Laboratories imited, P.O. Ferozsons, mangarh, Nowshera-	Legal Manufacturer: Boston Scientific	Brand Name: INTELLAGEN Cardiac Ablation System &	Deferred due to following deficiencies

KPK, Pakistan.

## (ELI-00120)

Date of R& I 16-06-2025

Fee: PKR 120,000/-Slip # 37227033937 Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA.

## **Manufacturing Sites:**

- 1. Stockert GmbH,
  Boetzinger Strasse 31
  Freiburg, BadenWurttemberg, Germany
  79111.
- Creation Technologies
   Ltd., 8977-8999 Fraserton
   Court Burnaby, British
   Columbia, Canada V5J
   5H8
- LOA

Type: Copy of Notarized Notarization: Notarized Validity: 30-06-2025

• FSC (Verified Online)

Type: Copy

**Issued By:** US FDA

Legalization: Not Legalized

Validity: 06-01-2027

• ISO – Certificate:

Type: Original

**Notarization:** Notarized **Validity:** 17-07-2027

Accessories

Generic Name: Cardiac Ablation System & Accessories.

Applied as: System

Class: C

## Models/Code/sizes:

- i. M004GEN100204010-INTELLAGEN RF Generator Kit
- ii. M004GEN10020401D0 -INTELLAGEN RF Generator Kit
- iii. M004GEN10020401H0 -INTELLAGEN RF Generator Kit
- iv. M004GEN10020401R0-INTELLAGEN RF Generator Kit
- v. M004GEN100204030-INTELLAGEN Remote Control Kit
- vi. M004GEN10020403R0-INTELLAGEN Remote Control Kit
- vii. M004GEN10020403H0 -INTELLAGEN Remote Control Kit
- viii. M004GEN10020403D0 -INTELLAGEN Remote Control Kit
- ix. M004GEN100204020-INTELLAGEN Irrigation Pump Kit
- x. M004GEN10020402D0 -INTELLAGEN Irrigation Pump Kit
- xi. M004GEN10020402H0 -INTELLAGEN Irrigation Pump Kit
- xii. M004GEN10020402R0-INTELLAGEN Irrigation Pump Kit
- xiii. M004GEN100200100-INTELLAGEN Foot Pedal
- xiv. M004GEN100206260-INTELLAGEN Tubing

in application;

- As per FSC, the system consists of 34 articles. The articles applied by the applicant need to be specified since fee of only Rs. 120,000/- has been deposited.
- LOA is copy and has expired. Moreover, LOA has been issued by Boston Scientific International B.V. Netherlands.
- Service life has not been mentioned.

	Set 1 PK
	xv. M004GEN100206251-
	INTELLAGEN Tubing
	Set 10 PK
	xvi. M004GEN100206241-
	INTELLAGEN Tubing
	Set 40 PK
	xvii. M004GEN100199510-
	INTELLAGEN Catheter
	Adapter Cable, 0.3
	Meter
G	xviii. M004GEN100199430-
	INTELLAGEN
70.480	Grounding Cable, 3
20001101	Meter
	xix. M004GEN100199470-
0, 70	INTELLAGEN
191,10,4	Grounding Cable, 3
187 17 101	Meter
6,6,6	xx. M004GEN100200900-
D2.01, C64	INTELLAGEN Foot
Y (0, 5°	Pedal Extension Cable,
	7 Meter
	xxi. M004GEN100200810-
	INTELLAGEN
7(0-)	Irrigation Pump
90	
	Connection Cable, 1 Meter
100	xxii. M004GEN100200840-
	INTELLAGEN
	Irrigation Pump
	Connection Cable, 3
	Meter
100	xxiii. M004GEN100199460-
7/J1 0C	INTELLAGEN
100 -i(0 -i)	Irrigation Pump
D. O. O.	Connection Cable, 5
	Meter
701, 76A	xxiv. M004GEN100200870-
icto IN all	INTELLAGEN
CIP ID ATE	Irrigation Pump
	Connection Cable, 10
K, (O, 20,	Meter
	xxv. M004GEN100200720-
	INTELLAGEN Remote
	Control Connection
205	Cable, 10 Meter
	xxvi. M004GEN100200750-
	INTELLAGEN Remote
	Control Connection
100	
· NO	Cable, 15 Meter

	Wednes	Apoli Director	xxvii. M004GEN100199440- INTELLAGEN Remote Control Connection Cable, 25 Meter xxviii. M004GEN100200780- INTELLAGEN Remote Control Connection Cable, 30 Meter xxix. M004GEN100200940- INTELLAGEN Serial Communication Cable, 3 Meter xxx. M004GEN100199480- INTELLAGEN Serial Communication Cable, 15 Meter xxxii. M004GEN100199490- INTELLAGEN Serial Communication Cable, 5 Meter xxxii. M004GEN100199450- INTELLAGEN Irrigation Pump IV Pole Clamp xxxiii. M004RA65010- Rhythmia HDx Ablation Connection Box (for INTELLAGEN) xxxiv. M004RA63020- Rhythmia HDx Ablation Connection Box- IntellaNav StablePoint (for INTELLAGEN)	TAN
105.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera- KPK, Pakistan.	Legal Manufacturer:  Boston Scientific Corporation, 300, Boston Scientific Way,	Brand Name: AngioJet <sup>TM</sup> Ultra 5000A Console Generic Name:	Deferred due to following deficiencies in application;  • LOA is copy and
	(ELI-00120)	Marlborough, MA 01752 USA.	Mechanical Atherectomy/Throbectomy drive.	has expired.  Moreover, LOA has been issued by Boston Scientific
	Date of R& I 24-06-2025	Manufacturing Sites:  1. Boston Scientific	Applied as: System	International B.V. Netherlands.
	Fee: PKR 100,000/- Slip # 76361236	Corporation, Two Scimed Place, Maple Grove, MN	Class: C  Models/Code/sizes:	• FSC is copy, not legalized, could not be verified online
	Megline	55311, USA. 2. Boston Scientific Corporation, 4100	105650-025 (Model No.	and has expired  ISO certificate is copy.

		Hamline Ave N, Saint Paul, MN, USA 55112 3. Boston Scientific Corporation, No. 12, RD No. 698, Dorado, PR, USA 00646 4. Minnetronix, Inc., 1635 Energy Park, Dr. Saint Paul, MN USA 55108  • LOA Type: Copy of Notarized Notarization: Notarized Validity: 30-06-2025	Service Life: Not mentioned	Service life has not been mentioned.
	P	• FSC Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 16-08-2025	loer,	
	Meglues	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 23-03-2027	(MIS) 0.55	TAM
106.	M/s Biologic Medical Systems, 166E Annex B, Block 3, PECHS, OFF Khalid Bin Waleed Road, Karachi.	Name of Manufacturer: IntraMedical Imaging LLC, 12569 Crenshaw.  • LOA Type: Copy	Brand Name: Intramedical Node Seeker 2000 Gamma Detection System with Gamma Detection Probe  Generic Name: Gamma Detection System with	Deferred due to following deficiencies in application;  • The application has been submitted as family having system and probes
	(ELI-00346)  Date of R& I 23-06-2025  Fee: PKR 31,000/-	Notarization: Not Notarized Validity: End of 2026  • FSC	Gamma Detection Probe.  Applied as: Family  Class: B  Models/Code/sizes:	but model/codes for system and probes have not been mentioned in application. Moreover, fee of
	<b>Slip</b> # 1123562369	Not submitted.  • ISO – Certificate:	Not mentioned  Service Life: 10 Years	family is required to be deposited.  • LOA is copy and not notarized.  • Valid legalized FSC has not been submitted.

		Not submitted		• Valid Notarized
		1 (ot submitted		ISO certificate has
				not been submitted.
				• Notarized DOC has
				not been submitted.
				• Service life data has
				not been submitted.
107.	M/s Biologic Medical	Name of Manufacturer:	Brand Name:	Deferred due to
	Systems, 166E Annex B,	Ingenious Medical GmbH,	Ingenious laproscopic system	following deficiencies
	Block 3, PECHS, OFF	Berta-Ottenstein-Strasse 11,	Generic Name:	in application;
	Khalid Bin Waleed Road, Karachi.	79106 Freiburg im Breisgau,	Laproscopic system.	• LOA is copy and
	Karaciii.	Germany.	Euproscopie system:	not notarized
		1100	Applied as: System	• The system applied
	(ELI-00346)	401, 60		has not been
	(EEI-00340)	• LOA	Class: A	mentioned in FSC
	2507	<b>Type:</b> Copy		submitted. The
	Date of R& I	Notarization: Not Notarized	Models/Code/sizes:	codes of the component devices
	23-06-2025	F.O. VIO. V	Not mentioned	are required to be
	Fee: PKR 25,000/-	Validity: 31-12-2027		mentioned.
	Slip # 7958125616	2.00		• FSC submitted is
		- FSC (Supin)	Service Life: 10 Years	copy and not
	*	• FSC (Spain)		legalized.
		Type: Copy		• ISO certificate is
		Issued By: Govt. Body		copy and not notarized.
		Legalization: Not legalized		Notarized DOC has
		Issue Date: 22-06-2022		not been submitted.
	400	X7-12-124 NY-4		• Service life data has
	100.	Validity: Not mentioned		not been submitted
		• ISO – Certificate:	(6)	
		Type: Copy	11 010	
			100.6	
		<b>Notarization</b> : Not Notarized	(18), 713,	
		Validity: 28-10-2025	1011, 00	
108.	M/s Biologic Medical	Name of Manufacturer:	Brand Name:	Deferred due to
100.	Systems, 166E Annex B,		WALZ Lithotron EL 27	following deficiencies
	Block 3, PECHS, OFF	Walz Electronik GmbH,	Compact with Probe	in application;
	Khalid Bin Waleed Road,	Walddorfer Str. 40 72229		
	Karachi.	Rohrdorf, Germany.	Generic Name:	• LOA is copy and
		5 0 × 6X	Laproscopic system.	not notarized. • FSC submitted is
	Y	• LOA	A multiplication Control	• FSC submitted is copy not original.
	(ELI-00346)	Type: Copy	Applied as: System	• Three different
			Class: B	systems have been
	Date of R& I	<b>Notarization</b> : Not Notarized	Ciass. D	mentioned in FSC.
	23-06-2025	Validity: 01-01-2027	Models/Code/sizes:	The applied one is
	Fact DVD 21 000/	7	Not mentioned	required to be
	<b>Fee:</b> PKR 31,000/- <b>Slip</b> # 157404520627			specified alongwith required probes
	Sup π 13/40432002/	• FSC		with their codes.
	N	<b>Type:</b> Copy of apostilled		• ISO certificate is
		I	J	150 certificate 18

		Legalization: apostilled	Service Life: 10 Years	copy and not
		<b>Issue Date:</b> 23-04-2024		notarized.  • Service life data has
		Validity: Not mentioned.		not been submitted
		• ISO – Certificate: Type: Copy	(6)	1 Alla
		Notarization: Not Notarized	1	
		Validity: 31-03-2027	1/12 0:22	
109.	M/s Endo-Kare, 14-A,	Name of Manufacturer:	Brand Name:	Deferred due to
	Aibak Block, New Garden Town, Lahore.	Olympus Winter & Ibe	ESG-410	following deficiencies in application;
	Town, Lanoic.	GmbH, Kuehnstrabe 61 22045 Hamburg, Germany.	Generic Name:	
	(EL 1 00153)	22043 Hamburg, Germany.	Electrosurgical Generator	• LOA is copy, not original. Moreover,
	(ELI-00153)	-013/1/18b	Applied as: Single	LOA has been
	Date of R& I	• LOA Type: Copy of notarized	Class: C	issued by Olympus, Singapore.
	23-06-2025	Notarization: Notarized		• ISO certificate is
	Fee: PKR 62,000/-	Validity: 31-03-2026	Models/Code/sizes:	<ul><li>copy, not original.</li><li>Service life data has</li></ul>
	<b>Slip</b> # 38921597	<b>Valuity:</b> 31-03-2020	WA91327W	not been submitted
		FRC		
	C	• FSC Type: Original	Service Life: 3 Years	
	100	Issued By: Govt. Body		VBI.
	1601	Legalization: Legalized		1
	Mo	Issue Date: 17-07-2024	11/21	
		Validity: Not mentioned.	(6)	
		valuity: Not mentioned.	1, 10,	
		TGO GAVES A	(19)	
		• ISO – Certificate: Type: Copy of notarized	01,0	
		Notarization: Notarized		
		Validity: 25-08-2027	100	
110.	M/s Endo-Kare, 14-A,	Legal Manufacturer (as	Brand Name:	Deferred due to
110.	Aibak Block, New Garden	per FSC):	ESG-410	following deficiencies
	Town, Lahore.	Olympus Medical Systems	Generic Name:	in application;
		Corp., 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-	Electrosurgical Generator	The name of legal manufacturer
	(ELI-00153)	8507, Japan.	Applied as: Single	mentioned on FSC
	Date of R& I	9.0.		is Olympus Medical Systems
	23-06-2025	Manufacturing Sites (as	Class: B	Corp., 2951
	<b>Fee:</b> PKR 62,000/-	per FSC):	Models/Code/sizes:	Ishikawa-cho, Hachioji-shi, Tokyo
	Slip # 38921597	1. Aizu Olympus Co., Ltd.,	Multiple Models mentioned in	192-8507, Japan

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		Legalization: Legalized		• Service life and
		Issue Date: 30-06-2021		data has not been submitted.
		Validity: Not mentioned.		submitted.
112.	M/a Warrag International	• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 03-06-2027	Brand Name:	Deferred due to
112.	M/s Womas International, Saadat House, Aqsa Street,	Name of Manufacturer:	Inflation Device	Deferred due to following deficiencies
	Capital Road, Nia Miana	G-Flex Europe SPRL 20, Rue de l' Industries 1400-	Generic Name:	in application;
	Pura, Sialkot.	Nivelles-Belgium.	Inflation Device	• Justification of
	(ELI-00153)	100	Applied as: Single	applying multiple models of Inflation
	(ELI-00133)	LOA	Class: A	device in single application, is
	Date of R& I	<b>Type:</b> Copy of notarized	Class. A	required
	13-06-2025	Notarization: Notarized	Models/Code/sizes (as per tech documents and	• LOA is copy, not original.
	<b>Fee:</b> PKR 6,000/- <b>Slip</b> # 0322351243	<b>Issue Date:</b> 15-10-2018	application)	• ISO certificate is
	<b>Sup</b> # 0322331243	Validity: Not mentioned	INFL20	copy and not notarized.
	<u> </u>	Tag	INFL40	_/\
	7Ue.	• FSC Type: Original	Chalettee 2 X	
	Megr	Issued By: Federal Agency of Medicines	Shelf Life: 3 Years	
		Legalization: Legalized	16.9 0:3	
		<b>Issue Date:</b> 30-06-2021	i cho ob	
		Validity: Not mentioned.	Olis O.	
		Plo Oil bi		
		• ISO – Certificate:	10811	
		Type: Copy  Notarization: Not Notarized		
		Validity: 03-06-2027		
113.	M/s Womas International,	Name of Manufacturer:	Brand Name:	Deferred due to
	Saadat House, Aqsa Street,	G-Flex Europe SPRL 20,	Disposable Endoscopic Forceps Retrievers	following deficiencies
	Capital Road, Nia Miana Pura, Sialkot.	Rue de I' Industries 1400-		in application;  • Justification of
	_6	Nivelles-Belgium.	Generic Name: Disposable Endoscopic	applying multiple
	(ELI-00153)	LOA	Forceps & Retrievers	models of Forceps & Retrievers in
	Date of R& I	Type: Copy of notarized	Applied as: Single	single application, is required.

	12-06-2025	Notarization: Notarized	Class: B	• FSC is copy, not
	Fee: PKR 31,000/- Slip # 0413561883	Issue Date: 15-10-2018 Validity: Not mentioned	Models/Code/sizes (as per tech documents and application)	original. Moreover, models have not been mentioned in FSC.
		<ul> <li>FSC         Type: Copy of Legalized     </li> <li>Issued By: Federal Agency of Medicines</li> <li>Legalization: Legalized</li> <li>Issue Date: 25-06-2021</li> <li>Validity: Not mentioned.</li> <li>ISO – Certificate: Type: Copy</li> <li>Notarization: Not Notarized</li> <li>Validity: 03-06-2027</li> </ul>	i. Sharp Prongs:	<ul> <li>LOA is copy, not original.</li> <li>ISO certificate is copy and not notarized.</li> </ul>
114.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.	Name of Manufacturer:  G-Flex Europe SPRL 20, Rue de I' Industries 1400- Nivelles-Belgium.	Brand Name: Sensor Generic Name: Disposable Polypectomy Snares	Deferred due to following deficiencies in application;  • Justification of applying multiple
	(ELI-00153)	LOA	Applied as: Single	models of Snares in single application, is required.
	Date of R& I 12-06-2025	Type: Copy of notarized  Notarization: Notarized	Class: C	• FSC is copy, not original. Moreover,
	Fee: PKR 62,000/- Slip # 34770194250	Issue Date: 15-10-2018  Validity: Not mentioned	Models/Code/sizes (as per tech documents and application):	models have not been mentioned in FSC.  • LOA is copy, not
	D.	• FSC Type: Copy of Legalized Issued By: Federal Agency of Medicines	i. GF4532R (Asymmetrical, Rotatable, Multibraded with lateral connection) ii. GF4564R (Oval, Rotatable, Multibraided,	original.  • ISO certificate is copy and not notarized.
		Legalization: Legalized Issue Date: 25-06-2021 Validity: Not mentioned.	with lateral connection) iii. GF4580R (Oval, Rotatable, Multibraided, with lateral connection) iv. GF4300 (Hexagonal,	
	Meque.	• ISO – Certificate: Type: Copy	Multibraided) v. GF4301 (Hexagonal, Multibraided) vi. GF4406 (Oval,	

Validity: 03-06-2027  Validity: 03-06-2027  Validity: 03-06-2027  Validity: 03-06-2027  Validity: 03-06-2027  Validity: 03-06-2027  Vii. GF4406 (Coval, Multibraided, Rotatable) ix. GF460R (Coval, Multibraided, Rotatable) ix. GF4610R (Oval, Multibraided, Rotatable) ix. GF4615R (Oval, Multibraided, Rotatable) ix. GF462SR (Oval, Multibraided, Rotatable) ix. GF46710R (Round, Multibraided) ix. GF46710R (Round, Multibraided) ix. GF4616 (Oval, Multibraided) ix. GF4615 (Oval, Multibraided) ix. GF46152 (Oval,			Notarization: Not Notarized	Multibraided, No HF	
vandry: 03-06-2027  vii. GF440 (Oval, Multibraided, No HF Connection) viii. GF460R (Oval, Multibraided, Rotatable) ix. GF461R (Oval, Multibraided, Rotatable) ix. GF462SR (Oval, Multibraided, Rotatable) ixi. GF463SR (Oval, Multibraided) ixi. GF463SR (Oval, Multibraided) ixi. GF463SR (Oval, Multibraided) ixi. GF462S (Oval, Multibraided) ixi. GF463S (Oval, Mult				· · · · · · · · · · · · · · · · · · ·	
Multibraided, No HF Connection) viii. GF4606R (Oval, Multibraided, Rotatable) ix. GF4610R (Oval, Multibraided, Rotatable) xi. GF4615R (Oval, Multibraided, Rotatable) xi. GF4625R (Oval, Multibraided, Rotatable) xii. GF4708 (Oval, Multibraided, Rotatable) xii. GF4710R (Round, Multibraided, Rotatable) xiii. GF4710R (Round, Multibraided) xiii. GF4710R (Round, Multibraided) xv. GF4606 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xviii. GF4708 (Oval, Monofilament, Rotatable) xx. GF4815R (Oval, Monofilament, Rotatable) xx. GF4815R (Oval, Monofilament, Rotatable) xxiii. GF461525CR (Oval, Contbi, Monofilament, Rotatable) xxiii. GF461525CR (Oval, Multibraided) xxiii. GF461525CR (Oval, Multibraided) xxiii. GF461525CR (Oval, Multibraided) xxiii. GF46152CR (Oval, Multibraided)			<b>Validity:</b> 03-06-2027	· ·	
Connection) viii. GF4606R (Oval, Multibraided, Rotatable) ix. GF4618R (Oval, Multibraided, Rotatable) xi. GF4625R (Oval, Multibraided, Rotatable) xii. GF4625R (Oval, Multibraided, Rotatable) xii. GF4625R (Oval, Multibraided, Rotatable) xii. GF4626R (Oval, Multibraided, Rotatable) xii. GF4618R (Oval, Multibraided) xvii. GF4616 (Oval, Multibraided) xvi. GF4610 (Oval, Multibraided) xvii. GF4615 (Oval, Multibraided) xvii. GF4625R (Oval, Multibraided) xvii. GF4615R (Oval, Multibraided) xvii. GF4615C (Oval, Multibraided) xvii. GF4815SC (Oval, Multibraided) xvii. GF4815SC (Oval, Combi, Monofilament, Rotatable) xx. GF4815SC (Oval, Combi, Multibraided, Rotatable) xxii. GF4615C (Oval, Multibraided) xvii. GF4615C (Oval, Multibraided) xvii. GF4615C (Oval, Multibraided) xvii. GF4615C (Oval, Multibraided) xxii. GF4815SC (Oval, Combi, Multibraided, Rotatable) xxii. GF4615C (Oval, Multibraided)				•	
viii. GF460R (Oval, Multibraided, Rotatable) ix. GF461GR (Oval, Multibraided, Rotatable) ix. GF461GR (Oval, Multibraided, Rotatable) ix. GF461SR (Oval, Multibraided, Rotatable) ix. GF462SR (Oval, Multibraided, Rotatable) ix. GF462SR (Oval, Multibraided, Rotatable) ixi. GF460G (Oval, Multibraided, Rotatable) ixi. GF460G (Oval, Multibraided, Rotatable) ixi. GF471GR (Round, Multibraided, Rotatable) ixi. GF471GR (Round, Multibraided) ixi. GF461G (Oval, Multibraided) ixi. GF485SR (Oval, Monofilament, Rotatable) ixi. GF485SR (Oval, Monofilament, Rotatable) ixi. GF485SR (Oval, Monofilament, Rotatable) ixi. GF461G52SCR (Oval, Monofilament, Rotatable) ixi. GF461G52SCR (Oval, Monofilament, Rotatable) ixi. GF485SR (Oval, Monofilament, Rotatable) ixi. GF461G52SCR (Oval, Monofilament, Rotatable) ixi. GF485SR (Oval, Monofilament, Rotatable) ixi. GF461G52SCR (Oval, Multibraided, Rotatable) ixi. GF461G52SCR (Oval, Multibraided, Rotatable) ixi. GF461G52SCR (Oval, Multibraided, Rotatable) ixi. GF461G52SCR (Oval, Multibraided) ixi. GF485SR (Oval, Multibraided) ixi. GF485SR (Oval, Multibraided) ixi. GF485SR (Oval, Multibraided) ixi. GF465SCR (Oval, Multibraided) ixi. GF465SCR (Oval, Multibraided) ixi. GF485SR (Oval, Multibraided) ixi. GF465SCR (Oval,				1	
Multibraided, Rotatable) ix. GF4615R (Oval, Multibraided, Rotatable) xi. GF4625R (Oval, Multibraided, Rotatable) xii. GF4625R (Oval, Multibraided, Rotatable) xii. GF4625R (Oval, Multibraided, Rotatable) xii. GF4616 (Oval, Multibraided, Rotatable) xii. GF4610 (Oval, Multibraided) xvi. GF4610 (Oval, Multibraided) xvi. GF4615 (Oval, Multibraided) xvii. GF4615 (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided) xxiii. GF461525CR (Oval- Combi, Multibraided) x				,	
ix. GF4610R (Oval, Multibraided, Rotatable) x. GF461SR (Oval, Multibraided, Rotatable) xi. GF463SR (Oval, Multibraided, Rotatable) xii. GF463SR (Oval, Multibraided, Rotatable) xiii. GF463SR (Oval, Multibraided, Rotatable) xiv. GF460 (Oval, Multibraided) xv. GF460 (Oval, Multibraided) xv. GF4615 (Oval, Multibraided) xviii. GF4635					
Multibraided, Rotatable) x, GF4615R (Oval, Multibraided, Rotatable) xi, GF4635R (Oval, Multibraided, Rotatable) xii, GF4635R (Oval, Multibraided, Rotatable) xii, GF4635R (Oval, Multibraided, Rotatable) xii, GF466 (Oval, Multibraided) xvii, GF4610 (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided) xvii, GF4625R (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided) xvii, GF4625R (Oval, Multibraided) xvii, GF4635R (Oval, Monofilament, Rotatable) xxii, GF4815R (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided) xvii, GF4615 (Oval, Monofilament, Rotatable) xxii, GF4815R (Oval, Multibraided) xvii, GF4615 (Oval, Multibraided, xvii, GF46					N V
x, GF4615R (Oval, Multibraided, Rotatable) xi, GF4635R (Oval, Multibraided, Rotatable) xii, GF4635R (Oval, Multibraided, Rotatable) xiii, GF4710R (Round, Multibraided, Rotatable) xiv. GF4606 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xviii, GF4635 (Oval, Multibraided) xviii, GF46182SCR (Oval, Monofilament, Rotatable) xx. GF4825R (Oval, Monofilament, Rotatable) xxiii, GF46182SCR (Oval-Combi, Munofilament, Rotatable) xxiii, GF46182SCR (Oval-Combi, Munofilament, Rotatable) xxiii, GF46182SCR (Oval-Combi, Munofilament, Rotatable) xxiii, GF46182SCR (Oval-Combi, Multibraided, Rotatable) xxiiii, GF46182SCR (Oval-Combi, Multibraided) xviiii, GF46182SCR (Oval-Combi, Multibraided) xxiii, GF46182SCR (Oval-Combi, Multibraided) xxiiii, GF46182SCR (Oval-Combi, Multibraided) xxiiiii, GF4635 (Oval-Combi, Multibraided) xxiiii, GF46182SCR (Oval-Combi, Multibraided) xxiiii, GF46182SCR (Oval-Combi					
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Multibraided, Rotatable) xii, GF4635R (Oval, Multibraided, Rotatable) xiii, GF4710R (Round, Multibraided) xiii, GF4606 (Oval, Multibraided) xvii. GF4610 (Oval, Multibraided) xvii. GF4615 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xvii. GF4635 (Oval, Multibraided) xvii. GF4635 (Oval, Multibraided) xvii. GF4635 (Oval, Multibraided) xvii. GF4635 (Oval, Multibraided) xvii. GF4815R (Oval, Monorilament, Rotatable) xx. GF48152CR (Oval- Combi, Monorilament, Rotatable) xxi. GF48152CR (Oval- Combi, Multibraided, Rotatable) xxi. GF48152CR (Oval- Combi, Monorilament, Rotatable) xxi. GF48152CR (Oval- C			2011		
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Multibraided, Rotatable) xiii. GF4710R (Round, Multibraided) xiv. GF460 (Oval, Multibraided) xvi. GF4610 (Oval, Multibraided) xvi. GF4615 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xvii. GF4635 (Oval, Monofilament, Rotatable) xxi. GF481582CR (Oval. Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone Beltone Generic Name: Hearing Aid Applied as: Single  Manufacturing Sites: 1. GN ReSound (Malaysia) Sdn, Bld No. 5, Jalan i- Date of R& I  Models/Code/sizes (as per Models/Code/sizes (as per Models/Code/sizes (as per Models/Code/sizes (as per			11 0 210	Multibraided, Rotatable)	
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Niv. GF4616 (Oval, Multibraided)   Niv. GF4610 (Oval, Multibraided)   Niv. GF4615 (Oval, Multibraided)   Niv. GF4615 (Oval, Multibraided)   Niv. GF4625 (Oval, Multibraided)   Niv. GF4625 (Oval, Multibraided)   Niv. GF4825 (Oval, Multibraided)   Niv. GF4815R (Oval, Monofilament, Rotatable)   Niv. GF4815R (Oval, Monofilament, Rotatable)   Niv. GF481525CR (Oval-Combi, Monofilament, Rotatable)   Niv. GF481525CR (Oval-Combi, Multibraided, Rotatable)   Niv. GF481525CR (Oval-Combi, Multibraided, Rotatable)   Niv. GF461525CR (Oval-Combi, Multibraided)			V. O. O.	xiii. GF4710R (Round,	
xiv. GF4616 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xvi. GF4615 (Oval, Multibraided) xvi. GF4625 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xvii. GF4635 (Oval, Multibraided) xix. GF4815R (Oval, Multibraided) xxi. GF4815R (Oval, Monofilament, Rotatable) xxi. GF4815SCR (Oval, Monofilament, Rotatable) xxi. GF481525CR (Oval, Multibraided) xxi. GF48158 (Oval, Multibraided) xxi. GF4815R (Oval, Multib			, 2/2, 70,	Multibraided, Rotatable)	
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xv. GF4610 (Oval, Multibraided) xvi. GF4625 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xviii. GF4625 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xix. GF4815R (Oval, Monofilament, Rotatable) xx. GF4815R (Oval, Monofilament, Rotatable) xx. GF48152SCR (Oval-Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF48158 (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF48158 (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF48158 (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF48158 (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF48158 (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF4815R (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided) xxii. GF4815R (Oval, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided, Rotatable) xxii.			is to the self		
Multibraided) xvii. GF4615 (Oval, Multibraided) xviii. GF4625 (Oval, Multibraided) xviii. GF4625 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xiii. GF4815R (Oval, Monofilament, Rotatable) xx. GF4815R (Oval, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid Applied as: Single Class: B  Class: B  Class: B  Models/Code/sizes (as per  Multibraided)  xvii. GF4615 (Oval, Multibraided)  xvii. GF4635 (Oval, Multibraided)  xvii. GF4615 (Oval, Multibraided			Charles Tile		
xvi. GF4615 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xviii. GF4815R (Oval, Monofilament, Rotatable) xviii. GF4615R (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xviii. GF46152 (Oval-Combi, Multibraide			5 O/Y ~ 6X	•	
Multibraided) xvii. GF4625 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xix. GF4815R (Oval, Monofilament, Rotatable) xx. GF4825R (Oval, Monofilament, Rotatable) xxi. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided) xviii. GF481525CR (Oval- Combi, Multibraided) xviii. GF481525CR (Oval- Combi, Multibraided) xxii. GF481525CR (Oval- Combi, Multibraided) xviii. GF4815R (Oval, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided) xviii. GF4815R (Oval, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval- Combi, Multibraided, Rotatable) xxii. GF48152 (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval- Combi, Multibraided, Rotatable) xxii. GF48152 (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval- Combi, Multibraided, Rotatable) xxii. GF48158 (Oval- Combi, Multib			(0, 5)	,	
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Multibraided) xix. GF4815R (Oval, Monofilament, Rotatable) xx. GF4825R (Oval, Monofilament, Rotatable) xxi. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided) xxii. GF481525CR (Oval- Combi, Multibraided) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable) xxii. GF48152 (Oval- Combi, Multibraided, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xii. GF481525CR (Oval- Combi, Multibraided, Rotatable) xii. GF4815			702	· ·	
xix. GF4815R (Oval, Monofilament, Rotatable) xx. GF4825R (Oval, Monofilament, Rotatable) xx. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone Gon Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid Applied as: Single  Manufacturing Sites: 1. GN ReSound (Malaysia) Sdn, Bld No. 5, Jalan i- Date of R& I  Models/Code/sizes (as per  Models/Code/sizes (as per		C	O	•	
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xx. GF4825R (Oval, Monofilament, Rotatable) xxi. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Brand Name: Beltone  GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid Applied as: Single  Manufacturing Sites: 1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Date of R& I  Xx. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone Generic Name: Hearing Aid Applied as: Single Class: B  Models/Code/sizes (as per Models/Code/sizes (as per  Models/Code/sizes (as per					
Monofilament, Rotatable) xxi. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  GELI-01209)  Manufacturing Sites: 1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i Date of R& I  Monofilament, Rotatable) xxii. GF481525CR (Oval- Combi, Monofilament, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone Generic Name: Hearing Aid Applied as: Single Class: B Class: B  Models/Code/sizes (as per Models/Code/sizes (as per		100			
xxi. GF481525CR (Oval- Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Brand Name: Beltone Beltone  GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i Date of R& I  Xxii. GF481525CR (Oval- Combi, Monofilament, Rotatable)  Xiii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Brand Name: Beltone Generic Name: Hearing Aid Applied as: Single Class: B  Models/Code/sizes (as per Models/Code/sizes (as per		N			
Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Brand Name: Beltone  Generic Name: Hearing Aid Applied as: Single  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Brand Name: Beltone  Generic Name: Hearing Aid Applied as: Single Class: B  Class: B  Class: B  Models/Code/sizes (as per  Models/Code/sizes (as per			2.22		
Rotatable) xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Shelf Life: 3 Years  Legal Manufacturer: for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289- Ferozpur Road, 12-L, Gulberg, Lahore.  GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid Applied as: Single Class: B  Manufacturing Sites: 1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Roals 1/1 Konnean  Models/Code/sizes (as per  Rotatable)  Xxii. GF461525CR (Oval- Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Deferred due to following deficiencies in application;  Justification of applying multiple models two families of hearing devices in a single application since fee of Rd. 31000/-				xxi. GF481525CR (Oval-	
xxii. GF461525CR (Oval-Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Shelf Life: 3 Years  Brand Name: Beltone  GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i-Deale of R& I  Date of R& I  Axii. GF461525CR (Oval-Combi, Multibraided, Rotatable)  Brand Name: Beltone  Generic Name: Hearing Aid  Applied as: Single  Class: B  Models/Code/sizes (as per  Models/Code/sizes (as per				Combi, Monofilament,	
Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Shelf Life: 3 Years  Shelf Life: 3 Years  Brand Name: Beltone  Goneric Name: Hearing Aid  Forozpur Road, 12-L, Gulberg, Lahore.  Manufacturing Sites:  1. GN ReSound (Malaysia) Sch., Bhd No. 5, Jalan i- Date of R& I  Combi, Multibraided, Rotatable)  Brand Name: Beltone  Generic Name: Hearing Aid  Applied as: Single  Class: B  Models/Code/sizes (as per  Combi, Multibraided, Rotatable)  Deferred due to following deficiencies in application;  Following deficiencies in application;  Forozpur Name: Class: B  Models/Code/sizes (as per  Models/Code/sizes (as per			, G, 40	Rotatable)	
Combi, Multibraided, Rotatable)  Shelf Life: 3 Years  Shelf Life: 3 Years  Shelf Life: 3 Years  Shelf Life: 3 Years  Brand Name: Beltone  Goneric Name: Hearing Aid  Forozpur Road, 12-L, Gulberg, Lahore.  Manufacturing Sites:  1. GN ReSound (Malaysia) Sch., Bhd No. 5, Jalan i- Date of R& I  Combi, Multibraided, Rotatable)  Brand Name: Beltone  Generic Name: Hearing Aid  Applied as: Single  Class: B  Models/Code/sizes (as per  Combi, Multibraided, Rotatable)  Deferred due to following deficiencies in application;  Following deficiencies in application;  Forozpur Name: Class: B  Models/Code/sizes (as per  Models/Code/sizes (as per			1111 2010	xxii. GF461525CR (Oval-	
Shelf Life: 3 Years    115. M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore.   CELI-01209)    Manufacturing Sites:			1000		
Shelf Life: 3 Years    115.   M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore.   CELI-01209)    The problem of R& I   Comparison of the problem of the			VD. 011 01		
115. M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore.  (ELI-01209)  M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore.  Brand Name: Beltone  Gon Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Class: B  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i-Bode 14 Models/Code/sizes (as per Models/Code/sizes (					
115. M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore.  (ELI-01209)  M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore.  Brand Name: Beltone  Gon Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Class: B  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i-Bode 14 Models/Code/sizes (as per Models/Code/sizes (			300		
for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289- Ferozpur Road, 12-L, Gulberg, Lahore.  Manufacturing Sites:  1. GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Class: B  Models/Code/sizes (as per  Models/Code/sizes (as per			i chia Mo an	Shelf Life: 3 Years	
for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289- Ferozpur Road, 12-L, Gulberg, Lahore.  Manufacturing Sites:  1. GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Class: B  Models/Code/sizes (as per  Models/Code/sizes (as per	115.	M/s Rehabilitation Centre	Legal Manufacturer:	Brand Name:	Deferred due to
Ltd., Ghafoor Plaza, 289- Ferozpur Road, 12-L, Gulberg, Lahore.  GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Class: B  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i-Bode 14 (1) Kayawara Ballerup, Denmark.  Generic Name: Hearing Aid  Applied as: Single  Class: B  Models/Code/sizes (as per fee of Rd. 31000/-					
Ferozpur Road, 12-L, Gulberg, Lahore.    Cautrupbjerg					_
Gulberg, Lahore.    Hearing Aid   Applied as: Single   Applied as: Single   Manufacturing Sites:   1. GN ReSound (Malaysia)   Sdn, Bhd No. 5, Jalan i-   Sdn, Bhd No. 5, Jalan i-   Park   1/1   Kayasar   Models/Code/sizes (as per   Models/Code/sizes (as p				Generic Name:	
(ELI-01209)  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Date of R& I  Date of R& I  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Date of R& I  Models/Code/sizes (as per  applying multiple models two families of hearing devices in a single application since fee of Rd. 31000/-			Ballerup, Denmark.	Hearing Aid	
(ELI-01209)  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Bork 1/1 Kayasar  Models/Code/sizes (as per families of hearing devices in a single application since fee of Rd. 31000/-		Caroeig, Lanoie.	11		11.0
(ELI-01209)  Manufacturing Sites:  1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Date of R& I  Date of R& I  Models/Code/sizes (as per  families of hearing devices in a single application since fee of Rd. 31000/-			107	Applied as: Single	
1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i- Borle 1/1 Kayasar Models/Code/sizes (as per fee of Rd. 31000/-		(FL L-01200)	<b>Manufacturing Sites:</b>		_
Date of R& I  Sdn, Bhd No. 5, Jalan i- Book 1/1 Kowygon Models/Code/sizes (as per fee of Rd. 31000/-		(121.1-01.207)	1 GN ReSound (Malaysia)	Class: B	
Date of R& 1 Nowgoon Models/Code/sizes (as per Rec of Rd. 51000/		400			
			Park 1/1 Kawasan	Models/Code/sizes (as per	
FSC and application:		12-06-2025		FSC and application:	
Perindustrian i-Park 81000   • FSC is apostilled					•

	<b>Fee:</b> 31,000/-	Bandar Indahpura, Kulai,	i. Rely:	not legalized by
	Slip # 24371263844	Johor, Malaysia.	• RLY4CIC-MP	embassy
	Sip # 213/1203011	2. GN ReSound China Ltd.,	• RLY4CIC-LP	Valid notarized ISO
		No. 15, Chuang Xin Road,	• RLY4CIC-HP	certificates of
		CTP Area 361006		manufacturing
		Xiamen, China.	RLY3CIC-MP	sites, have not been
		Zianien, Cinna.	• RLY3CIC-LP	submitted.
			• RLY3CIC-HP	• Service life data is
		LOA	ii. Amaze:	required.
		Type: Original	• AMZ9CIC-MP	
			AMZ9CIC-LP	
		<b>Notarization</b> : Notarized	AMZ9CIC-HP	
		<b>Issue Date:</b> 15-10-2018	AMZ6CIC-MP	
		Validity: 19-03-2028	AMZ9CIC-LP  AMZ9CIC-LP	
			AMZ9CIC-HP	
		W. D. A.	• AMZ17CIC-MP	
		• FSC	• AMZ17CIC-LP	
		Type: Original	• AMZ17CIC-HP	
		<b>Issued By:</b> Danish Medicine		
		Agency	Service Life: 10 Years	
	Y	Legalization: Apostilled		
		<b>Validity:</b> 27-10-2026		
		<b>Validity:</b> 27-10-2020		
		707.		
		• ISO – Certificate:		
	100	Type: Original		
	1601	Notarization: Notarized		1
	Mo	Validity: 31-12-2026		
116.	M/s Meditech Supplies &	Name of Manufacturer:	Brand Name:	Deferred due to
	Solutions, Office No. 1,		1. Wallace IUI Catheters	following deficiencies
	First Floor, AKLASC	Cooper Surgical, Denmark	2. Wallace Sure-Pro & Sure-	in application;
	Commercial Plaza, Sector	(Complete address and		• The applicant has
	G-10 Markaz Islamabad.	manufacturing sites are not	3. Pipettes	submitted
		clear)	4. Origio Equipment	application forms
		1, 2, 10,	5. Sage Vitrification	for all devices in
	(ELI-00787)	10 × 21 × 10 × 2	Solutions	single application
		LOA	6. Sage 1 <sup>st</sup> Step Medium	under one R&I and
	Date of R& I	Not submitted	7. Sage Quinn's Advantage	has deposited one
	23-06-2025	5 Oly COX	Medium with HEPES	fee challan of Rs.
		(6/3)	8. Sage PVP	31,000/- for Class-
	Fee1: 31,000/-	• FSC	9. Sage PureCeption	B and another fee challan of Rs.
	Fee2: 6,000/-	Not Submitted	10. Sage Oil for Tissue Culture.	6000/- for all Class-
	<b>Slip1</b> # 049311458113 <b>Slip2</b> # 233493611871	(8)	11. Sage Human Serum	A Devices.
	<b>σπρω</b> π 255+950110/1	00.	Albumin	Separate Sevices.
		• ISO – Certificate:	12. Sage Quinn's Advantage	application for each
	700	Not submitted	Sperm Freezing Medium	device with
	100		13. Sage Quinn's Advantage	separate fee
	'Va		Fertilization Medium	alongwith required
1			1 Cranzadon Mediani	documents is

		Alodul Orectors Sistant Neber Septen	14. Sage Hyluronidase 15. Origio Biopsy Medium  Generic Name: 1. IUI Catheters 2. Ultra Catheter 3. Pipettes 4. Gas Analyzer 5. Vitrification Solutions 6. Medium 7. Medium with HEPES 8. PVP 9. PureCeption 10. Oil for Tissue Culture. 11. Human Serum Albumin 12. Sperm Freezing Medium 13. Fertilization Medium 14. Hyluronidase 15. Biopsy Medium  Applied as: Not clear  Class: Not clear  Models/Code/sizes: Not clear	required to be submitted.  The documents such as LOA, FSC, ISO Certificate, DOC, Shelf life data etc., as per relavant application form, have not been submitted.
117.	M/s FT Surgical, 916, Sagar Road, Saddar Bazar Near Post Office, Lahore.  (ELI-01015)  Date of R& I 27-05-2025  Fee: 62,000/-Slip # 382378953	Name of Manufacturer:  Aditus Medical GmbH, Kurfurstendamm 224 10719 Berlin, Germany.  LOA  Type: Copy of notarized  Notarization: Notarized  Validity: 31-12-2026  • FSC  Type: Copy of legalized	Shel Life: Not clear  Brand Name: Cemad S40  Generic Name: Standard Viscosity Bone Cement  Applied as: Single  Class: C  Models/Code/sizes (as per FSC and application: ADCEMS40  Shelf Life: 3 Years	Deferred due to following deficiencies in application;  • Fee of system is required to be deposited.  • LOA is copy, not original.  • ISO certificate is copy, not notarized.  • FSC is copy not original.
	Medhes	Issued By: Govt. Body Legalization: legalized Issue Date: 12-07-2023 Validity: Not Mentioned	Shell Bile. 3 Tellis	

		• ISO – Certificate: Type: Copy of Notarized Notarization: Notarized Validity: 21-03-2027		AN
118.	M/s Nassir Trading Company, Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp. Sindh Madrasa, Karachi.  (ELI-00511)	Name of Manufacturer:  Adria S.R.L., Via Modena, 46-40017 San Giovanni in Persiceto (BO), Italy.  LOA  Type: Copy	Brand Name: P-Drain  Generic Name: Direct Pucture Drainage Set  Applied as: Set  Class: C	Deferred due to following deficiencies in application;  • Justification of applying three types of sets in single application, is required.  • LOA is copy, not
	Date of R& I 24-06-2025 Fee: 62,000/- Slip # 14077184996	Notarization: Not Notarized Validity: 09-03-2027  • FSC Type: Copy of Apostilled Issued By: MOA Legalization: Apostilled Issue Date: 28-03-2025 Validity: Not Mentioned  • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 06-11-2026	Models/Code/sizes (as per FSC and application:  i. 14/xxxx	original and not notarized.  ISO certificate is copy, not notarized.  FSC is copy not original.
	Medue		<ul><li>34/0730</li><li>34/0830</li><li>34/0930</li></ul>	

			• 34/1030	
			• 34/1030	
			Shelf Life: 5 Years	
119.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	Name of Manufacturer:  Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.  • LOA: Type: Copy of notarized	Brand name: Exigo System Cleaner  Generic Name: Enzyme based cleaner for Veterinary Hematology Analyzer  Applied as: Kit	Deferred due to following deficiencies in application;  • The FSC has not been submitted rather a statement has been submitted stating that the product is for
	ELI-00160	Notarization: Notarized Validity: 31-12-2025	Class: A	veterinary use and there is no authority
	Date of R& I 03-06-2025	(Original in Exigo C200 File)	Code/sizes (as per DOC & Application):	in Sweden to issue FSC to Veterinary Medical devices.
	Fee: <b>6,000</b> /- Slip # 948444076	• FSC Not submitted	1504203 (Exigo System Cleaner 1.9L) 1504503 (Exigo System Cleaner 1.9L RFID)	• Justification of applying as Kit is required.
	Medines	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)	Shelf Life: 36 Months	TAN
120.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.  • LOA: Type: Copy of notarized	Brand name: Exigo EOS Reagent  Generic Name: Hematology Lytic Reagent for cell Counting  Applied as: Kit  Class: A	Deferred due to following deficiencies in application;  • The FSC has not been submitted rather a statement has been submitted stating that the
	ELI-00160	Notarization: Notarized  Validity: 31-12-2025	Code/sizes (as per DOC &	product is for veterinary use and there is no authority in Sweden to issue
	Date of R& I 03-06-2025	(Original in Exigo C200 File)	Application): 1504278 (Exigo EOS Reagent	FSC to Veterinary Medical devices.
	Fee: <b>6,000</b> /- Slip # 6695588130	• FSC	1.9L) 1504502 (Exigo EOS Reagent 1.9L RFID)	• Justification of applying as Kit is required.

		Not submitted		
		• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)	Shelf Life: 24 Months	TAM
121.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.  ELI-00160  Date of R& I 03-06-2025  Fee: 6,000/-Slip # 18816254224	Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original in Exigo C200 File)  • FSC Not submitted  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)	Brand name: Boule Vet Cal & Cont.  Generic Name: Control & Calibration Kit for  Applied as: Kit  Class: A  Code/sizes (as per DOC & Application):  • 1440184 (Boule Vet-Cal-5Diff 1x3ml  • 1440181 (Boule Vet-Con-5Diff Normal 1x3ml  • 1440182 (Boule Vet-Con-5Diff Normal 6x3ml  Shelf Life: Control 160 Days  Calibrator 70 Days  (2-10oC)	Deferred due to following deficiencies in application;  • The FSC has not been submitted rather a statement has been submitted stating that the product is for veterinary use and there is no authority in Sweden to issue FSC to Veterinary Medical devices.  • Justification of applying as Kit is required.
122.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	Name of Manufacturer:  Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.  • LOA: Type: Copy of notarized Notarization: Notarized	Brand name: Exigo H 400  Generic Name: Automatic Veterinary Hematology Analyzer  Applied as: Set  Class: A	Deferred due to following deficiencies in application;  • The FSC has not been submitted rather a statement has been submitted stating that the product is for veterinary use and

	ELI-00160	Validity: 31-12-2025		there is no authority
	Date of R& I 03-06-2025	(Original in Exigo C200 File)	Code/sizes (as per DOC & Application):  • 142000	in Sweden to issue FSC to Veterinary Medical devices.  • Justification of
	Fee: <b>6,000</b> /- Slip # 48066884	• FSC Not submitted	Service Life: Not mentioned	applying as set is required.  • Service life and data has not been
		• ISO – Certificate: Type: Copy of notarized Notarization: Notarized	1 (hei) 0:50	submitted.
		Validity: 20-05-2028 (Original in Exigo C200	10112 50 re	
		File)	losi,	
123.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.  ELI-00160  Date of R& I 03-06-2025  Fee: 6,000/-Slip # 4798512457	Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original in Exigo C200 File)  • FSC Not submitted  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)	Brand name: Exigo Diluent & Lyse Reagent  Generic Name: Automatic Veterinary Hematology Analyzer  Applied as: Kit  Class: A  Code/sizes (as per DOC & Application):  • 1504201 (Exigo Diluent 1.9L)  • 1504328 (Exigo Diluent 10L)  • 1504504 (Exigo Diluent 10L)  RFID)  • 1504202 (Exigo Lyse 1.9L)  • 1504500 (Exigo Lyse 1.9L)  Shelf Life: 36 Months	Deferred due to following deficiencies in application;  • The FSC has not been submitted rather a statement has been submitted stating that the product is for veterinary use and there is no authority in Sweden to issue FSC to Veterinary Medical devices.  • Justification of applying as Kit is required.
124.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building,	Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163	Brand name: Exigo C200 & C200 Consumables	Deferred due to following deficiencies in application;  • The FSC has not
	0 0 T th 3 5	ting of MDR (28		2 a a 2 153   327

P	Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)	Rotors)  • 1430005 (Kidney Panel, 20 Rotors)  • 1430006 (Electrolyte Panel, 20 Rotors)  • 1430008 (Preparation Panel,	
Mednes	997,	20 Rotors)  • 1430009 (Canine CRP Panel, 20 Rotors)  • 1430011 (Feline SAA Panel, 20	TAM
	Abdul Oadil	Service Life:  • 1430001 (Analyzer) (Not mentioned)  • 1430002(Comprehensive Panel, 20 Rotors)-12 Months  • 1430003 (Health check Panel, 20 Rotors)-15 Months  • 1430004 (Liver Panel, 20 Rotors)-12 Months	
Anes.	gay, lebie,	<ul> <li>1430005 (Kidney Panel, 20 Rotors)-12 Months</li> <li>1430006 (Electrolyte Panel, 20 Rotors)-12 Months</li> <li>1430008 (Preparation Panel, 20 Rotors)-12 Months</li> <li>1430009 (Canine CRP Panel, 20 Rotors)-12 Months</li> <li>1430011 (Feline SAA Panel, 20)-12 Months</li> </ul>	
M/s Martin Dow Specialties (Private)	Name of Manufacturer:	Brand name: Microlab 300	The Board approved

	Limited., 7th Floor, Nice	VitalScientific B.V., Van		the case.
	Trade Orbit Building,	Rensselaerweg 4, 6956 AV	Generic Name:	
	Block-6, PECHS, Main Shahrah-e-Faisal, Razi	Spankeren, The Netherlands.	Semi-automated chemistry analyzer	
	Shahrah-e-Faisal, Razi Road, Karachi East,		unuryzer	
	Jamshed Town.	• LOA:	Applied as: Single	
		<b>Type:</b> Copy of notarized	Class: A	1 1/2
	ELI-00160	Notarization: Notarized	.(5)	
		Validity: 16-10-2027	Code/sizes (as per Free sale	•
	Date of R& I	(Original submitted	certificate & Application):	
	02-07-2025	separately vide R&I dated 20-11-2024)	6002-310	
	Fee: <b>6,000</b> /- Slip # 3137126119	1000	Service Life: 7 Years	
	•	Type: Copy of legalized		
		Issued By: MOH	100	
		Legalization: Legalized	~	
		Validity: 08-10-2029		
		(Original submitted		
		separately vide R&I dated 20-11-2024)		
		707,		
	108	• ISO – Certificate: Type: Copy of notarized		aph
	160,	Notarization: Notarized	(6)	
	The same of the sa	Validity: 21-06-2027	زکی اللی	
		(Original submitted separately vide R&I dated 20-11-2024)	"elled o:	
126.	M/s Martin Dow	Name of Manufacturer:	Brand name:	The Board approved
	Specialties (Private)	VitalScientific B.V., Van	Selectra ProM	the case.
	Limited., 7th Floor, Nice Trade Orbit Building,	Rensselaerweg 4, 6956 AV	Generic Name:	
	Block-6, PECHS, Main	Spankeren, The Netherlands.	Automated chemistry analyzer	
	Shahrah-e-Faisal, Razi Road, Karachi East,	Clark Me	Applied as: Single	
	Jamshed Town.	• LOA:		
	V	<b>Type:</b> Copy of notarized	Class: A	
	ELI-00160	<b>Notarization</b> : Notarized		
	221 00100	Validity: 16-10-2027	Code/sizes (as per Free sale	
	Date of R& I	(Original submitted	certificate & Application):	
	02-07-2025	separately vide R&I dated 20-11-2024)	6003-404 Selectra ProM (O/ISE/PSID)	
	Fee: <b>6,000</b> /-	,	Comica Life, 7 V	
	Slip # 08342918531		Service Life: 7 Years	

128.	M/s Martin Dow	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 21-06-2027 (Original submitted separately vide R&I dated 20-11-2024) Name of Manufacturer:	Brand name:	The Board approved
	Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	VitalScientific, Zone Industrielle 61500 Sees, France.  • LOA: Type: Copy of notarized	Bilirubin Direct  Generic Name: In-vitro diagnostic reagent kit for direct bilirubin  Applied as: Kit  Class: B	the case.
	ELI-00160  Date of R& I 02-07-2025	Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)	Code/sizes (as per Free sale certificate & Application): BIDI-0500	
	Fee: <b>31,000</b> /- Slip # 953803674630	• FSC Type: Copy of legalized Issued By: CCI Legalization: Legalized Issue Date: 06-06-2024 Validity: Not mentioned (Original in another file	Shelf Life: 24 Months (2-8oC)	
129.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building,	Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees,	Brand name: Microalbumin IP Generic Name:	The Board approved the case.

	Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.  ELI-00160  Date of R& I 02-07-2025  Fee: 31,000/-	France.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)	In-vitro diagnostic reagent kit for urine albumin  Applied as: Kit  Class: B  Code/sizes (as per Free sale certificate & Application):  IMAL-M230	TAM
	Slip # 47711078871	• FSC Type: Copy of legalized Issued By: CCI Legalization: Legalized Issue Date: 06-06-2024 Validity: Not mentioned (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 27-07-2026 (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)	Shelf Life: 60 Months (2-8oC)	AM
130.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.  • LOA: Type: Copy of notarized Notarization: Notarized	Brand Name: Direct TIBC  Generic Name: In-vitro diagnostic reagent kit for serum Total Iron Binding Capacity  Applied as: Kit  Class: B	The Board approved the case.
	ELI-00160  Date of R& I 02-07-2025  Fee: 31,000/-	Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)	Class: B  Code/sizes (as per Free sale certificate & Application):  TIBC-0250	
	Slip # 2018332562			

		• FSC	Shelf Life: 24 Months (2-8oC)	
		<b>Type:</b> Copy of legalized	Shen Life. 24 Wolldis (2-80C)	
		Issued By: CCI		
		Legalization: Legalized		
		<b>Issue Date:</b> 06-06-2024		OB
		Validity: Not mentioned	(6)	(1)
		(Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)	il (Miss) 9:55	
		• ISO – Certificate: Type: Copy of notarized	Jolie, 50,52	
		Notarization: Notarized	1001,	
		Validity: 27-07-2026		
	P	(Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)		
131.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027	Brand name: HDL Cholestrol  Generic Name: In-vitro diagnostic reagent kit for HDL Cholestrol  Applied as: Kit  Class: B	The Board approved the case.
	Date of R& I 02-07-2025	(Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)	Code/sizes (as per Free sale certificate & Application): CHDL-0600	
	Fee: <b>31,000</b> /- Slip # 03852829	• FSC	Shelf Life: 24 Months (2-8oC)	
		Type: Copy of legalized		
		Issued By: CCI		
		Legalization: Legalized		
		Issue Date: 06-06-2024		
	, edne	Validity: Not mentioned (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)		
	We			

132.	M/s Martin Dow	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 27-07-2026 (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024) Name of Manufacturer:	Brand name:	The Board approved
	Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	VitalScientific, Zone Industrielle 61500 Sees, France.  • LOA: Type: Copy of notarized	LDL Cholestrol  Generic Name: In-vitro diagnostic reagent kit for LDL Cholestrol  Applied as: Kit  Class: B	the case.
	ELI-00160  Date of R& I 02-07-2025	Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)	Code/sizes (as per Free sale certificate & Application): CLDL-0250	
	Fee: <b>31,000</b> /- Slip # 43926521644	• FSC Type: Copy of legalized Issued By: CCI Legalization: Legalized	Shelf Life: 24 Months (2-8oC)	TARN
		Issue Date: 06-06-2024  Validity: Not mentioned  (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)	iper, 5052, 0:22	
	P	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 27-07-2026 (Original in another file SMI/mm/RA/205/2024		
133.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building,	dated 16-09-2024)  Name of Manufacturer:  VitalScientific, Zone Industrielle 61500 Sees,	Brand name: Magnesium XB Generic Name:	The Board approved the case.

Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.  ELI-00160  Date of R& I 02-07-2025  Fee: 31,000/-Slip # 67562479916	France.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)  • FSC	In-vitro diagnostic reagent kit for Magnesium  Applied as: Kit  Class: B  Code/sizes (as per Free sale certificate & Application):  MGXB-0250  Shelf Life: 14 Months (2-8oC)	AM AM
	Type: Copy of legalized  Issued By: CCI  Legalization: Legalized  Issue Date: 06-06-2024	loer,	
Wednes	Validity: Not mentioned (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 27-07-2026 (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)	lisher) 9:55	TAM
134. M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.	Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.  • LOA: Type: Copy of notarized	Brand name: HDL LDL Calibrator  Generic Name: Calibrator Kit for HDL or LDL IVD Reagent Kits  Applied as: Kit  Class: B	The Board approved the case.
ELI-00160  Date of R& I 02-07-2025	Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024	Code/sizes (as per Free sale certificate & Application):	
Fee: <b>31,000</b> /- Slip # 070618832436	dated 20-11-2024)	HLCA-0041	

		• FSC Type: Copy of legalized	Shelf Life: 30 Months (2-8oC)	
		Issued By: CCI		
		Legalization: Legalized		
		Issue Date: 06-06-2024		DW.
		Validity: Not mentioned		1
		(Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)	11 (MI) 9:55	
		• ISO – Certificate:  Type: Copy of notarized	1012,5052	
		Notarization: Notarized	108.	
		Validity: 27-07-2026		
	P	(Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)		
135.	M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East,	Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.	Brand name: HbA1c Enzyme Calibrator Set  Generic Name: Calibrator Kit for HbA1c IVD Reagent Kits	The Board approved the case.
	Jamshed Town.	• LOA: Type: Copy of notarized	Applied as: Kit	
		Notarization: Notarized	Class: B	
	ELI-00160	Validity: 28-07-2027	1, 10, 0,	
	Date of R & I	(Original in another file	Code/sizes (as per Free sale certificate & Application):	
	02-07-2025	SMI/mm/RA/331/2024 dated 20-11-2024)	HBAE-0043	
	Fee: <b>31,000</b> /- Slip # 6180527101	Col. Jo	Shelf Life: 15 Months (2-8oC)	
	1	• FSC Type: Copy of legalized		
		Issued By: CCI		
	Y	Legalization: Legalized		
		Issue Date: 06-06-2024		
		Validity: Not mentioned		
	i ednes	(Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)		
	N			

136.	M/s Deejhons Pharma, 185, F-Block Sabzazaar, Lahore.  ELI-00976  Date of R & I 03-07-2025  Fee: 62,000/-Slip # 5931492624  M/s Deejhons Pharma, 185, F-Block Sabzazaar, Lahore.	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 27-07-2026 (Original in another file SMI/mm/RA/205/2024 dated 16-09-2024)  Name of Manufacturer: EyeKon Medical Inc., 2451 Enterprise Rd., Clearwater, FL 33763, USA.  • LOA: Type: Original Notarization: Notarized Validity: 31-05-2027  • FSC (Verified Online) Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 15-04-2027  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-02-2026  • EC FQA – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 05-07-2020	Brand name: MDR Viscoelastics  Generic Name: Viscoelastic Fluid  Applied as: Single  Class: C  Code/sizes (as per Free sale certificate & Application):  • HPMC MD GEL MD GEL PLUS • Sodium Hyaluronate MD GEL SH  Shelf Life: Not Mentioned	Deferred due to following deficiencies in the application;  • FSC (Certficate of Exportability) submitted mentions that the product is not approved for marketing in US.  • Justification of applying two types of viscoelastic fluids in single application, is required.  • ISO certificate is copy not original.  • EC certificate submitted is copy and expired.  • Shelf life & stability studies data has not been submitted.
	ELI-00976	EyeKon Medical Inc., 2451 Enterprise Rd., Clearwater, FL 33763, USA.	Generic Name: Hyrophobic Acrylic IOL Applied as: Single	in the application;  • FSC (Certficate of Exportability) submitted mentions
	Date of R& I	• LOA:	-1	that the product is

03-07-2025	Type: Original	Class: C	not approved for
Fee: <b>62,000</b> /- Slip # 6939834385	Notarization: Notarized Validity: 31-05-2027  • FSC (Verified Online) Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 15-04-2027  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-02-2026  • EC FQA – Certificate: Type: Copy of notarized	Code/sizes (as per Free sale certificate & Application):  • MB60B-0UV  • MY60B-0UV  • MB60-P22  • MB60-P28  • MY60-P22  • MY60-P28  Shelf Life: 5 Years	marketing in US.  Justification of applying multiple models in single application, is required.  ISO certificate is copy not original.  EC certificate submitted is copy and expired.
	Notarization: Notarized Validity: 12-03-2024		
138. M/s Deejhons Pharma, 185 F-Block Sabzazaar, Lahore ELI-00976	~	Brand name: MDR PMMA  Generic Name: Posterior Chamber IOLs	Deferred due to following deficiencies in the application; • FSC (Certficate of Exportability)
Date of R & I 03-07-2025 Fee: <b>62,000</b> /- Slip # 5931492624	<ul> <li>LOA: Type: Original Notarization: Notarized Validity: 31-05-2027</li> <li>FSC (Verified Online)</li> </ul>	Applied as: Single  Class: C  Code/sizes (as per Free sale certificate & Application):  PN148-BUV	submitted mentions that the product is not approved for marketing in US.  • Justification of applying multiple models in single application, is required.
, dhe	Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 15-04-2027  • ISO – Certificate: Type: Copy of notarized	<ul> <li>P165-0UV</li> <li>P165-2UV</li> <li>P146-CUV</li> <li>P260-0UV</li> <li>P260-2UV</li> <li>P160-0UV</li> <li>P160-2UV</li> <li>TC65C-2UV</li> <li>PN55-BUV</li> <li>SJ65D-2UV</li> </ul>	<ul> <li>ISO certificate is copy not original.</li> <li>EC certificate submitted is copy and expired.</li> <li>Shelf life &amp; stability studies data has not been submitted.</li> </ul>
Medine		<ul><li>P160-2UV</li><li>TC65C-2UV</li><li>PN55-BUV</li></ul>	stability data has n

		Validity: 01-02-2026	<ul> <li>PN50A-0UV</li> <li>\$155-AUV</li> </ul>	
		• EC FQA – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 05-07-2020	<ul> <li>\$155-BUV</li> <li>\$165-BUV</li> <li>PS55-BUV</li> <li>\$N55-BUV</li> </ul> Shelf Life: Not Mentioned	TAM
139.	M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK.	Brand name: Optilite® IgE Control  Generic Name: Immuno-chemistry Control  Applied as: Single	The Board approved the case subject to verification/confirmat ion of availability of storage facility at 2-8°C before issuance of registration letter.
	Date of R & I 04-07-2025 Fee: <b>31,000</b> /- Slip # 060135723	• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)	Class: B  Code/sizes (as per Free sale certificate & Application):  NQ014.OPT  Shelf Life: 24 Months (2-8oC)	
	Medines	• FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027 (Original in Optilite Freelite	clisher) 9:55	TAM
	P	<ul> <li>• ISO – Certificate:</li> <li>Type: Copy of notarized</li> <li>Notarization: Notarized</li> </ul>	loet, le	
		Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)		
140.	M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham,	Brand name: Optilite® IgE Reagent Generic Name:	The Board approved the case subject to verification/confirmat ion of availability of

	ELI-00105  Date of R & I 04-07-2025  Fee: 31,000/- Slip # 387270884	West Midlands, B15 1QT, UK.  • LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)	Immuno-chemistry test reagent Applied as: Single Class: B  Code/sizes (as per Free sale certificate & Application):  • LK014.OPT  Shelf Life: 24 Months (2-8oC)	storage facility at 2-8°C before issuance of registration letter.
		• FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027	Shell Eller 24 Months (2-80C)	
	Mednes	(Original in Optilite Freelite Kappa Free Kit Dossier)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)	1 (MIS) 9:55	T AM
141.	M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK.	Brand name: Optilite® IgE Calibrator  Generic Name: Immuno-chemistry calibrator  Applied as: Single	The Board approved the case subject to verification/confirmat ion of availability of storage facility at 2- 8°C before issuance of registration letter.
	Date of R & I 04-07-2025 Fee: <b>31,000</b> /- Slip # 0867358976	<ul> <li>LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)</li> <li>FSC</li> </ul>	Class: B  Code/sizes (as per Free sale certificate & Application):  NC014.OPT  Shelf Life: 24 Months (2-8oC)	

	Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027 (Original in Optilite Freelite Kappa Free Kit Dossier)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)	ioer, 2025, 9:55	
M/s Labserv, House No. B 165/2, Block 3A Gulistan e-Jauhar, Scheme 36 Karachi.  ELI-00105  Date of R & I 04-07-2025  Fee: 31,000/- Slip # 216913847	The Rinding Site Group	Brand name: Optilite® Low Level IgG Kit Generic Name: Immuno-chemistry test kit Applied as: Single Class: B  Code/sizes (as per Free sale certificate & Application):  • NK004.LL.OPT  Shelf Life: 24 Months (2-8oC)	The Board approved the case subject to verification/confirmat ion of availability of storage facility at 2-8°C before issuance of registration letter.

		Notarization: Notarized		
		Validity: 10-04-2027		
		(Original in Optilite IgE		
		Reagent Dossier)		
143.	M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK.	Brand name: Optilite® Low Level Albumin Kit Generic Name: Immuno-chemistry test kit Applied as: Single	The Board approved the case subject to verification/confirmat ion of availability of storage facility at 2- 8°C before issuance of registration letter.
	Date of R & I 04-07-2025	• LOA: Type: Original	Class: B	
	Fee: <b>31,000</b> /- Slip # 57649836849	Notarization: Notarized Validity: 31-12-2025	Code/sizes (as per Free sale certificate & Application):	
	P	(Original in Optilite IgE Reagent Dossier)	• NK032.L.OPT	
	Medines	• FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027 (Original in Optilite Freelite Kappa Free Kit Dossier)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)	Shelf Life: 18 Months (2-8oC)	
144.	M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK.	Brand name: Optilite® Alpha-1-Antitrypsin Kit Generic Name: Immuno-chemistry test kit Applied as: Single	The Board approved the case subject to verification/confirmat ion of availability of storage facility at 2- 8°C before issuance of registration letter.

	Date of R & I 04-07-2025	• LOA: Type: Original	Class: B	
	Fee: <b>31,000</b> /- Slip # 1154236080	Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)	Code/sizes (as per Free sale certificate & Application):  NK034.OPT  Shelf Life: 18 Months (2-8oC)	T AM
		• FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027 (Original in Optilite Freelite Kappa Free Kit Dossier)	iper, 5052, 8:22	
	, edne	• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)		AM
145.	M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad.	Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy.	Brand name: Clarinet  Generic Name: Middle Ear Analyzer/Tympanometer	Deferred due to following deficiencies in application;  • Justification for applying two
	ELI-01125  Date of R & I 04-07-2025  Fee: 31,000/- Slip # 64967856353	<ul> <li>LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier)</li> <li>FSC</li> </ul>	Applied as: Family  Class: B  Code/sizes (as per DOC, Application & Lables):  • 10517 (Clarinet Basic)  • 10542 (Clarinet Plus)	models in single application with fee of Rs. 31,000/- is required.  • FSC is copy and not legalized.  • The models applied have not been mentioned in FSC.  • Service life studies data has not been
	Mednes	Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023	Service Life: 10 Years	submitted.

146 M/a Haaring Co	Validity: Not mentioned (Original in Audiometer Education)  • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Education)	ell (Miss)	Defermed the to
146. M/s Hearing Ca Shop No. 4, Panorama Cent Blue Area, Islan ELI-01125  Date of R & I 04-07-2025  Fee: 31,000/- Slip # 18475710	Mazzanine re, Avenue, nabad.  INVENTIS SRL, Corso S Uniti n.1/3-35127 Padova Italy.  • LOA:  Type: Copy of notarized  Notarization: Notarized  Validity: 31-12-2026	Generic Name: Audiometer/Middle Ear Analyzer  Applied as: Family  Class: B  Code/sizes (as per DOC, Application & Lables):  • 11440  Service Life: 10 Years	Deferred due to following deficiencies in application;  • Justification for applying two models in single application with fee of Rs. 31,000/- is required.  • FSC is copy and not legalized.  • The models applied have not been mentioned in FSC.  • Service life studies data has not been submitted.
147. M/s Hearing Ca Shop No. 4, Panorama Cent	Mazzanine INVENTIS SRI Corso S	Brand name: Flute Model	Deferred due to following deficiencies

	Blue Area, Islamabad.	Uniti n.1/3-35127 Padova,	Generic Name:	in application;
		Italy.	Middle Ear Analyzer/Tympanometer	• Justification for
	ELI-01125			applying three
		• LOA:	Applied as: Family	models in single application with fee
	Date of R & I	<b>Type:</b> Copy of notarized	Class: B	of Rs. 31,000/- is
	04-07-2025	Notarization: Notarized		required.
	Fee: <b>31,000</b> /-	Validity: 31-12-2026	Code/sizes (as per DOC,	• FSC is copy and not legalized.
	Slip # 91278885380	(Original in Audiometer Bell	Application & Lables):	• The models applied
		Dossier)	• 10337 (Flute Basic)	have not been
		1/0-40	• 10340 (Flute Plus)	mentioned in FSC.
		• FSC	• 10409 (Flute HF)	• Service life studies data has not been
		Type: Copy	Service Life: 10 Years	submitted.
		Issued By: MOH	100°	
		Legalization: Not legalized		
		<b>Issue Date:</b> 19-09-2023		
	D	Validity: Not mentioned		
	•	(Original in Audiometer Bell		
		Dossier)		
		103		
	_6	• ISO – Certificate:		
	100	<b>Type:</b> Copy of notarized		
	160,	Notarization: Notarized		
	Mo	Validity: 03-04-2028	1113	
		(Original in Audiometer Bell	16,7 0.5	
		Dossier)	(1) (8) (9)	
148.	M/s Hearing Care Services, Shop No. 4, Mazzanine	Name of Manufacturer:	Brand name: Harp	Deferred due to following deficiencies
	Panorama Centre, Avenue,	INVENTIS SRL, Corso Stati	0. 15	in application;
	Blue Area, Islamabad.	Uniti n.1/3-35127 Padova, Italy.	Generic Name:	• Justification for
			Audiometer	applying two
	ELI-01125	1610 10 161	Applied as: Family	models in single
		• LOA: Type: Copy of notarized	Class: B	application with fee of Rs. 31,000/- is
	Date of R & I	Notarization: Notarized		required.
	04-07-2025		Code/sizes (as per DOC,	• FSC is copy and
	Fee: <b>31,000</b> /-	Validity: 31-12-2026	Application & Lables):	<ul><li>not legalized.</li><li>The models applied</li></ul>
	Slip # 217120507	(Original in Audiometer Bell Dossier)	• 10145 (Harp Basic)	have not been
	_6	Doublet)	• 10146 (Harp Plus)	mentioned in FSC.
	700	TGG.	G	• Service life studies
	160,	• FSC Type: Copy	Service Life: 10 Years	data has not been submitted.
		<b>-</b> у <b>рс.</b> Сору		Submitted.

		Issued By: MOH		
		<b>Legalization:</b> Not legalized		
		Issue Date: 19-09-2023		
		Validity: Not mentioned		. 1
		(Original in Audiometer Bell Dossier)	,(5)	17 AM
		• ISO – Certificate:  Type: Copy of notarized	"I (Mill 9:55)	
		Notarization: Notarized	Alls O'V	
		Validity: 03-04-2028		
		(Original in Audiometer Bell Dossier)	pel,	
149.	M/s A & E Medical, 323-	Name of Manufacturer:	Brand name:	Deferred due to
	Ata Turk Block, New Garden Town, Lahore.	FIAB S.p.A., Via P, Costoli 4, 50039 Vicchio (FI), Italy.	Easypace with Accessories  Generic Name: External Cardiac Stimulator	following deficiencies in application;  • Justification for
	ELI-00023	• LOA:	Applied as: Single	applying System as single.
	Date of R & I	Type: Copy of notarized	Class: C	• LOA is copy not original.
	05-06-2025	<b>Notarization</b> : Notarized	Class. C	• FSC is copy not
	Fee: <b>62,000</b> /- Slip # 8307284031	Validity: 31-12-2025	Code/sizes (as per FSC, Application):	original. • ISO certificate has
		• FSC	4427	<ul><li>not been notarized.</li><li>Service life and</li></ul>
		<b>Type:</b> Copy of legalized	16, 9 0:5	studies data has not
		Issued By: MOH	Service Life: Not Mentioned	been submitted.
		Legalization: Legalized	lie Os	
		<b>Issue Date:</b> 19-09-2023	N. 12	
		Validity: Not mentioned	loel,	
		• ISO – Certificate: Type: Copy	. ▼	
	Y	Notarization: Not Notarized		
		Validity: 31-07-2027		
150.	M/s Maxitech Pharma	Legal Manufacturer:	Brand name:	Deferred due to
	(Pvt.) Ltd., E-178, S.I.T.E., Super Highway Phase-II,	SIFI S.p.A., Ercol Patti, 36-	Mini Well Proxa Toric	following deficiencies in application;
	Karachi.	95025 Aci S. Antonio (CT), Italy.	Generic Name: IOLs	• Justification for applying two
	Ne		Applied as: Single	different models of

	ELI-00769	Manufacturing Sites		IOLs in single
		(FSC):	Class: C	application.
	Date of R & I	1. IOLs:		Moreover, two
	27-06-2025	SIFI S.p.A., Ercol Patti, 36-	Code/sizes (as per FSC,	models have been mentioned
	Fee: <b>62,000</b> /-	95025 Aci S. Antonio (CT),	Application):	separately in FSC
	Slip # 870820486784	Italy	1121CCZ (Mini Well Proxa)	but the applicant
	Sup :: 0,0020100,0	2. Injector:	X7560CZ (Mini Well Toric)	has combined them
		•		in one brand.
		Medicel AG-Altenrhein, Switzeland.	Shelf Life: Not Mentioned	• The FSC mentions
		S WILLDIAMA.	of 1 . O.	both models as Kit comprising of
		1 0 10	, ell 05,	Injector & IOLs.
		• LOA:	Alls O'V	Clarification is
		Type: Copy	10.1	required whether
		<b>Notarization</b> : Not Notarized	011	complete Kit has
		Validity: 31-12-2025	100	been applied or otherwise.
		icio Wigi		• The ISO certificate
		• FSC		of the manufacturer
		<b>Type:</b> Copy of legalized		(Switzeland)
	•			mentioned in FSC,
		Issued By: MOH		has not been submitted.
		Legalization: Legalized		• LOA is copy and
		<b>Issue Date:</b> 10-02-2021		not notarized.
	-01	Validity: Not mentioned		• FSC is copy not
		-		original.
	1180	IGO G 400 4	.6)	• ISO certificate has
		• ISO – Certificate: Type: Copy	ركاي الله	not been notarized and has been
			16, 9 0.3	expired.
		Notarization: Not Notarized	11 10 11 3	• DOC of the product
		Validity: 12-09-2023	(18), U.S.	has not been
		90,400	1011,00	submitted.
		VO. 011 01		• Shelf life and studies data has not
		0, 10	(O),	been submitted.
151.	M/s Hanson International,	Name of Manufacturer:	Brand name:	The Board approved
	No. 57-D., Block DHA,	SIBEL HEALTH INC.,	Anne View Central Hub	the case subject to
	EME Multan Road, Lahore.	2017 N Mendell Street, Suite	System	submission of differential fee &
	Y	2SE Chicago, IL USA	Generic Name:	service/shelf life
	ELI-00773	60614.	Patient Monitor System	information.
			Applied as: System	
	Date of R & I	• LOA:	ripplied as. System	
	02-07-2025	Type: Original	Class: B	
	Fee: <b>31,000</b> /-	Notarization: Notarized	Code/sizes (as per FSC &	
	Slip # 9709851681		Application):	
	N	Validity: 28-05-2030	** /.	

152.	M/s Cor-Med, 2 <sup>nd</sup> Floor,	• FSC Type: Original Issued By: US FDA Legalization: Apostilled Validity: 09-04-2027  • ISO – Certificate: Type: Original Notarization: Notarized Validity: 01-10-2025	<ul> <li>35-019 (Anne Chest Sensor)</li> <li>17-039 (Anne Limb Sensor)</li> <li>17-009 (Anne Wireless Charger)</li> <li>35-025 (Anne Tablet with Anne View Application)</li> <li>12-095 (Anne 24-Hour Chest Adhesive)</li> <li>43-048 (Anne 7-Day Chest Adhesive)</li> <li>17-041 (Anne Limb Adhesive)</li> <li>17-041 (Wireless Charger Wall Adapter)</li> <li>17-011 (Charger for Anne Tablet)</li> <li>Service/Shelf Life: Not provided (Only adhesive's shelf life mentioned)</li> <li>Brand name:</li> </ul>	Deferred due to
	38/62, Rehman Plaza, Bank Road, Saddar, Rawalpindi. ELI-00226	Iberhopsitex S.A., Avda Cataluna, 4, 08185-LLICA DE VALL (BARCELONA),Spain.	Oper Cat Classic  Generic Name: Self-adhesive dressing Pouch for catheters	following deficiencies in application;  • LOA is copy and validity has not been mentioned.
	Date of R & I 03-07-2025 Fee: <b>25,000</b> /- Slip # 2896981017	• LOA: Type: Copy of notarized Notarization: Notarized Issue Date: Not mentioned Validity: Not mentioned  • FSC Type: Copy of legalized Issued By: Regulatory Body Legalization: Legalized Issue Date: 30-07-2024 Validity: Not mentioned.  • ISO – Certificate:	Applied as: Family Class: A  Code/sizes (as per FSC & Application):  • 0037438 (8x7.5cm) • 0037448 (16x5cm)  Shelf Life: Not provided	been mentioned.  FSC is copy not original.  ISO Certificate is copy not original.  Shelf life and data has not been submitted.

		<b>Type:</b> Copy of Notarized		
		Notarization: Notarized		
		<b>Validity:</b> 16-02-2027		
153.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e-Iqbal, Karachi.  ELI-01364  Date of R & I 02-06-2025  Fee: 62,000/-Slip # 838569842	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.  • LOA: Type: Copy of notarized Notarization: Notarized Validity: 29-08-2029  • FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023	Brand name: Xpert Lense 5.25 PMMA  Generic Name: PMMA IOL  Applied as: Single  Class: C  Code/sizes (as per DOC & Application): PCC12052CRN  Shelf Life: 5 Years	Deferred due to following deficiencies in application;  • LOA is copy not original.  • FSC is copy and not legalized.  • ISO certificate is copy and not notarized.  • Model applied has been mentioned in DOC but not mentioned in FSC.
	Medines	Validity: Not mentioned.  • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	.1(MIS) 9:55	TAN
154.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e- Iqbal, Karachi.	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.  • LOA: Type: Copy of notarized	Brand name: Xpert Lense PMMA  Generic Name: PMMA IOL  Applied as: Single  Class: C	Deferred due to following deficiencies in application;  • LOA is copy not original.  • FSC is copy and not legalized.  • ISO certificate is
	Date of R & I 02-06-2025 Fee: <b>62,000</b> /- Slip # 52651769901	Notarization: Notarized Validity: 29-08-2029  • FSC Type: Copy Issued By: MHRA Legalization: Not Legalized	Code/sizes Application): PJ313565CRO Shelf Life: 5 Years	copy and not notarized.  • Model applied has been mentioned in DOC but not mentioned in FSC.

		<b>Issue Date:</b> 13-12-2023		
		Validity: Not mentioned.		
		valuity. Not mentioned.		
		• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	MS) 5	TAN
155.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e- Iqbal, Karachi.	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.	Brand name: Mesto Hydrophobic Preloaded Lense Generic Name: Hydrophobic Preloaded IOL	Deferred due to following deficiencies in application;  • Justification for application as single, is required
	ELI-01364  Date of R & I	• LOA: Type: Copy of notarized Notarization: Notarized	Applied as: Single Class: C	<ul><li>LOA is copy not original.</li><li>FSC is copy and</li></ul>
	02-06-2025 Fee: <b>62,000</b> /-	Validity: 29-08-2029	Code/sizes (as per DOC & Application):	not legalized.  • ISO certificate is copy and not
	Slip # 52651769901	• FSC Type: Copy	FCL113060-CRA-PL Shelf Life: 5 Years	<ul><li>notarized.</li><li>Model applied has not been mentioned</li></ul>
	Medines	Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned.	(MIS) 0:55	in DOC & FSC.
		• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	olishe 5052	
156.	M/s Crown Traders, Flat No. G-01, Ground Floor, Seacon Arcade, Block-13, D/2 Scheme-42, Gulshan-e- Iqbal, Karachi.	Name of Manufacturer: Ophthalmic Experts Ltd., 50 Ripplr Road, Barking, Essex, IG11 7PG, England.	Brand name: I-Xpert IOL Generic Name: Hydrophilic Clear Foldable	Deferred due to following deficiencies in application;  • LOA is copy not original.
	ELI-01364	• LOA: Type: Copy of notarized	IOL Applied as: Single Class: C	<ul><li>FSC is copy and not legalized.</li><li>ISO certificate is</li></ul>
	Date of R & I 02-06-2025 Fee: <b>62,000</b> /-	Notarization: Notarized Validity: 29-08-2029	Code/sizes (as per FSC & Application):	copy and not notarized.
	Slip # 3205927362	ting of MDP (28	HFL1125606CRA	Daga 176   207

	1	T =0.0	T	Ţ
		• FSC Type: Copy	Shelf Life: 5 Years	
		Issued By: MHRA		
		Legalization: Not Legalized		
		<b>Issue Date:</b> 13-12-2023		DIV.
		Validity: Not mentioned.	(6)	(1)
		2.5.	in in	
		• ISO – Certificate:	16.41 0:5	
		Type: Copy Notarization: Not Notarized	i cho ob	
		Validity: 17-11-2027	10/13/00/	
157.	M/s Medco, 19-Khyber	Name of Manufacturer:	Brand name:	The Board approved
157.	Bazar, Peshawar.	Ecotron Co., Ltd., 501, 502,	Ecotron Mobile/Portable X-	the case subject to
		504, 505, 506 Ho, Hanshin	Ray System	submission of differential fee before
	ELI-00686	IT Tower, 47 Digital-ro 9-	Generic Name:	issuance of
	P	gil, Geumcheon-gu Seoul, Korea South 08511.	Portable X-Ray System	registration letter.
	Date of R & I 19-06-2025		Applied as: System	
	Fee: <b>31,000</b> /-	• LOA:	Class: C	
	Slip # 5474828092	Type: Original	Code/sizes (as per FSC &	
	Fee: <b>31,000</b> /- Slip # 08896687824	Notarization: Notarized	Application):	OB.
	1601	Validity: 14-05-2029	EPX-F5000	(1)
	W.	• FSC (Korea) Type: Original	Service Life: 10 Years	
		Issued By: National Ins. Of Medical Device Safety Info.	lighe 25.	
		Legalization: Apostilled	101. Jo.	
		Issue Date: 22-052025	eli	
		Validity: Not mentioned.	No.	
		FOC (UO)/V: #-1		
	P	• FSC (US)(Verified Online)  Type: Copy		
		Issued By: USFDA		
		Legalization: Not Legalized		
	1,08	Validity: 26-01-2027.		
	Megi			

		<ul> <li>ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027</li> <li>CE – Certificate: Type: Copy Notarization: Not Notarized Validity: 26-05-2024</li> </ul>	1.1 (MIS) 9:55	17 AM
158.	M/s MAZ International Office No. 42,43,44, Ibrahim Block, Al-Hafeez Garden Phase-I, Manawan, G.T. Road, Lahore.  (ELI-00862)  Date of R& I 16-04-2022  Fee: 5,000/-Slip # 14077184996	Name of Manufacturer: A1 Globe SDN. BHD. A1-2, Block A, Jalan Haruan 5/9, Pusat Komercial Oakland II, 70300, Seremban, Negeri Sembilan, Malaysia.  LOA  Type: Copy of Notarized  Notarization: Notarized  Validity: 24-10-2027  • FSC  Type: Copy of Legalized  Issued By: MOH  Legalization: Legalized  Issue Date: 19-06-2027	Brand Name: Handex Glove  Generic Name: Powdered Latex Examination Gloves Powder Free Latex Examination Gloves  Applied as: Single  Class: A  Models/Code/sizes Small Medium Large Extra Large  Shelf Life: 5 Years	The Board decided to call the instant applicant alongwith two other applicants for personal hearing with the direction to present following documents before the Board;  i.Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii.Copy of Receiving (R&I) of application(s) under discussion.
	Nednes	• ISO – Certificate: Type: Copy of Notarized Notarization: Notarized Validity: 26-09-2027	lost, Sorg	The Board further directed the Division of MD&MC to convey following deficiencies to the instant applicant;  • Justification of applying two types of examination gloves (Powdered & Powder Free) in single application, is required.  • Evidence of available sizes is requirted.  • Stability studies data confirms shelf

				life of 3 Years while, the applican has claimed 5 years in Form.
·				1 AM
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PSS (	17500			
esday			9:55	. N
 Sque		or (MS)		1 A.

## **Evaluator: Dr. Ghayour Ahmed, Deputy Director (DD-IV)**

S#	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
159.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred for
	Akbar Biotech, Plot No. 5- C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi	M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD 20878, USA	Medifil II Particles  Generic Name: Collagen Particles  Class-D  Shelf life: 5 Years	submission of the clarification of the brand name since the applied name is Medifil II Particles Hoever the name in the FSC is medifill Collagen based Wound care
	ELI-01304	LOA Validity:	Models/ Specification	Dressing.
	Date of R&I 26-06-2025	30-04-2027 (Copy) FSC: USA	Models/ Specification	Also submit valid and Apostilled FSC of USFDA if not submitted
	Fee Details:	Validity: 18-03-		already. Also
	Paid Fee: 62,000/-	2027(Copy)		submit ed Notasreid and
	Fee Challan No:	3,		valid LOA,
	25496997	ISO Validity:		Desigh nexamniation and
	Mediues	28-11-2027 (Copy) EU QA/ EC Certificate	(MIS) 9:55.	ISO 13485 certificaite.
160.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred for
	Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi	Inc. 940 Clopper Road,	SkinTemp II  Generic Name: Collagen Sheets  Class-D  Shelf life: 5 Years	submission of the clarification of the brand name since the applied name is SkinTemp II Hoever the name in the FSC is SkinTemp collagen based wound care
	ELI-01304	LOA Validity:	Models/ Specification	dressing
	Date of R&I 26-06-2025	30-04-2027 (Copy)		Also submit valid and Apostilled
	Fee Details:	FSC: USA Validity: 18-03-		FSC of USFDA if not submitted

	Paid Fee: 62,000/-	2027(Copy)		already. Also
	Fee Challan No:			submit ed Notasreid and
	6371025106	ISO Validity:		valid LOA,
		28-11-2027 (Copy)		Desigh
		(17)		nexamniation and ISO 13485
		ELLOA/EC Contiguoto	(6)	certificaite.
		EU QA/ EC Certificate		
			(10, 7 5.2)	
161.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred for
			Callatale Callagae Cal	submission of the clarification of the
	Akbar Biotech, Plot No. 5-	M/s Human Biosciences	Collatek Collagen Gel	brand name since
	C, Mezzanine Floor,	Inc. 940 Clopper Road,	Generic Name:	the applied name
	Bukhari Commercial, Lane	Gaithersburg, MD 20878,	Collagen Wound Dressing	is Collatek
	No. 06, Phase 06, DHA,	USA		Collagen Gel
	Karachi	12, 1, 40,	Class-D	Hoever the name
	.5	5, 10 -60,	C11C1':C 2 X/	in the FSC is
		(O, 20,	Shelf life: 3 Years	Collatek gel
	ELI-01304			Collagen based
	LLI-01304	LOA Validity:	Models/ Specification	Wound Care
	Date of R&I	30-04-2027 (Copy)		Dressing
	26-06-2025			
	1700	FSC: USA		Ola,
	Fee Details:			Also submit valid
		Validity: 18-03-		and Apostilled
	Paid Fee: 62,000/-	2027(Copy)	(M), (Q).	FSC of USFDA if not submitted
	Fee Challan No:	00,, 7	(1) 0:	already. Also
	24443048499	ISO Validity:	and and	submit ed
		28-11-2027 (Copy)	112.01	Notasreid and
			). Do	valid LOA,
				Desigh
		EU QA/ EC Certificate		nexamniation and ISO 13485
		Cha. No Cu.		certifcaite.
		S OF		
	V2.	EU QA/ EC Certificate		Clarify the
		(1)		stability studies
				for 03 years
162.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred for
				submission of the
	200		Myopore	clarificaion of the
	Global Marketing Services,	M/s GreatBatch Medical,		brand name since
	111, Hali Road, Westridge 1, Rawalpindi	2300 Berkshire Lane North, Minneapolis, MN	Generic Name:	the applied name
	1, Kawaipinui	rvorui, iviiinicapolis, iviiv	Sutureless Pacing Lead	is Myopore and

		55441 USA		name in the FSc is
		33441 05/1	Class-D	Myopore Myopore
				bipolar
	ELI-00109		Shelf life: 3 Years	Sutureless
	Date of R&I	LOA Validity:		myocardialPacing
	04-07-2025	31-12-2026 (Copy)	Models/ Specification	Lead Further the code
		( 17)	511210 (25cm), 511211	are also not
		Edd May	(35mm), 511212 (54 cm)	present in the FSC
	Fee Details:	FSC: USA	(19, 7)	clarify
	Paid Fee: 62,000/-	Validity: validity	611 9.	
	Fee Challan No: 3683919435	04.2026	112,052,	
		ISO 13485 Validity:	-5.9	
		10.12.2027	O, .	
		431 No. W.		
		EU QA/ EC Certificate		
	0.5			
		28-02-2026		
	A /	Design examination		
	60	certificate notarized		
	65	15.09.2029		
				1
163.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred for
			W// 20.	submission of the
	Nassir Trading Company,	M/s Adria s.r.1 Via	Herniatome	clarificaion of the accessories since
	Suite No. 109, 1 <sup>st</sup> Floor, Al-	Modena 46, 40017 San	Generic Name:	nema e and code
	Rehman Trade Centre,	Giovanni in Persiceto	Percutaneous Discectomy	not mentioned.
	Shahra-e-Liquat, Opp,	(BO) – Italy	Device and Accessories	Therefore, metione
	Sindh Madrassa, Karachi	Va O Ca		the name and codes of the
		Operational Headquarter	Class-D	accesoreis duly
	************************************	address:	Shelf life: 5 Years	refleted frm FSC.
	ELI-00511	Via San Francesco d'		., ,
	D'S.	Assisi 15, 46020	M-1.1-/C 'C' '	Also submit valid and Apostilled
	Date of R&I	Pegognaga (MN) – Italy	Models/ Specification	FSC of USFDA if
	24-06-2025	7,		not submitted
	<b>A</b>	9,		already. Also
	Fee Details:	LOA Validity:		submit ed
	Paid Fee: 100000/-	·		Notasreid and valid LOA,
	When checked online	09-03-2027 (Copy)		Desigh
	Fee Challan No:			nexamniation and

ISO Validity: 03.12.2024  EU QA/ EC Certificate 01-11-2028 (Copy)  164. Applicant Name:  Name of Manufacturer:  Name:  Name of Manufacturer:  Allure RF  Submiss Original	y the ty studies
ISO Validity: 03.12.2024  ISO Validity: 03.12.2024  EU QA/ EC Certificate 01-11-2028 (Copy)  164. Applicant Name:  Name of Manufacturer:  Brand name:  Deferre submis Allure RF  Origina	ty studies years y the address factuere the
EU QA/ EC Certificate 01-11-2028 (Copy)  164. Applicant Name:  Name of Manufacturer:  Name:  Name of Manufacturer:  Allure RF  Calrify of the manufa addres mentio FSC sh applied  Allure RF  Origina	actuere the
addres mention FSC sk applied  164. Applicant Name:  Name of Manufacturer:  Brand name:  Deferre submis  Allure RF  Origina	
164. Applicant Name:  Name of Manufacturer:  Brand name:  Deferre submis  Allure RF  Origina	
submis Allure RF Origina	
submis Allure RF Origina	ed for
	ssion of
Global Marketing Services, Abbott Medical 15900 Valid I	al Legalized FSC ,
111, Hali Road, Westridge Valley View Court, Generic Name: Nortize	ed LOA,
1, Rawalpindi Sylmar, California-91342, Cardiac USA Cardiac Resynchronization	
Therapy Pacemaker	
ELI-00109 Manufacturing site: Abbott Medical (Also Class-D	
Date of R&I 10-06-2025 Known as ST, Jude Medical) 15900 Valley View Court, Sylmar, Shelf life: 18 months	
California, USA Models/ Specification	
Fee Details: PM 3222	
Paid Fee: 62,000/- Abbott Medical (Also	
Fee Challan No:  Medical) Plot No. 102,	
Lebuhraya Kampung	
Jawa, Bayan Lepas, Industrial Zone, 11900	
Penang, Malaysia,	
Country, Malaysia	
Abbott Medical (Also	
know as ST Jude Medical)	
Puerto Rico, LLC Lot a Interior No. 2 RD Km	
67.5 Santana Industrial	
Park, Arecibo, PR USA	
Negline	

	1	T	T	T
		LOA Validity: 31-12-2026 (Copy)		
		FSC: USA Validity: 31-03-2027 (Copy)	(MIS)	1 Ala
		ISO Validity: 31-03-2028 (Copy)	ileher 1999	
		EU QA/ EC Certificate Validity: 14-08-2027		
165.	Applicant Name:  Global Marketing Services, 111, Hali Road, Westridge	Name of Manufacturer:  Abbott Medical 15900 Valley View Court,	Brand name: Optisure Generic Name:	Deferred for submission of the clarification of the brand name since the applied name
	1, Rawalpindi	Sylmar, California-91342, USA  Manufacturing site:	Defibrillation Leads Class-D	is Optisure  Generic Name: Defibrillation
	ELI-00109  Date of R&I 10-06-2025	Abbott Medical (Also Known as ST, Jude Medical) 15900 Valley View Court, Sylmar, California, USA	Shelf life: 3 Years  Models/ Specification	Leads and name in the FSc is Implantable Cardioveter/Defibr illator Leads.
	Fee Details: Paid Fee: 100000/- Fee Challan No: 15622816060	Abbott Medical (Also Know as ST, Jude Medical) Plot No. 102, Lebuhraya Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia, Country, Malaysia Abbott Medical (Also know as ST Jude Medical) Puerto Rico, LLC Lot a Interior No. 2 RD Km		Also submit valid and Apostilled FSC of USFDA if not submitted already. Also submit ed Notasreid and valid LOA, Desigh nexamniation and ISO 13485 certificaite.

		Park, Arecibo, PR USA		
		LOA Validity: 31-12-2026 (Copy)  FSC: USA Validity: 05-09-2026 (Copy)  ISO Validity: 31-03-2028 (Copy)	isher) 9:55:A	
		EU QA/ EC Certificate		
		Validity: 14-08-2027		
	8	DE Validity: 23-05-2029		
166.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred for
100.	Audio Medics, 13-F, Fatima Centre, 14-A Queens Road, Lahore	Cochlear Limited, 1 University Avenue, Macquarie University, NSW 2109, Australia	Cochlear  Generic Name: Hearing Prosthesis System  Class-D	submission of the clarificaion of the brand name since the applied name is Cochlear  Hearing Prosthesis System
	ELI-01011	Vo. Di. So.	Shelf life: 2 years	And name in the FSC is cochlear
	Date of R&I 02-06-2025	LOA Validity: 31-03-2027 (Copy)	Models/ Specification: CI422	nucleus C1422 cochlear implant with straight electrode
	Fee Details: Paid Fee: 62,000/-	FSC: Australia TGA		
	Fee Challan No: 31528363257	Issue Date: 08-05-2025 (Copy of embassy attested)		
	"Meo,	ISO Validity:		

		14-07-2026 (Copy)		
		EU QMS / EC Certificate Validity: 05-08-2026 notarized copy		arl
167.	Applicant Name:  Cardiac Care, 848-C, Shadman-1 Lahore-54610  ELI-00070  Date of R&I 02-06-2025  Fee Details: Paid Fee: 62,000/- Fee Challan No: 346047687	Name of Manufacturer:  On-X Life Technologies, Inc. 1300 East Anderson Lane building B Austin, TX USA  LOA Validity: 31-12-2025 (Copy)  FSC: USA Issue Date: 28-01-2027 (Copy)  ISO Validity: 29-03-2026 (Copy)  EU QA/ EC Certificate Validity: 26-05-2024  Design examination certificate Valid till 26.05.2024 extension letter given	Brand name:  ON-X conform –X Aortic Prosthetic Heart Valve  On-X Confrom-X Mitral Prosthetic Heart Valve  Generic Name: Heart Valve Aortic/Mitral  Class-D  Shelf life: 6 years  Models/ Specification: ONXACE-19 ONXACE-21 ONXACE-23 ONXACE-25 ONXACE-25 ONXACE-25/33	Deferred for submission of the submit valid and Apostilled FSC of USFDA if not submitted already. Also submit ed Notasreid and valid LOA, Desigh nexamniation certificaite
168.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain	Brand name:  Inno-Ce Mesha Intense  Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml	Deferred for submission of the clarification of the formulation in the FSC is not identical with the one mentioned Also submit valid

	ELI-00412  Date of R&I 30-05-2025  Fee Details: Paid Fee: 62,000/-1160861088	LOA Validity: 30-11-2026 (Copy)  FSC: Spain Issue date: 14-05-2024(Copy)  ISO Validity: 15-03-2027 (Copy)  EU QA/ EC Certificate	Route of administration: Intradermal injections Class-D Shelf life: 3 Years Models/ Specification	and Apostilled FSC of spain if not submitted already. Also submit ed Notasreid and valid LOA, Desigh nexamniation certifcaite
		Validity:	8,,	
169.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi  ELI-00412  Date of R&I 30-05-2025	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain  LOA Validity: 30-11-2026 (Copy)  FSC: Spain Issue date: 14-05- 2024(Copy)	Brand name:  Inno-Ce Mesha Essence  Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml  Route of administration: Intradermal injections  Class-D  Shelf life: 3 years	Deferred for submission of the clarification of the brand name since the applied name is Inno-Ce Mesha Essence and name in the FSC is MESHA® ESSENCE fuethermore the formulation in the FSC is not identical with the applied one need clarification
	Fee Details: Paid Fee: 62,000/- 3180943871	ISO Validity: 15-03-2027 (Copy) EU QA/ EC Certificate Validity:	Models/ Specification	Also submit valid and Apostilled FSC of spain if not submitted already. Also submit ed Notasreid and valid LOA, Desigh nexamniation certificaite
170.	Applicant Name:  Zam Zam Corporation, Suit No. 205, 206, Beaumont	Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona,	Brand name: Inno-Ce Bi-Dens 2.5	Deferred for submission of the clarification of the brand name since

	Plaza, 6-CL-10, Beaumont	Spain	Generic Name:	the applied name
	Road, Karachi	Spain	1 x 3ml/0.07 fl oz.	is Inno-Ce Bi-
	Koau, Karaciii		Sodium Hyaluronate 2.5%	Dens 2.5
			Socium Hyaruronate 2.570	Dens 2.5
		I O A V a1: 4:4		and name in the
	ELI-00412	LOA Validity:	Route of administration:	FSC is BI-DENS
	ELI-00412	30-11-2026 (Copy)	Intradermal injections	2.5 fuethermore
			.6)	the formulation in
	Date of R&I		Class-D	the FSC is not
	30-05-2025	FSC: Spain	(19)	identical with the
	30-03-2023	Issue date: 14-05-	Shelf life: 3 years	applied one need
		2024(Copy)	100-61	clarification
	Fee Details:			
	D:1E <2.000/	1.000 1100 110	Models/ Specification	Also submit valid
	Paid Fee: 62,000/-	ISO Validity:	5.	and Apostilled
	040092056372	15-03-2027 (Copy)	(S),	FSC of spain if
		13-03-2027 (Copy)		not submitted
		Gr W. all		already. Also
	_6	EU QA/ EC Certificate		submit ed
	0.5			Notasreid and
	No.	Validity:		valid LOA,
		<b>X</b>		Desigh
		-1 - Y		nexamniation
171	A 11 (N)		D 1	certifcaite
171.	Applicant Name:	Laboratorio SI C/ Pont	Brand name:	Deferred for
	283	Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just	D 1	submission of the
	Zam Zam Corporation, Suit	Desvern, Barcelona,	Brand name:	clarificaion of the
	No. 205, 206, Beaumont	Spain		brand name since
	Plaza, 6-CL-10, Beaumont	Spani	Inno-Ce Mesha Smile	the applied name
	Road, Karachi			is Inno-Ce Mesha
		020.	Generic Name: 1 x 1.2ml/0.04 fl oz.	Smile
		LOAN BE	Crosslinked Hyaluronic	
		LOA Validity:	Acid 20mg/ml	
	ELI-00412	30-11-2026 (Copy)	Acid 2011g/1111	and name in the
	LL1-00412	VA On On	-51	FSC is MESHA®
		1 0, 10, 10	Route of administration:	SMILE fuethermore the
	Date of R&I	FSC: Spain	Intradermal injections	fuethermore the formulation in the
	30-05-2025	Issue date: 14-05-		FSC is not
		2024(Copy)	Class-D	identical with the
	D'S.	10,1,004		applied one need
	Fee Details:	(1)	Shelf life: 3 years	clarification
	Paid Fee: 62,000/-	ISO Validity:		
		15-03-2027 (Copy)		Also submit valid
	42247277229	2027 (Copj)	Models/ Specification	and Apostilled
	-60			FSC of spain if
	05	EU QA/ EC Certificate		not submitted
				already. Also
1		Validity:		submit ed
I				Notasreid and

_	T			
				valid LOA,
				Desigh
				nexamniation
172	A 1' ANY	T 1	D 1	certifcaite
172.	Applicant Name:	Laboratorio	Brand name:	Deferred for
		Innoaesthetics SL C/ Pont		submission of the
	Zam Zam Corporation, Suit	Reixat 3, 08960, Sant Just Desvern, Barcelona,	Brand name:	clarificaion of the
	No. 205, 206, Beaumont	Spain	. (2)	brand name since
	Plaza, 6-CL-10, Beaumont	Spain	Inno-Ce Mesha Scars	the applied name
	Road, Karachi	00111		is Inno-Ce Mesha
	11000, 12010011	0.00	Generic Name:	Scars
		LOAN BY	1 x 1.2ml/0.04 fl oz.	and name in the
		LOA Validity:	Crosslinked Hyaluronic	FSC is MESHA®
	ELI-00412	30-11-2026 (Copy)	Acid 20mg/ml	SCARS fuethermore the
	ELI-00412	A. A		formulation in the
		100 00	Route of administration:	FSC is not
	Date of R&I	FSC: Spain	Intradermal injections	identical with the
	30-05-2025	Issue date: 14-05-		applied one need
	15	2024(Copy)	Class-D	clarification
	Fee Details:	N. I	Shelf life: 3 years	Also submit valid
	Paid Fee: 62,000/-	ISO Validity:		and Apostilled
		15-03-2027 (Copy)		FSC of spain if
	8174193787	(147)	Models/ Specification	not submitted
				already. Also
		EU QA/ EC Certificate		submit ed
	180	Validity:	.6) A	Notasreid and
		variaty.	-113	valid LOA,
			(19, 2:2)	Desigh nexamniation
			(1 9.	certificaite
173.	Applicant Name:	Laboratorio	Brand name:	Deferred for
173.	Applicant Name.	Innoaesthetics SL C/ Pont	Brand name.	submission of the
		Reixat 3, 08960, Sant Just	Inno-Ce Moist 1.5	clarification of the
	Zam Zam Corporation, Suit		mino-ce ivioist 1.5	brand name since
	No. 205, 206, Beaumont	Spain	Generic Name:	the applied name
	Plaza, 6-CL-10, Beaumont	10, 10, 41	1 x 1.2ml/0.04 fl oz.	is Inno-Ce Moist
	Road, Karachi	12, 1, 461,	Crosslinked Hyaluronic	1.5
		5, 10 30 C	Acid 20mg/ml	1.5
		LOA Validity:		and name in the
	•			FSC is MOIST 1.5
	ELI-00412	30-11-2026 (Copy)	Route of administration:	fuethermore the
		1	Intradermal injections	formulation in the
	2	FSC: Spain		FSC is not
	Date of R&I	_	Class-D	identical with the
	30-05-2025	Issue date: 14-05-	01 10110 2	applied one need
	1001	2024(Copy)	Shelf life: 3 years	clarification
	Ne			

	Fee Details:	ISO Validity:	Models/ Specification	Also submit valid
	Paid Fee: 62,000/-	15-03-2027 (Copy)	,	and Apostilled
	•	13-03-2027 (Copy)		FSC of spain if
	5143040484			not submitted
		EU QA/ EC Certificate		already. Also submit ed
		Validity:		Notasreid and
			(6)	valid LOA, ISO
				13485.
174.	Applicant Name:	Laboratorio	Brand name:	Deferred for
		Innoaesthetics SL C/ Pont	9.	submission of the
	Zam Zam Composition Suit	Reixat 3, 08960, Sant Just	Inno-Ce Mesha Deep	clarificaion of the
	Zam Zam Corporation, Suit No. 205, 206, Beaumont	Desvern, Barcelona, Spain	10 CO	brand name since
	Plaza, 6-CL-10, Beaumont	Spain	Generic Name: 1 x 1.2ml/0.04 fl oz.	the applied name
	Road, Karachi	Do ' O . A	Crosslinked Hyaluronic	is Inno-Ce Mesha
	,	100 70	Acid 20mg/ml	Deep and name in the
		LOA Validity:		FSC is MESHA®
	_6			DEEP
	ELI-00412	30-11-2026 (Copy)	Route of administration:	fuethermore the
	Y -	(0,19)	Intradermal injections	formulation in the
		FSC: Spain	Class	FSC is not
	Date of R&I	-	Class-D	identical with the
	30-05-2025	Issue date: 14-05- 2024(Copy)	Shelf life: 3 years	applied one need
	350	2024(Сору)	Short inc. o yours	clarification
	Fee Details:			Also submit valid
	Paid Fee: 62,000/-	ISO Validity:	Models/ Specification	and Apostilled
		15-03-2027 (Copy)	((3)	FSC of spain if not
	4082100844	(1173)	(N), (Q).	submitted already.
		00,, 1	(1) 0:3	Also submit
		EU QA/ EC Certificate	10.61	Notasreid and valid LOA, and
		Validity:	(9, 7)	ISO 13485.
175.	M/s ACP Systems	M/s Japan Lifeline Co.,	Device name:	Approved subjet to
175.	Pakistan, 13 & 23 Naval	Ltd.	- ( )	submission of the
	Fleet Club, Iqbal (S.J)	1, 01, 10 ' W	JLL EP Diagnostic Catheter	fee for family as
	Shaheed Road, Karachi –	Address: 2-2-20,	Catheter	per SRO.
	75530, Pakistan	Higashishinagawa		
	Tel: +92 21 32783726	Shinagawa-ku, Tokyo	Product Class: class D	
	101. 172 21 32/03/20	140-0002, Japan	as per DOC	
	License No: ELI-00001			
	License 140. LLI-00001	Manufacturing site		
	A	Japan Lifeline Co., Ltd.	G. 10-10	
	DRAP receiving date	Toda Factory Medical	Shelf Life: 3 years	
	29.05.2025	Technology Park, 5-22		
	Fee Rs. 62000 Slip	Minami-cho, Toda-shi,	Models as per FSC	
	No.8792893931 dt.	Saitama, 335-0025 Japan		
L		l .	I	

27.05.2025 4552M, 4552L, 5555HIS-120R, 5555M-120R, Manufacturing site 10255M-L100, 10255M-L100R, 10245M-L100R, 13445HV-R, 10256CS-Japan Lifeline Co., Ltd. 80. F5554J-120R, Oyama Factory 2399-12 F5555J-120R, F5555RV-Oaza Nobushima, Oyama-120R, F10556CSL-65HT, shi, Tochigi, 323-0152 F10444HV-120, Japan F13445HV-120R, F8552, FSC: F105527AVL, F11556CSL-95HT, Issue Date: 03/04/2025 10556BI-100, Expiry Date: will remain 10556BITS, 10556BITSvalid until drawn by the 3D. 11555BITS-R. manufacturer 11556BITS-3DR, (APOSTILLE 20156BI, 201106BI, ATTACHED) 20226BI, 202586BITS, (NOTARIZED (original) 20226BITS, PVI1015-PVI1017.5-110, 110, PVI1020-110, PV2012.5-LOA: 110, PV2015-110, PV2017.5-110, PV2020-Validity Date: 110 28/02/2025 - 27/02/2028(APOSTILLE ATTACHED) NOTARIZED (original) ISO Validity Date: 20/04/2023 to 20/04/2026 NOTARIZED (original) **EC-FQAS:** Validity Date: 25/05/2023 to 20/04/2026 (notarized)(original) DOC: Issue date: 01/04/2025 Expiry Date: N/A (Original)

176.	M/s FT Surgical, 916, Sagar	M/S Aditus Medical	Brand name:	Approved
	Road, Saddar Bazar, Near Post Office Lahore	GmbH, Kurfurstendamm 224 10719 Berlin /Germany	Cemad G40 Generic Name:	1 AM
	ELI- 01015	LOA Validity: 31-12-2026 (embassy	Standard Viscosity Bone Cement with Gentamicin	
	ELI- 01013	31-12-2026 (embassy attested)	Class-D	
	R& I dated 27-05-2025	FSC: Germany	Shelf life: 3 years	
	Fee details:	Issue date: 13-06- 2023(Copy) (Embassy	Models/ Specification	
	Amount paid: PKR 62,000	attested) Expiry NA	S	
	Paid Slip/ challan No. 66300736506	ISON-IN-		
		ISO Validity: 21-03-2027(Copy) (embassy attested)		
	10 <sup>890</sup>	EU QA/ EC/ DE		MA
	Meo.	Certificate  Validity: 24-05-2024	(1)	7,
	•	(copy) (embassy attested)	(4) 0:22	
177.	M/s Varitron, First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore,	Smith & Nephew INC, Endoscopy Division 150 Minuteman Rd, Andover,	Brand name: Biosure HA Screw	Dferred for submission of the notasried and valid
	Pakistan.	MA, USA as per fsc	Generic Name:	LOA and submit stability studies.
	ELI-00510	Legal Manufacturer: Smith & Nephew INC, Endoscopy Division 150	Interference screws	Also submit the Catalogue for
	R& I dated 26-05-2025	Minuteman Rd, Andover, MA, USA	Class-D Shelf life: 03 Years	justfciaion of the product in family under the MDR
	Fee details:	Manufacturer: Smith &		2017.
	Amount paid: PKR 100,000	Nephew INC Endoscopy 120 Forbes BLVD / 130 Forbes BLVD Mansfield,	Models/ Specification 72201771	
	Paid Slip/ challan No.	MA USA	72201772 72201773	
	705171599440	Arthrocare Corporation, B32.1, St2, Zona Franca	72201774	

	T		T	T
		Coyol, Coyol ALajuela Costa Rica	72201775	
		Costa Rica	72201776	
		Contract Manufacturer:	72201777	
		Henke-Sass Wolf, GmbH	72201778	
		Keltenstrasse 1 Tuttlingen, Baden-	72201779	
		Wurttemberg Germany	72201780	
			. 1119	
		Manufacturer: Smith & Nephew INC, Endoscopy	72201781	
		76-S Meridian Ave	72201782	
		Oklahoma City, Ok USA	72201783	
		I ON I was also	72201784	
		LOA Issue date:	72201785	
		02-06-2022 (Copy) Notarized	72201786	
		Expiry NA	72201787	
	C	91-18-01	72201788	
		FSC: USA		
	V		72201789	
		Validity: 14-05-2026 (Copy) apostille attached	72201790	
	X	(copy) aposime acaenea		
	350	MO M THE		
	400	ISO Validity:		
	160	06-03-2028 (Copy) apostille attached	(C)	7
		apostine attached	6	
			(1,9)	
		EU QA/ EC Certificate	, 70, 2	
		Validity: 02-03-2027	(8), 50,	
		(Copy) Notarized	), Un	
178.	M/s Varitron,, First Floor	VA Dis Sa	Brand name:	Dferred for
	60-D Zahoor Elahi road,	Legal Manufacturer:	D' D 1	submission of the notasried and valid
	Gulberg IV, Lahore, Pakistan.	Smith & Nephew INC, Endoscopy 150	Biosure Regenesorb Interference Screw	LOA and submit
	- milituii	Minuteman Rd, Andover,	interference Screw	stability studies.
	EL 1 00510	MA, USA	Generic Name:	Also submit the
	ELI-00510	Manufacturer: Smith &	Interference screws	Catalogue for justfciaion of the
		Nephew INC Endoscopy		product in family
	R& I dated 26-05-2025	120 Forbes BLVD / 130	72204391	under the MDR
	cò	Forbes BLVD Mansfield,	72204392	2017
	Fee details:	MA USA As per fsc	72204394	
		710 pci 180	72204395 72204397	
	Amount paid: PKR 100,000	Arthrocare Corporation,	72204397	
			I	

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	/-	B32.1, St2, Zona Franca	72204399	
	Paid Slip/ challan No.	Coyol, Coyol ALajuela	72204401	
	01172465	Costa Rica	72204402	
	011/2103		72204403	
		Contract Manufacturer:	72204404	
		Henke-Sass Wolf, GmbH	72204405	
		Keltenstrasse 1	72204406	
		Tuttlingen, Baden-	72204407	
		Wurttemberg Germany	72204408	
			72204409	
		Manufacturer: Smith &	72204410	
		Nephew INC, Endoscopy	72204411	
		76-S Meridian Ave	72204412	
		Oklahoma City, Ok USA	72204413	
		-10° 011° 011°	Class-D	
		LOA Issue date:		
		, 4/2 70 10	Shelf life: 03 Years	
		02-06-2022 (Copy)		
		(Notarized)		
	- 63	6. 10 30,	Models/ Specification	
		101160	1	
	•	FSC: USA		
		Validity: 14-05-2026		
		(Original) Apostille		
		Attached		
	20			
	-65			
		ISO Validity:		
	180	·	(6)	
		06-03-2028 (Original)		
		Notarized	(6)	
		2011	(, '() 0;	
		EU OA / EG G : G	, 70, 7	
		EU QA/ EC Certificate	(8), (15)	
		Validity: 02-03-2027	11200	
		(Original) Notrized		
170	M/o Nime Madini (D.A.		NCE America ( ac	Dformed for
179.	M/s Nipro Medical (Pvt)	M/s Goodman Co. Ltd,	NSE Asperta (coronary	Dferred for
	Ltd	5F KDX Nagoya Sakae	dilatation catheter)	submission of the
	Building No.24, Central	Building,4-5-3 Sakae	Class D	notasried and valid
	Commercial Area, DHA	Naka-ku, Nagoya, Aichi		LOA , ISO 13485,
	Phase 8, Ex-Park View,	460-0008, Japan	Shelf life 03 years	Design
	Lahore	ECC1 A (III 1	Codes	examination
		FSC japan Apostilled	APN20013	certificate
		issue date 31.08.2024	APN22513	Diffrentail fee of
	Fee 50000/-	expiry not mentioned	APN25013	the family shall be
	20		APN27513	submitted as per
	-0,5	LOA copy Issue date	APN30013	SRO.
	ACIO	11.03.2024 Copy	APN32513	
	100	ISO 13485 14.05.2027	APN35013	
	'Wa		APN40013	

180.	M/s TEK Enterprises,  Office No. MZ-9 Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore.	Legal Manufacturer: M/s Neurosafe Medical Co., Ltd., Building B, NO. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone Zhuahi, Guangdong, China	Brand name: Glutton Aspiration Catheter Generic Name: Aspiration Catheter	Deferred for Submission of apostilled and valid FSC of china
	ELI-00189	All I	5F-115	
		LOA Validity:	5F-125	
	R& I dated 29-05-2025	31-12-2026(Original) Apostille Attached	5F-132	
	Ess details	100 100	6F-105	
	Fee details: Amount paid: PKR 100,000	FSC: Spain Issue date: 18-11-2024	6F-115	
	/- Daid Clin / shallon	(Original) Notarized	6F-125	
	Paid Slip/ challan No. 147406503113	ISO Validity:	6F-115BGC	
		08-10-2025(copy)	6F-125BGC	
	650	Apostille Attached	6F-132BGC	M
	16911	EU QA/ EC Certificate	6F-115S	1 12
		Validity: 27-5-2024 (Original) Apostille	6F-125S	
		Attached	6F-132S	
		dul rection	Class-D	
		Mor Dir bon	Shelf life: 3 Years	
		CISH NEW MI	onen me. 5 Tems	
	D.S.	OBCOLLO	Models/ Specification	
181.	M/s TEK Enterprises,	Legal Manufacturer: M/s	Brand name:	Deferred for
	Office No. MZ-9 Al-Hafeez	Neurosafe Medical Co., Ltd., Building B, NO. 10, Keji 1st Rd, Hi-Tech	Dredger	Submission of apostilled and valid FSC of china
	Heights Sir Syed Road,	Industrial Development	Generic Name:	
	Gulberg, Lahore.	Zone Zhuahi, Guangdong, China	Revascularization Device	
	Ne		Class-D	

	ELI-00189	LOA Validity:		
	ELI-00107	-	Shelf life: 3 Years	
		31-12-2026(Copy) Apostille Attached		
	R& I dated 29-05-2025	FSC: Spain	Models/ Specification Dredger Revascularization Device	AN
	Fee details:	Issue date: 18-11-2024 (Copy) Notarized	RD-3-20	
	Amount paid: PKR 100,000	116	RD-3-30 RD-4-20	
	Paid Slip/ challan	ISO Validity:	RD-4-30	
	No. 8505649726	08-10-2025(Copy)	RD-4-40 RD-5-20	
		Apostille Attached	RD-5-30 RD-5-40	
		EU OA/EC Contificato	RD-6-24	
		EU QA/ EC Certificate Validity: 27-5-2024	RD-6-30 RD-6-42	
		(Copy) Apostille Attached	RD-7-30 RD-7-42	
		413	KD-7-42	
wednesday, and a secisions of 97th Meeting of MDB (28-08-2025)  Page 196   327				
ecisio	ons of 97 <sup>th</sup> Meeti	ng of MDB (28-0	8-2025) P	age 196   327

## Item No. IV: <u>DEFERRED APPLICATIONS FOR REGISTRATION/ENLISTMENT OF MEDICAL DEVICE</u> FOR IMPORT.

## (Evaluator Mr.Rana Ahsan-ul-Haq Athar, DD-VIII)

S#	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Medtronic Pakistan Private Limited	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA	Carelink TM Personal Software  MMT-7350  Class: A Shelf life: NA	Deffered for  1.Submission of original, legalized and valid FSC, ISO 13485:2016, LoA.  2.Clarification of Insuline pumps, BG meters and CGM system (alongwith manufacturers name) for which Carelink  Personal Software  MMT-7350 will be used.  3.Submit product broucher/catalogue.
2.	M/s Medtronic Pakistan	Manufacturer:	Carelink TM System	Deffered for
	Private Limited	Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA	(Software)  MMT- 7333	1.Submission of original, legalized and valid FSC, ISO 13485:2016, LoA.
		Os in	Class:A	2.Clarification of
	Anes.	sister Negten	Shelf life: NA	Insuline pumps, BG meters and CGM system (alongwith manufacturers name) for which Carelink TM Personal Software MMT-7333 will be used.  3.Submit product
	Medi			broucher/catalogue

3.	M/s Medtronic Pakistan Private Limited	Legal Manufacturer: MEDTRONIC INC 710 Medtronic Pkwy Minneapolis MN USA 55432  Manufacturing facilities: MEDTRONIC PERFUSIONS SYSTEMS 7611 Northland Dr Minneapolis MN USA 55428	HMS Plus Instrument 30514, 30515, 30517, 30518, 30522, 30524, 30526, 30527, 30528 Shelf life:3 years Class: B	Approved subject to submission of  1. Prescribed Form 7A.  2. Fee for family of class B medical Devices as per revised SRO.
4.	M/s Medtronic Pakistan Private Limited	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com +1 763 514 4000 Manufacturing site: Contract Manufacturer  DONATELLE, 501 Country Rd, E-2 Extension, New Brington, MN USA55112	Medtronic Slitter  Adjustable Slitter 6232ADJ Universal Slitter II 6230UNI  Shelf life: 2 years  Class: D	Defrred for submission of (last oppotunity);  1. Form 7A.  2. original notarized, legal and valid FSC, ISO 13485:2016, FQA, Design Examination, EPSP and stability studies.  3. clarification that Adjustable Slitter and Universal slitter are one product or two different
5.	Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I. Chundrigar Road, Karachi.  (ELI-00004) 4638 30-06-2022	Legal Manufacturer:  Zimmer Trabecular Metal Technology inc.  10 Pomeroy Road, Parsippany, New Jersey 07054 USA.  FSC US FDA validity 04-03-2022	Trabecular Metal Acetabular Revision System (Hip implants, Trabecular Metal Acetabular Augment)  Class-C  Shelf life: 5 years	Deffered the case for (as last opportunity for);  1. Legalized valid FSC.  2. Correction of the applied name of the medical device.  3. submission of the Form 7A as per corrected name.

		dif	Codes to be registered are following.	<ul><li>4. submission of copy of Fee Challan.</li><li>5. Submission of separate application for Butters and Restrictors.</li></ul>
6.	Ali Gohar & Company (Pvt) Ltd  State Life Building 1-B, I.I Chundrigarh Road, Karachi  Eli-00004 1557-C 13-03-2023	Legal Manufacturer: Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343- 8801.  FSC USFDA Valid till 14-04-2023	Zimmer A.T.S 2200TS Tourniquet System (Automatic tourniquet system)  Class-C  Shelf life: 5 years  Codes as per FSC	Derrered the case for submission of (as last opportunity);  1.Original, notarized, legalized documents including LOA, valid FSC, ISO 13485 and FQA certificates.  2. Separate application for cuffs.
7.	Ali Gohar & Company (Pvt) Ltd  State Life Building 1-B, I.I Chundrigarh Road, Karachi  Eli-00004 1558-C 13-03-2023	Legal Manufacturer:  Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343- 8801.  FSC USFDA Valid till 14-04-2023	Zimmer Dermatome Skin Grafting System  (Dermatome Skin Grafting System)  Class-C  Shelf life: 5 years  Codes as per FSC	Deffered the case for submission of (last opportunity);  1. Legalized valid FSC.  2. correct of name as per Brochure.  3. name of compnents as per brochure.  4. Revised Form 7A as per corrected name.  5. copy of fee challan (for verification of fee as system).  6. Original and valid duments

8.	Ali Gohar & Company (Pvt) Ltd State Life Building 1-B, I.I Chundrigarh Road, Karachi	Legal Manufacturer:  Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343- 8801.	Zimmer Mesh Graft II Expansion System (Mesh Graft II Expansion System)	Deffered the case for submission of (last opportunity);  1. legalized valid FSC.  2. product name and
	Eli-00004 1558-C 13-03-2023	FSC USFDA Valid till 14-04-2023	Shelf life: 5 years	compnents as per submitted brochure. <b>3.</b> Form 7A as per correct name.
		Abdul Direct	Codes as per FSC: Meshgraft II Tissue Expansion System Complete	<ul><li>4. Product label.</li><li>5. copy of fee challan (for verication as fee for</li></ul>
	P	SSIOIR SERIES	(00219500000)  Meshgraft II Dermatome with Rachet	system).
	dhes	gay,	(00219500100) Graft II Autoclave Case (00219500600)	7 AM
	Ne		(19)	
9.	Hakimsons (PVt) Ltd, Hakimsons House, A- 58/B S.i.t.E,Manghopir Road, Karachi (ELI-00396	Atrasorb IndustriA De Products Hospitalares Ltda, Avenida Piracicaba, 351, Vila Nova Sao Roque/SP- Brazil	Atrasorb Soda Lime Soda Lime	Deferred for clarification that;  1. FSC issued by Brazilian Medical Device Manufacturer Association and SNS Servico Nacional de Saude instead of Health Regulatory Authority of RRA.  2. both FSC were not valid at the time of submission.
	Medines			<ul><li>3. Name of product not as per FSC.</li><li>4. /Submission of valid legalized FSC,</li></ul>

				and Notrized ISO13485, DoC, LOA etc.
10.	M/s F Y Diagnostics & Surgicals  Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi  (ELI-00323)  Date of R&I: 01-04-2024  Fee Challan No.: 3208379373  PKR: 25000/- Dated: 23-02-2024	Manufacturing site:  M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.  ISO 13485 certificate validity: 25-03-2024	MD group: Cluster	Approved subject to submission of fee as cluster.
	Ne		Monoclonal Primary	

Antibod 258R-14, 258R-15, 258R-16, 258R-18 Glial Fibrillary Acidic Protein (GFAP) (SP78) Rabbit Monoclonal Antibody 258R-24, 258R-25, 258R-26, 258R-28 Glucagon (EP74) Rabbit Monoclonal Primary Antibody 259R-14, 259R-15, 259R-16, 259R-18 Glucagon Rabbit Polyclonal Antibod 259A-14, 259A-15, 259A-16, 259A-18 IDH-1 R132H (MRQ-67) Rabbit Monoclonal Antibody 456R-34, 456R-35, 456R-36, 456R-38 INSM1 (MRQ-70) Rabbit Monoclonal Antibody 475R-94, 475R-95, 475R-96, 475R-98 Islet-1 (EP283) Rabbit Monoclonal Primary Antibody 431R-14, 431R-15, 431R-16, 431R-18 Neurofilament (2F11) Mouse Monoclonal Antibody 302M-14, 302M-15, 302M-16, 302M-18 Neurofilament (EP79) Rabbit Monoclonal Primary Antibody 302R-14, 302R-15, 302R-16, 302R-18

NSE (MRQ-55) Mouse Monoclonal Antibody 306M-24, 306M-25, 306M-26, 306M-28 Olig2 (211F1.1) Mouse Monoclonal Antibody 387M-14, 387M-15, 387M-16, 387M-18 Olig2 (EP112) Rabbit **Monoclonal Primary** Antibody 387R-14, 387R-15, 387R-16, 387R-18 Parathyroid Hormone (PTH) (MRQ-31) Mouse Monoclonal Antibody 310M-24, 310M-25, 310M-26, 310M-28 PGP 9.5 Rabbit Polyclonal Antibody 318A-14, 318A-15, 318A-16, 318A-18 PHOX2B (EP312) Rabbit Monoclonal Primary Antibody 422R-14, 422R-15, 422R-16, 422R-18 SF-1 (EP434) Rabbit **Monoclonal Primary** Antibody 462R-14, 462R-15, 462R-16, 462R-18 Somatostatin (EP130) Rabbit Monoclonal Primary Antibody 332R-14, 332R-15, 332R-16, 332R-18 Somatostatin Receptor 2a (EP149) Rabbit Monoclonal **Primary Antibody** 486R-14, 486R-15, 486R-

			STAT6 (EP325) Rabbit Monoclonal Primary Antibody	
	. Tednes	Abdul Director	426R-14, 426R-15, 426R-16, 426R-18  Synaptophysin (EP158) Rabbit Monoclonal Primary Antibody 336R-14, 336R-15, 336R-16, 336R-18  Synaptophysin (MRQ-40) Rabbit Monoclonal Antibod 336R-94, 336R-95, 336R-96, 336R-98  Synaptophysin Rabbit Polyclonal Antibody 336A-74, 336A-75, 336A-76, 336A-78  Tyrosine Hydroxylase (LNC1) Mouse Monoclonal Antibod 490M-14, 490M-15, 490M-16, 490M-18	AM
S A 2 2 S S K K T T T T T T T T T T T T T T T T	M/s F Y Diagnostics & Surgicals  Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi  (ELI-00323)  Date of R&I: 08-08-2024  Fee Challan No.: 77727461  PKR: 25000/- Dated: 12-07-2024	Manufacturing site:  M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.  ISO 13485 certificate validity: 25-03-2024	Viral Infection Markers (Immunohistochemistry)  MD group: Cluster Class B  LOA validity: 31-12-2025 Shelf Life: 03 years  Codes: Adeno virus (20/11 & 2/6) Mouse Monoclonal Antibody 212M-14, 212M-15, 212M-16, 212M-18  Epstein-Barr Virus (CS1-4)	Approved subject to submission of fee as cluster.

			Mouse Monoclonal	
			Antibody 245M-14, 245M-15, 245M-16, 245M-18	
			13, 243141-10, 243141-10	
		)/ <sub>1</sub>	Epstein-Barr Virus (MRQ-47) Rabbit Monoclonal Antibody 245R-14, 245R-15, 245R-16, 245R-18	TAM
		Abdul Qaoio	Herpes Simplex Virus I (10A3) Mouse Monoclonal Antibody 361M-14, 361M-15, 361M-16, 361M-18	
	P	sistall New Septen	Herpes Simplex Virus I Rabbit Polyclonal Antibody 361A-14, 361A-15, 361A- 16, 361A-18	
	Medines	day	Herpes Simplex Virus II Rabbit Polyclonal Brief Description Viral infection markers are used to diagnose and monitor viral infections Remarks Antibody 362A-74, 362A- 75, 362A-76, 362A-78	TAM
		Modul Cirecto	Parvovirus B19 (R92F6) Mouse Monoclonal Antibody 218M-14, 218M- 15, 218M-16, 218M-18	
	P	sister Noter	Varicella Zoster Virus (SG-1, SG1-SG4, NCP-1 & IE-62) Mouse Monoclonal Antibody 364M-14, 364M-15, 364M-16, 364M-18	
12.	M/s F Y Diagnostics & Surgicals	Manufacturing site: M/s CELL MARQUE	Mesothelioma Markers (Immunohistochemistry)	Approved subject to submission of fee as cluster
	Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal,	CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA	MD group: Cluster	ciusiei

Karachi	95677.	Class B	
(ELI-00323)		LOA validity:	
Date of R&I:	ISO 13485 certificate	31-12-2025	
01-04-2024	validity: 25-03-2024	Shelf Life: 03 years	1/2
Fee Challan No.:			Alla
3860649777		Codes:	
PKR: 25000/-	244	Calretinin (SP13) Rabbit	•
Dated: 23-02-2024	odul crecto	Monoclonal Antibody 232R-14, 232R-15, 232R- 16, 232R18	
	sistant Neber	Cytokeratin 5 & 6 (D5 & 16B4) Mouse Monoclonal Antibody 356M-14, 356M-15, 356M-16, 356M-18	
P	997, 128x	Cytokeratin 5 & 6 (EP24 & EP67) Rabbit Monoclonal Primary Antibody 356R-14, 356R-15, 356R-16, 356R18	
Meque	Qadir	Cytokeratin 5 (EP1601Y) + Cytokeratin 14 (LL002) Mouse & Rabbit Monoclonal Antibody 905H-08	17 AM
	World Ditecto	HBME-1 (HBME-1) Mouse Monoclonal Antibody 283M-14, 283M-15, 283M- 16, 283M-18	
P	sign Septer	HBME-1 (HBME-1) Mouse Monoclonal Antibody 283M-14, 283M-15, 283M- 16, 283M-18	
Medines	gay,	Thrombomodulin (1009) Mouse Monoclonal Antibody 339M-14, 339M- 15, 339M-16, 339M-18	

13.	M/c F V Diagnostics &	Manufacturing site:	Cancer Markers	Approved subject to
13.	M/s F Y Diagnostics & Surgicals	_	(Immunohistochemistry)	submission of fee as
	Anum Blessing, Suite#	M/s CELL MARQUE CORP 6600 SIERRA	, , , , , , , , , , , , , , , , , , , ,	cluster.
	203, Near Duty Free Shop, BL7/8, K.C.H.S.U,		MD group: Cluster	
	Shahrah-e-Faisal,	95677.	Class B	
	Karachi		LOA validity:	
	(ELI-00323)	ISO 13485 certificate	31-12-2025	
	Date of R&I:	validity: 25-03-2024	Shelf Life: 03 years	
	08-08-2024	, Q'a , a	in horas	
	Fee Challan No.:	Aul Colo	Codes:	
	3860649777	" Population	Androgen Receptors	
	PKR: 25000/-	W. A. W. Y.	(EP120) Rabbit Monoclonal	
	Dated: 12-07-2024	431, 1184	Antibody 200R-24, 200R-	
		cis 12 1, 16,	25, 200R-26, 200R-28	
	0.5	5 0 0		
	Y	0,15	Androgen Receptors	
			(SP107) Rabbit Monoclonal Antibody 200R-14, 200R-	
		. 21	15, 200R-16, 200R-18	
		900		
	0		Beta-Catenin (14) Mouse	
	18011		Monoclonal Antibody	1
	No		224M-14, 224M-15, 224M-	
		772	15, 224M-18	
		201	31, 91, 9.	
		1/02/20	Hepatocyte Specific Antigen (Hep-Par1)	
		40, 60	(EP265) Rabbit Monoclonal	
		Vo. Oli Ol	Antibody 264R-14, 264R-	
		100,10	15, 264R-16, 264R-18	
		'Say No. 30		
		SIS B OIL	Hepatocyte Specific	
	D	5 OIL COX	Antigen (Hep-Par1) (OCH1E5) Rabbit	
		513	Monoclonal Antibody	
			264M-94, 264M-95, 264M-	
		2037	96, 264M-98	
	7400		p27 kip1 (SX53G8) Mouse	
	~16 <sub>O</sub> ,		Monoclonal Brief Description The cancer	
			Description The Calicei	

			market encompasses the global industry focused on the diagnosis, treatment, and management of cancer Remarks Antibody 427M-98, 427M-96, 427M-95, 427M-94	T AN
14.	M/s F Y Diagnostics & Surgicals  Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi	Manufacturing site:  M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.	Undifferentiated Tumor Marker (Immunohistochemistry)  MD group: Cluster Class B	Approved subject to submission of fee as cluster.
	(ELI-00323) Date of R&I:	ISO 13485 certificate	LOA validity: 31-12-2025	
	08-08-2024	validity: 25-03-2024	Shelf Life: 03 years	
	Fee Challan No.:	6,13	Shell Elic. 03 years	
	248268717588		Codes:	
	PKR: 25000/-	907.	CD99 (EPR3097Y) Rabbit	
	Dated: 12-07-2024		Monoclonal Antibody 199R-14, 199R-15, 199R- 16, 199R-18	TAM
		odul Ordin	Cytokeratin Cocktail (AE1 & AE3) Mouse Monoclonal Antibody 313M-14, 313M-15, 313M-16, 313M-18	
		sistant Nebren	Galectin-3 (9C4) Mouse Monoclonal Antibody 255M-14, 255M-15, 255M- 16, 255M-18	
		997,	Vimentin (EP21) Rabbit Monoclonal Antibody 347R-24, 347R-25, 347R- 26, 347R-28	
	Medine		Vimentin (V9) Mouse Monoclonal Antibody	

			347M-14, 347M-15, 347M- 16, 347M-18	
15.	M/s F Y Diagnostics & Surgicals Anum Blessing, Suite#	Manufacturing site:  M/s CELL MARQUE CORP 6600 SIERRA	Undifferentiated Tumor Marker (Immunohistochemistry)	Approved subject to submission of fee as cluster.
	203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi	COLLEGE BLVD ROCKLIN, CA USA 95677.	MD group: Cluster Class B	
	(ELI-00323)	ISO 13485 certificate	LOA validity:	
	Date of R&I:	validity: 25-03-2024	31-12-2025	
	08-08-2024	bo'O'. b.	Shelf Life: 03 years	
	Fee Challan No.:	13/1/16p	100	
	248268717588	cision In the	Codes:	
	PKR: 25000/-	50000	CD99 (EPR3097Y) Rabbit	
	Dated: 12-07-2024	673	Monoclonal Antibody 199R-14, 199R-15, 199R- 16, 199R-18	
	Mednes	993	Cytokeratin Cocktail (AE1 & AE3) Mouse Monoclonal Antibody 313M-14, 313M-15, 313M-16, 313M-18	17 AM
		Plogni O'sou	Galectin-3 (9C4) Mouse Monoclonal Antibody 255M-14, 255M-15, 255M- 16, 255M-18	
	P	sistant Web ten	Vimentin (EP21) Rabbit Monoclonal Antibody 347R-24, 347R-25, 347R- 26, 347R-28	
	dne.	gay,	Vimentin (V9) Mouse Monoclonal Antibody 347M-14, 347M-15, 347M- 16, 347M-18	
16.	M/s F Y Diagnostics &	Manufacturing site:	Hematolymphoid Marker	Approved subject to

Surgicals	M/s CELL MARQUE	(Immunohistochemistry)	submission of fee as
Anum Blessing, Suite#	CORP 6600 SIERRA COLLEGE BLVD		cluster.
203, Near Duty Free	ROCKLIN, CA USA	MD group: Cluster	
Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal,	95677.	Class B	
Karachi		LOA validity:	
(ELI-00323)	ISO 13485 certificate	31-12-2025	$\langle 1 \rangle$
Date of R&I:	validity: 25-03-2024	Shelf Life: 03 years	
01-04-2024	COLL	Shell Elic. 03 years	
Fee Challan No.:	, Q. *o	Codes:	
62799881	AUI CCL		
PKR: 25000/-	MO OIL	A-1 Antitrypsin Rabbit Polyclonal Antibody 223A-	
Dated: 23-02-2024	1,01,00	14, 223A-15, 223A-16,	
Butod. 23 02 2024	431,1164	223A18	
	cis B ster		
D	5"OIY COY	ALK Protein (ALK-1)	
	6,19	Mouse Monoclonal Antibody 204M-14, 204M-	
		15, 204M-16, 204M-18	
	107,		
		Annexin A1 (MRQ-3)	
108		Mouse Monoclonal	DIA.
180"		Antibody 221M-14, 221M-15, 221M-16, 221M-18	$\langle 1 \rangle$
		13, 22111-10, 22111-10	
		Por a standard	
	Que d	BCL2 (124) Mouse Monoclonal Antibody	
		226M-94, 226M-95, 226M-	
	" Moralison	96, 226M-98	
	br "O. b.	- oli	
	100	BCL2 (E17) Rabbit	
	1910 W 101	Monoclonal Primary	
	55, NO - 60,	Antibody 226R-14, 226R-15, 226R-16, 226R18	
	, (O, 20,		
		BCL2 (SP66) Rabbit	
	di	Monoclonal Antibody	
	9.0-2	226R-24, 226R-25, 226R-	
		26, 226R28	
Ne		BCL6 (EP278) Rabbit	

	Monoclonal Primary Antibody 227R-24, 227R- 25, 227R-26, 227R28
	BCL6 (GI191E/A8) Mouse Monoclonal Antibody 227M-94, 227M-95, 227M- 96, 227M-98
Abdul Ozoro	BOB.1 (SP92) Rabbit Monoclonal Antibody 294R-14, 294R-15, 294R- 16, 294-18
Asistan Weber	CD10 (56C6) Mouse Monoclonal Antibody 110M-14, 110M-15, 110M- 16, 110M-18
odne dell'	CD103 (EP206) Rabbit Monoclonal Primary Antibody 437R-14, 437R- 15, 437R-16, 437R- 18
Mee	CD11c (5D11) Mouse Monoclonal Antibody 111M-14, 111M-15, 111M- 16, 111M-18
About Director	CD123 (6H6) Mouse Monoclonal Antibody 198M-14, 198M-15, 198M- 16, 198M-18
Hay Old Seb	CD13 (EP117) Rabbit Monoclonal Primary Antibody 113R-24, 113R- 25, 113R-26, 113R28
18dhes	CD13 (SP187) Rabbit Monoclonal Antibody 113R-14, 113R-15, 113R-

<u></u>	<del>,</del>
	16, 113R18
	CD138 (EP201) Rabbit Monoclonal Primary Antibody 138R-24, 138R- 25, 138R-26, 138R28
dul Gadir	CD138/syndecan-1 (B-A38) Mouse Monoclonal Antibody 138M-14, 138M- 15, 138M-16, 138M-18
Abe Dir Pi	CD14 (EPR3653) Rabbit Monoclonal Primary Antibody 114R-14, 114R- 15, 114R-16, 114R18
997,	CD15 (MMA) Mouse Monoclonal Antibody 115M-14, 115M-15, 115M- 16, 115M-18
Medine	CD16 (SP175) Rabbit Monoclonal Antibody 116R-14, 116R-15, 116R- 16, 116R18
Apqui Directo	CD163 (MRQ-26) Mouse Monoclonal Antibody 163M-14, 163M-15, 163M- 16, 163M-18
Asiste Wester	CD19 (EP169) Rabbit Monoclonal Primary Antibody 119R-14, 119R- 15, 119R-16, 119R18
Meques gay,	CD19 (MRQ-36) Mouse Monoclonal Antibody 119M-14, 119M-15, 119M- 16, 119M-18

	CD1a (EP3622) Rabbit Monoclonal Primary Antibody 101R-14, 101R- 15, 101R-16, 101R18
	CD2 (EP222) Rabbit
	Monoclonal Primary Antibody 102R-14, 102R- 15, 102R-16, 102R18
Abdul Oracio	CD2 (MRQ-11) Mouse Monoclonal Antibody 102M-14, 102M-15, 102M- 16, 102M-18
Asistal Weiter	CD20 (L26) Mouse Monoclonal Antibody 120M-84, 120M-85, 120M- 86, 120M-88
Mednesday,	CD20 (SP32) Rabbit Monoclonal Antibody 120R-14, 120R-15, 120R- 16, 120R18
adul oradii	CD21 (2G9) Mouse Monoclonal Antibody 121M-14, 121M-15, 121M- 16, 121M-18
AU DIE P	CD21 (EP3093) Rabbit Monoclonal Primary Antibody 121R-14, 121R- 15, 121R-16, 121R18
997,	CD23 (1B12) Mouse Monoclonal Antibody 123M-14, 123M-15, 123M- 16, 123M-18
Medne	CD23 (MRQ-57) Mouse Monoclonal Antibody 123M-24, 123M-25, 123M-

	26, 123M-28
	CD23 (SP23) Rabbit Monoclonal Antibody 123R-14, 123R-15, 123R- 16, 123R18
adul Gadir	CD25 (4C9) Mouse Monoclonal Antibody 125M-14, 125M-15, 125M- 16, 125M-18
ADO DII P	CD3 (MRQ-39) Rabbit Monoclonal Antibody 103R-94, 103R-95, 103R- 96, 103R98
99A, 11 20, 12 20, 1	CD3 Rabbit Polyclonal Antibody 103A-74, 103A- 75, 103A-76, 103A78
Medines	CD30 (Ber-H2) Mouse Monoclonal Antibody 130M-94, 130M-95, 130M- 96, 130M-98
Alodul Oirecte	CD31 (EP78) Rabbit Monoclonal Primary Antibody 131R-24, 131R- 25, 131R-26, 131R28
Asistant Nebes	CD31 (JC70) Mouse Monoclonal Antibody 131M-94, 131M-95, 131M- 96, 131M-98
que goay,	CD33 (PWS44) Mouse Monoclonal Antibody 133M-14, 133M-15, 133M- 16, 133M-18
No	CD35 (EP197) Rabbit

	Monoclonal Primary
	Antibody 135R-14, 135R-
	15, 135R-16, 135R18
	CD38 (SP149) Rabbit
	Monoclonal Antibody
	118R-14, 118R-15, 118R-
	16, 118R- 18
	1 (19, 5)
	CD4 (EP204) Rabbit
10-11	Monoclonal Primary
701, 16 <sub>C</sub>	Antibody 104R-24, 104R-
	25, 104R-26, 104R28
Project Control of the Control of th	
	CD4 (CD25) Pakkii
icio Mu	CD4 (SP35) Rabbit Monoclonal Antibody
SI B OIL	104R-14, 104R-15, 104R-
D5.01,004	16, 104R18
( ) ( ) ( )	
100	CD43 (MT1) Mouse
7,0-1	Monoclonal Antibody
	143M-14, 143M-15, 143M- 16, 143M-18
400	10, 1431/1-10
180.	(6)
	CD45 (LCA) (2B11 &
	PD7/26 Mouse Monoclonal
	Antibody 145M-94, 145M-
, Q	95, 145M-96, 145M-98
AUI CC	Alis Oir
" " " " " " " " " " " " " " " " " " "	CD45RO (UCHL-1) Mouse
Pr. V.	Monoclonal Antibody
001,100	147M-94, 147M-95, 147M-
· c'io · No	96, 147M-98
ASSISTANT NOD	
DE OIY COY	CD5 (4C7) Mouse
1 613	Monoclonal Antibody
	205M-14, 205M-15, 205M-
	16, 205M-18
20-7	
35	CD5 (ED77) Pobbit
700	CD5 (EP77) Rabbit Monoclonal Primary
16:01	Antibody 205R-24, 205R-
	1 milloug 2001 27, 2001

		25, 205R-26, 205R28	
		CD5 (SP19) Rabbit Monoclonal Antibody 205R-14, 205R-15, 205R- 16, 205R18	
	adul Gadir	CD57 (NK-1) Mouse Monoclonal Antibody 157M-94, 157M-95, 157M- 96, 157M-98	
	AU DII PI	CD61 (2f2) Mouse Monoclonal Antibody 161M-14, 161M-15, 161M- 16, 161M-18	
	997,	CD68 9Kp-1) Mouse Monoclonal Antibody 168M-94, 168M-95, 168M- 96, 168M-98	
	Mednes	CD7 (EP132) Rabbit Monoclonal Primary Antibody 107R-14, 107R- 15, 107R-16, 107R18	
	Apqui Directo	CD7 (MRQ-56) Mouse Monoclonal Antibody 107M-24, 107M-25, 107M- 26, 107M-28	
	Assistant Web	CD71 (EP232) Rabbit Monoclonal Primary Antibody 171R-14, 171R- 15, 171R-16, 171R18	
	Meque gay,	CD71 (MRQ-48) Mouse Monoclonal Antibody 171M-94, 171M-95, 171M- 96, 171M-98	
1			1

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	CD79a (JCB117) Mouse Monoclonal Antibody 179M-94, 179M-95, 179M- 96, 179M-98
	CD79a (SP18) Rabbit Monoclonal Antibody 179R-14, 179R-15, 179R- 16, 179R18
Abdul Qiacto	CD8 (C8/144B) Mouse Monoclonal Antibody 108M-94, 108M-95, 108M- 96, 108M-98
Assistian Medien	CD8 (SP16) Rabbit Monoclonal Antibody 108R-14, 108R-15, 108R- 16, 108R18
requesquy,	c-Myc (EP121) Rabbit Monoclonal Primary Antibody 395R-14, 395R- 15, 395R-16, 395R18
We dill Gadin	Cyclin D1 (EP12) Rabbit Monoclonal Primary Antibody 241R-44, 241R- 45, 241R-46, 241R48
Alou Dillo Projection	Cyclin D1 (SP4) Rabbit Monoclonal Antibody 241R-14, 241R-15, 241R- 16, 241R18
B (0), 30,	Factor XIIIa (AC-1A1) Mouse Monoclonal Antibody 251M-14, 251M- 15, 251M-16, 251M-18
Medines	Factor XIIIa (EP3372) Rabbit Monoclonal Primary Antibody 251R-14, 251R-

		15, 251R-16, 251R18
		Fascin (55-k2) Mouse Monoclonal Antibody 252M-14, 252M-15, 252M- 16, 252M-18
	in duli or a dili	FoxP1 (EP137) Rabbit Monoclonal Primary Antibody 350R-24, 350R- 25, 350R-26, 350R28
	Assistant Neb P	FoxP1 (SP133) Rabbit Monoclonal Antibody 350R-14, 350R-15, 350R- 16, 350R18
	4994, G. 1 201	Glycophorin A (GA-R2) Mouse Monoclonal Antibody 260M-14, 260M- 15, 260M-16, 260M-18
	Mednes	Granzyme B Rabbit (EP230) Monoclonal Primary Antibody 262R-14, 262R-15, 262R-16, 262R18
	Alodul Direct	Granzyme B Rabbit Polyclonal Antibody 262A- 14, 262A-15, 262A-16, 262A18
	Assista Mode	Hemoglobin A (EPR3608) Rabbit Monoclonal Primary Antibody 360R-14, 360R- 15, 360R-16, 360R18
	Meglue eggs,	HGAL (MRQ-49) Mouse Monoclonal Antibody 375M-94, 375M-95, 375M- 96, 375M-98
1		

IgA (EP170) Rabbit Monoclonal Primary Antibody 267R-14, 267R- 15, 267R-16, 267R18  IgA Rabbit Polyclonal Antibody 267A-14, 267A- 15, 267A-16, 267A18  IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R- 15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18
Antibody 267R-14, 267R-15, 267R-16, 267R-18  IgA Rabbit Polyclonal Antibody 267A-14, 267A-15, 267A-16, 267A-18  IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R-15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A-15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A-18  IgG Rabbit Polyclonal Antibody 269A-14, 369A-15, 269A-16, 269A-18
IgA Rabbit Polyclonal Antibody 267A-14, 267A- 15, 267A-16, 267A18  IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R- 15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG Rabbit Polyclonal Antibody 269R-14, 369A- 15, 269A-16, 269A18
Antibody 267A-14, 267A-15, 267A-16, 267A-18  IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R-15, 268R-16, 268R-18  IgD Rabbit Polyclonal Antibody 268A-14, 268A-15, 268A-16, 268A-18  IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A-18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 267A-14, 267A-15, 267A-16, 267A-18  IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R-15, 268R-16, 268R-18  IgD Rabbit Polyclonal Antibody 268A-14, 268A-15, 268A-16, 268A-18  IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A-18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 267A-14, 267A-15, 267A-16, 267A-18  IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R-15, 268R-16, 268R-18  IgD Rabbit Polyclonal Antibody 268A-14, 268A-15, 268A-16, 268A-18  IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A-18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R- 15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Monoclonal Primary Antibody 268R-14, 268R- 15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Monoclonal Primary Antibody 268R-14, 268R- 15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 268R-14, 268R-15, 268R-16, 268R18  IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
IgD Rabbit Polyclonal Antibody 268A-14, 268A- 15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 268A-14, 268A-15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 268A-14, 268A-15, 268A-16, 268A18  IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
IgG Rabbit Polyclonal Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Antibody 269A-14, 269A- 15, 269A-16, 269A18  IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-
Monoclonal Primary Antibody 367R-14, 367R-
Monoclonal Primary Antibody 367R-14, 367R-
Antibody 367R-14, 367R-
15, 367R-16, 367R18
IgG4 (MRQ-44) Mouse
Monoclonal Antibody 367M-14, 367M-15, 367M-
16, 367M-18
IgM Rabbit Polyclonal Antibody 270A-14, 270A-
15, 270A-16, 270A18
Kappa (EP171) Rabbit
Monoclonal Primary Antibody 274R-14, 274R-
15, 274R-16, 274R18
Kappa (L1C1) Mouse

	Monoclonal Antibody 274M-94, 274M-95, 274M- 96, 274M-98
	Lambda (EP172) Rabbit Monoclonal Primary Antibody 277R-14, 277R- 15, 277R-16, 277R18
Apqui Oilecto	Lambda (Lamb 14) Mouse Monoclonal Antibody 277M-94, 277M-95, 277M- 96, 277M-98
Asistal Web	Langerin (12D6) Mouse Monoclonal Antibody 392M-14, 392M-15, 392M- 16, 392M-18
Alle gley,	LEF1 (EP310) Rabbit Monoclonal Primary Antibody 442R-14, 442R- 15, 442R-16, 442R-18
Media	LMO2 (SP51) Rabbit Monoclonal Antibody 370R-14, 370R-15, 370R- 16, 370R18
Abduli Director	Lysozyme Rabbit Polyclonal Antibody 278A- 14, 278A-15, 278A-16, 278A18
Hay, Les Golf Color	MUM1 (EP190) Rabbit Monoclonal Primary Antibody 358R-14, 358R- 15, 358R-16, 358R18
1eque sor	MUM1 (MRQ-43) Rabbit Monoclonal Antibody 358R-74, 358R-75, 358R-

	,		
		76, 358R78	
		MUM1 (MRQ-8) Mouse Monoclonal Antibody 358M-14, 358M-15, 358M- 16, 358M-18	T AM
	odul Gadir	Myeloperoxidase (EP151) Rabbit Monoclonal Primary Antibody 289R-24, 289R- 25, 289R-26, 289R28	·
	sistant Director	Myeloperoxidase Rabbit Polyclonal Antibody 289A- 74, 289A-75, 289A-76, 289A78	
	997,	Myeloperoxidase (SP72) Rabbit Monoclonal Antibody 289R-14, 289R- 15, 289R-16, 289R18	
Mediles	o adir	Oct-2 (MRQ-2) Mouse Monoclonal Antibody 308M-14, 308M-15, 308M- 16, 308M-18	T AM
	Abdul Directo	PAX-5 (24) Mouse Monoclonal Antibody 312M-14, 312M-15, 312M- 16, 312M-18	
P	sister Negler	Pax-5 (EP156) Rabbit Monoclonal Primary Antibody 312R-24, 312R- 25, 312R-26, 312R28	
Medines	gay,	PAX-5 (SP34) Rabbit Monoclonal Antibody 312R-14, 312R-15, 312R- 16, 312R18	

	PD-1 (EP239) Rabbit Monoclonal Primary Antibody 315R-14, 315R- 15, 315R-16, 315R18
	PD-1 (NAT105) Mouse
	Monoclonal Antibody 315M-94, 315M-95, 315M- 9, 315M98
Apdul Oracio	Perforin (MRQ-23) Mouse Monoclonal Antibody 316M-14, 316M-15, 316M- 16, 316M-18
Assista Western	PU.1 (EPR3158Y) Rabbit Monoclonal Primary Antibody 328R-14, 328R- 15, 328R-16, 328R18
Medines day,	SOX-11 (MRQ-58) Mouse Monoclonal Antibody 382M-14, 382M-15, 382M- 16, 382M-18
W Gadir	Spectrin (RBC2/3D5) Mouse Monoclonal Antibody 333M-14, 333M- 15, 333M-16, 333M-18
sistant Director	T-bet (MRQ-46) Rabbit Monoclonal Antibody 368R-74, 368R-75, 368R-7, 368R-78
2898A, 1128	TCL1 (MRQ-7) Mouse Monoclonal Antibody 357M-14, 357M-15, 357M- 16, 357M-18
Medile	TdT (EP266) Rabbit Monoclonal Primary Antibody 338R-24, 338R-

			25, 338R-2, 338R-28	
		Aul Ozdif	TdT Rabbit Polyclonal Antibody 338A-74, 338A- 75, 338A, 76338A-78 Tryptase (G3) Mouse Monoclonal Antibody 342M-14, 342M-15, 342M- 16, 342M-18	TAM
17.	M/s F Y Diagnostics & Surgicals Anum Blessing, Suite#	Manufacturing site:  M/s CELL MARQUE CORP 6600 SIERRA	Melanoma Markers (Immunohistochemistry)	Approved subject to submission of fee as cluster.
	203, Near Duty Free Shop, BL7/8, K.C.H.S.U,	COLLEGE BLVD ROCKLIN, CA USA	MD group: Cluster	
	Shahrah-e-Faisal,	95677.	Class B	
	Karachi (FLL 00222)	413	LOA validity:	
	(ELI-00323) Date of R&I:	ISO 13485 certificate validity: 25-03-2024	31-12-2025	
	01-04-2024	validity. 25-05-2024	Shelf Life: 03 years	
	Fee Challan No.:		Codes:	1 AM
	65926424918		Cathepsin K (3F9) Mouse	1
	PKR: 25000/-	222	Monoclonal Antibody	
	Dated: 23-02-2024	, Q2dii	402M-14, 402M-15, 402M- 16, 402M-18	
		Plogni Ditect	CD63 (NKI/C3) Mouse Monoclonal Antibody 263M-14, 263M-15, 263M- 16, 263M-18	
		35 OB Septe	CDK4 (DCS-31) Mouse Monoclonal Antibody 478M-94, 478M-95, 478M- 96, 478M-98	
	Medines	,000	HMB-45 (HMB-45) Mouse Monoclonal Antibody 282M-94, 282M-95, 282M- 96, 282M-98	

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	Aul Cadif	KBA.62 (KBA.62) Mouse Monoclonal Antibody 366M-94, 366M-95, 366M- 96, 366M-98 MART-1 (Melan A) (A103) Mouse Monoclonal Antibody 281M-84, 281M- 85, 281M-86, 281M-88	TAN
	MOC OILCON	MART-1 (Melan A) (M2-7C10) Mouse Monoclonal	
	Oly in	Antibody 281M-94, 281M-95, 281M-96, 281M-98	
	cisto Water	, 2011.70, 2011.170	
	3,016 286	MART-1 (M2-7C10) +	
		Tyrosinase (T311) Mouse Monoclonal Antibody	
	· de	903H-08	
Medhes	gio.	Microphthalmia Transcription Factor (MiTF) (C5/D5) Mouse Monoclonal Antibody 284M-94, 284M- 95, 284M-96, 284M-98	TAM
	Q2CI	Nestin (10C2) Mouse	
	dul agoid	Monoclonal Antibody	
	Mor Dill Bi	388M-14, 388M-15, 388M- 16, 388M-18	
	13UINGO	PNL2 (PNL2) Mouse	
P	sion septer	Monoclonal Antibody 365M-98	
	997,	PRAME (EP461) Rabbit Monoclonal Primary Antibody 484R-14, 484R- 15, 484R-16, 484R18	
160II.		S100 beta (EP32) Rabbit	
 417		(2102) 140011	I

	Alodul Gadillo Bester Galler George Galler George G	Monoclonal Primary Antibody 449R-14, 449R- 15, 449R-16, 449R18  SOX-10 (EP268) Rabbit Monoclonal Primary Antibody 383R-14, 383R- 15, 383R-16, 383R18  SOX-10 Rabbit Polyclonal Antibody 383A-74, 383A- 75, 383A-76, 383A78  Tyrosinase (T311) Mouse Monoclonal Antibody 344M-94, 344M-95, 344M- 96, 344M-98	AM
18. M/s F Y Diagnostics & Surgicals  Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi  (ELI-00323)  Date of R&I: 01-04-2024  Fee Challan No.: 3310203182  PKR: 25000/- Dated: 12-07-2024	Manufacturing site:  M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.  ISO 13485 certificate validity: 25-03-2024	Endothelial Markers (Immunohistochemistry)  MD group: Cluster Class B  LOA validity: 31-12-2025 Shelf Life: 03 years  Codes: CD34 (EP88) Rabbit Antibody 134R-18, 134R-16, 134R-15, 134R-14  CD34 (QBEnd/10) Mouse Monoclonal Antibody 134M-18, 134M-16, 134M-15, 134M-14  Claudin-4 (EP417) Rabbit Monoclonal Antibody 468R-18, 468R-16, 468R-	Approved subject to submission of fee as cluster

		<u> </u>	15 460D 14	
			15, 468R-14	
		dul Cadil	ERG (EP111) Rabbit Monoclonal Primary Antibody 434R-18, 434R- 16, 434R-15, 434R-14 Factor VIII Related Antigin Rabbit Polyclonal Antibody 250A-18, 250A-16, 250A- 15, 250A-14	TAM
		sistant Neber	FLI-1 (MRQ-1) Mouse Monoclonal Antibody254M-18, 254M- 16, 254M-15, 254M-14	
		987,1	Podoplanin (D2-40) Mouse Monoclonal Antibody 322M-18, 322M-16, 322M- 15, 322M-14	
	Meque		SDHB (EP288) Rabbit Monoclonal Primary Antibody 466R-18, 466R- 16. 466R-15, 466R-14	17 Alan
19.	Hospital Solutions 174-E, Block-2, PECHS Karachi (ELI-00250)	Surgaid Medical (Xiamen) Co., Ltd. Building 5, No. 18, Shan Bia Nhong east Road, haicang District, 36 1026,	Disposable Trocars  Class B  Shelf Life	Deferred for submission of: copy of Aplication form & fee slip
	Fee Rs.31,00/ deposited vide slip no. 1011760802 dated 31.10.2024	Xiamen Fujian PR China	Dell'	Original FSC of reference countries or CE certificate required. Multiple products applied in single application and firm need to clarify for which product applied.
20.	M/s Hospital Solutions, H. No. 174-E Block 2, P.E.C.H.S Karachi.	Legal Manufacturer:  M/s Wuhan Snow	OPA Disinfectant (Ortho Phthalaldehyde 0.5% Solution 5L & 1L)	Deffered for submission of original FSC issued by concerned

	ELI No. 00250  Evaluator AD-II  (221-C)	Medical Disinfectant Co. Ltd, No. 18, Yinhu Science & Technology Industrial Park, Dongxihu District Wuhan Hubei, China 430040 FSC China  Issued on 28-01-2022  Valid for 2 years	Class B Shelf Life: 05 Years	regulatory authority of China AND original, legalized FSC of any reference country or CE Certificate
21.	M/s Hospital Solutions, H. No. 174-E Block 2, P.E.C.H.S Karachi.  ELI No. 00250  Evaluator AD-II  (4811-P)	Legal Manufacturer:  M/s Wuhan Snow Medical Disinfectant Co. Ltd, No. 18, Yinhu Science & Technology Industrial Park, Dongxihu District Wuhan Hubei, China 430040  FSC China  Issued on 28-01-2022  Valid for 2 years	Snow Xue Huan Glutaraldehyde Solution  (Glutaraldehyde disinfectant solution 2%)  Class D  Shelf Life: 02 Years	Deffered for submission of original FSC issued by concerned regulatory authority of China AND original, legalized FSC of any reference country or CE Certificate
22.	Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan Lic. No. (ELI-00005)	Haemonetics Corporation, 400 Wood Road, Braintree, Massachusetts, MA 02184, USA.  Reagents: Haemonetics Corporation Building 18, Avenue C, Leetsdale PA 15056 USA. Instruments: Sparton Medical Systems, 22740 Lunn Road,	TEG 5000 Thrombelastograph Hemostasis Analyzer System with Accessories and Disposables Item. TEG 5000 Thrombelastograph Hemostasis Analyzer System (07-033) TEG 5000 Kaolin Kit (07-004 (6300)) TEG 5000 Cups and Pins, Heparinase (07-006 (6212))	Deffered for following reasons;  1. The name of the device and accessories are not as per FSC.  2. Codes 07-033 and 07-047 not mentioned on FSC.  3. Brochure don't have codes 07-004, 07-007, 07-008, 07-012, 07-015, 07-

	Nednes	Strongsville, Ohio 44149, USA  Copy of FSC: USA Valid till: 20-08-2020	TEG 5000 Biological QC Level I Kit (07-007 (8001)) TEG 5000 Biological QC Level II Kit (07-008 (8002)) TEG 5000 Calcium Chloride, 0.2M, 5mL (07-012 (7003)) TEG 5000 PlateletMapping Full Assay Kit, ADP & AA (07-014) TEG 5000 PlateletMapping ADP Assay Kit (07-015) TEG 5000 PlateletMapping AA Assay Kit (07-016) TEG 5000 Rapid TEG Kit (07-032) TEG 5000 Functional Fibrinogen Kit (07-034) TEG 5000, KIT, SET-UP FG (07-047) TEG 5000 Kit, Cups and Pins, Natural (07-052 (6211))	4. Manufacturing site Sparton Medical Systems, 22740 Lunn Road, Strongsville, Ohio 44149, USA not mentioned on FSC and ISO 13485 and EC certificate.  5. Submission of valid ISO 13485:2016.  6. copy of fee challan (for verification).
		Apolli Gadin Sistant Neber OP Septen	07-033, 07-004 (6300), 07-006 (6212), 07-007 (8001), 07-008 (8002), 07-012 (7003), 07-014, 07-015, 07-016, 07-032, 07-034, 07-047, 07-052 (6211) Class: C, Shelf Life: 48 Months, Sizes and Model as per FSC, Date of submission: 07-04-2022	
23.	Allmed Solutions, A-21/3, KDA Scheme	M/s Nanjing Shouliang- Med Technology Co. Ltd.	SOLIANG NON-STERILE ELECTROSURGICAL	Board decided to reject the
	No.1 (ext) Stadium Road, Karachi	China Address: Zhongshan Science Park D9 block,	VESSEL SEALER/DIVIDER	application as the firm has not explained that it
	W.	No. 9 Kechuang Avenue,		will be sold in a

	(ELI-00029)	Jiangbei new area, Nanjing city, Jiangsu,	Class C	single pack as system or
		China Copy of FSC: China,	Shelf Life: 2 years	separately. Further firm has not provided the
	Date of submission:02.06.2022	Valid Till: 20-04-2024	Article no.	labeling,
	Submission:02.06.2022		1. Electrosurgical Generator (SL100)	instructions-for-use, brochures or
		No.	2. Sterile Vessel Sealer / divider (SL1120A)	catalogues for each constituent-
		O'creto	3. Sterile Vessel Sealer / divider (SL1137A)	component state that the constituent- component
		Mod Direct	4. Sterile Vessel Sealer / divider (SL1120S)	is intended for use with the system.
		ani Neb	5. Sterile Vessel Sealer / divider (SL1137S)	
		SISIB CEDIO	6. Sterile Vessel Sealer / divider (SL5137S)	
	V	613	7. Sterile Vessel Sealer / divider (SL5137A)	
		984,	8. Sterile Vessel Sealer / divider (SL5120S)	
	Mes		9. Sterile Vessel Sealer / divider (SL5300S)	AM
	Mec		10. Sterile Vessel Sealer / divider (SL0837)	
		Qadiii	11. Sterile Vessel Sealer / divider (SL0823)	
		dilligation	olish ops,	
		Mo Dir Pi	vel.	
		May Mer		
24.	M/s. Allmed Solutions Address:	Legal Manufacturer: KARL STORZ SE & CO.	KARL STORZ Imaging Systems	The case was deffered as firm has
	A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	KG Germany	(Camera Heads, CCU's, Monitors, Imaging Accessories)	failed to justify that how all devices have the same design
	Noau, Maracili	Address: DrKarl-Storz- StraBe 34 78532	Class A	and manufacturing process and
	ELI:00029	Tuttlingen, Germany	Shelf Life: N/A	have variations that are within the scope
	R&I details	FSC: Germany		of the permissible variants. MDB
			l .	l

	Date: 19/04/2021 Slip no. 1964790 Rs. 5000/-	Validity: Not mentioned, issued in 27/01/2020	Codes / Sizes: Codes as per FSC	decided to give last opportunity to justify that collection of applied medical devices fall in family
		Validity: 31/12/2025 ISO 13485 valid 31-05- 2025	MIS)	as per MDR 2017 with supporting documents.
25.	Applicant Name:  M/s. Allmed Solutions Address: A-21/3, KDA	Name of Manufacturer:  KARL STORZ SE & CO. KG Germany  Address: Dr. Karl-Storz- StraBe 34 78532	Brand Name:  KARL STORZ Motors (Motor Control Unit, Handpieces/Motors, Foot Switches for	The case was deffered as firm has faild to justify that how all devices have the same design and manufacturing process and have variations that are within the scope
	Scheme No.1 (ext) Stadium Road, Karachi	Tuttlingen, Germany FSC: Germany Validity: Not	Motor Control Unit, Shaver/Drills (sterile/non-sterile))	of the permissible variants. MDB decided to give last opportunity to justify that collection of
	ELI:00029	mentioned, issued in Oct. 2022	Class A Shelf Life: N/A	applied medical devices fall in family as per MDR 2017 along with
	R&I details Date: 03/01/2023 Slip no. 777237723643 Rs. 5000.	LOA Validity: 31/12/2025	Codes / Sizes S # Article No.	supporting documents e.g. brochure, catalogue etc.
	Dated: 28-12-2022 Tracking ID.	Abdul Direct	Description 1 UM100 PowerUnit 2	
	NX4-PJ5-RRNB	sister Wester	4071209 0 Handle for DRILLCUT-X II	
	1ednes	997,	Handpieces 3 2071168 0	

			Irrigation rod for	
			Unidrive ENT	
26.	Applicant Name:	Name of Manufacturer:	Brand Name:	The case was deffered as firm has
	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	KARL STORZ SE & CO. KG Germany  Address: Dr. Karl-Storz- StraBe 34 78532 Tuttlingen, Germany  FSC: Germany Validity: Not mentioned, issued	KARL STORZ Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without channel, Semiflexible endoscopes with and without channel)	deffered as firm has faild to justify that how all devices have the same design and manufacturing process and have variations that are within the scope of the permissible variants. MDB decided to give last opportunity to justify that collection of applied medical
	ELI:00029	in Oct. 2022	Class A	devices fall in family
	R&I details Date: 18/01/2023	LOA Validity: 31/12/2025	Shelf Life: N/A	as per MDR 2017 along with supporting documents e.g. brochure, catalogue
	Slip no. 47935234289	707,	Codes / Sizes:	brochure, catalogue etc.
	Rs. 5000.	O	S # Article	
	Dated: 12-01-2023		No.	1 Pile
	Nec		Description	
	Tracking ID.	lik.	1 (1)	•
	NDH-Y7N-3VAP	030	27033A	
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		" Mognition	Miniature Telescope	
		Branch A	0°, 1.2 mm, 20 cm	
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		cisis vie	Retromolar	
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	`	413	Endoscope 5,0x40	
			3 11014Y Fiber Fixation	
		707	4 11301CA	
	-0	9	Leaflet Valve, for	
	dille		single use, 20x	
	16		5 11301CF LIPP Tube	

			Holder	
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			Instrument Port, 1	
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			7 27001GF	VIII.
			Instrument Port, 2	
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	Medi		Renoscopes	
27.	Applicant Name:	Name of Manufacturer:	Brand Name:	The case was
		KARL STORZ	7 31 9.	deffered as firm has faild to justify that
	M/s. Allmed	SE & CO. KG	KARL STORZ OR1	how all devices
	Solutions	Germany	(Data Storage, Data	have the same design
	Address:	Address: Dr.	Management and	and manufacturing process and
	A-21/3, KDA	Karl-Storz-	Routing Systems, Active	have variations that
	Scheme No.1 (ext)	StraBe 34 78532	controlling systems, components of software)	are within the scope
	Stadium Road,	Tuttlingen, Germany	components of software)	of the permissible variants. MDB
	Karachi		Class A	decided to give last
	Karaciii	FSC: Germany Validity: Not	Class A	opportunity to justify that collection of
	FI 1 000C0	mentioned, issued	G1 107 10 27/1	applied medical
	ELI:00029	in Oct. 2022	Shelf Life: N/A	devices fall in family
		LOA		as per MDR 2017 along with
	R&I details	Validity:	Codes / Sizes	supporting
	Date: 03/01/2023	31/12/2025	S # Article	documents e.g. brochure, catalogue
L		<u>I</u>	<u>I</u>	

Slip no. 59976410		No.	etc.
Rs. 5000.		Description	
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	dif	3 WM200 OR1 SmartScreen	•
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		7000 JILO	OR1 Table	
28.	Applicant Name:	Name of Manufacturer:	Interface Unit Brand Name:	The case was
20.	Applicant Ivallie.	isto. No ac	Diana Ivanic.	deffered as firm has
	M/s. Allmed	KARL STORZ SE & CO. KG	KARL STORZ Equipment	faild to justify that how all devices
	Solutions	Germany	Carts	have the same design and manufacturing
	Address:	Address: Dr.	(Equipment Carts and accessories)	process and
	A-21/3, KDA	Karl-Storz- StraBe 34 78532	,	have variations that
	Scheme No.1 (ext)	Tuttlingen,	Class A	are within the scope of the permissible
	Stadium Road,	Germany		variants. MDB decided to give last
	Karachi	FSC: Germany Validity: Not	Shelf Life: N/A	opportunity to justify
		· minity · i · ot	1	l

	ELI:00029	mentioned, issued in Oct. 2022	Codes / Sizes	that collection of applied medical devices fall in family as per MDR 2017
	D 0 I 1 4 1	LOA Validity:	S # Article	along with
	R&I details	31/12/2025	No. Description	supporting documents e.g.
	Date: 03/01/2023		1 UG041 Beam package,	documents e.g. brochure, catalogue
	Slip no. 5136248360	. 4	equipment cart low	etc.
	Rs. 5000.		2 UG051 Beam package,	
	Dated: 28-12-2022	Oge of	equipment cart high	
		"Il cit	3 UG052 Beam package,	
	Tracking ID.	" Moderation	equipment cart LC	
	X9N-XZV-GZS6	Vo Di b	4 UG055 Beam Package high,	
		isto No. 81	CH version	
		SI OR COL	5 UG310	
		6, 60,	Isolation	
			Transformer 200V	
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			7 UG500 Monitor Holder	
		Q. 0.0	8 UG510 Monitor Holding	
		AUI CCIO	Arm	
		VO VIIIO	9 UG520 Monitor Holding	
		0, 10	Arm, long	
		Star No.	10 UG530 Swivel Arm for	
		sistal Noter	Navigation Camera	
	P	01,204	11 UG540 Monitor Swivel Arm	
29.	M/s Johnson & Johnson Pakistan (Pvt) Ltd,	Legal Manufacturer:	CEREBASE DA Guide Sheath_	Approved.
	Office No. 506, 5 <sup>th</sup> Floor, Horizon Tower, Block 3, Scheme No 5, Clifton,	Medos International SARL		
	Karachi.	Chemin Blanc 38, Le Locle CH-2400,	MDIR-0005568	

		Switzerland		
	(ELI 00154)		Date of Reg.:	
			6-Sep-23	
	(Post-registration variation for PM change)	All Control of the Co	Date of Registration Dossier Submission:  14-Jun-21	TAM
30.	M/s Johnson & Johnson Pakistan (Pvt) Ltd,	Legal Manufacturer:	PROWLER SELECT PLUS Infusion Catheter	Approved.
	Office No. 506, 5 <sup>th</sup> Floor, Horizon Tower, Block 3, Scheme No5, Clifton,	"Medos International SARL	MDIR-0005570	
	Karachi.	Chemin Blanc 38, Le Locle CH-2400,	Class D	
	(ELI 00154	Switzerland"	Date of Reg.: 6-Sep-23	
	(Post-registration variation for PM change)	9931,	Date of Registration Dossier Submission: 5-Aug-21	
31.	M/s Johnson & Johnson Pakistan (Pvt) Ltd,	Legal Manufacturer:	(2)	Approved.
	Office No. 506, 5 <sup>th</sup> Floor, Horizon Tower, Block 3, Scheme No5, Clifton, Karachi.	"Medos International SARL  Chemin Blanc 38, Le Locle CH-2400, Switzerland"	PROWLER SELECT LP- ES Infusion Catheter MDIR-0005569	
	(ELI 00154	Vo O. S.	Class D	
	(Post-registration variation for PM change)	sistant Neboter	Date of Reg.: 6-Sep-23	
	P	5 67 504	Date of Registration Dossier Submission: 28-Jun-21	
32.	M/s Johnson & Johnson Pakistan (Pvt) Ltd, Office No. 506, 5 <sup>th</sup> Floor,	Legal Manufacturer:  "Medos International	PROWLER Infusion Catheter (Intravascular Microflow Catheter)	Approved.
	Horizon Tower, Block 3, Scheme No5, Clifton,	SARL Chemin Blanc 38, Le	MDIR-0004563	
	Karachi.	Locle CH-2400,	Class D	

		Switzerland"		
	(ELI 00154	· · · · · · · · · · · · · · · · · · ·	Date of Reg.:	
	`		12-Jan-23	
	(Post-registration variation for PM change)		Date of Registration Dossier Submission: 28-Jun-21	TAM
33.	M/s Johnson & Johnson Pakistan (Pvt) Ltd,	Legal Manufacturer:	1/1/1/1/ 0:53	Approved.
	Office No. 506, 5 <sup>th</sup> Floor, Horizon Tower, Block 3,	"Medos International SARL	PROWLER PLUS Infusion Catheter	
	Scheme No5, Clifton, Karachi.	Chemin Blanc 38, Le Locle CH-2400, Switzerland"	108, 11	
	(ELI 00154	Switzerialid	Class D	
	(Post-registration variation for PM	35,015 26 br	Date of Reg.: 12-Jan-23	
	change)		Date of Registration Dossier	
		.04,	Submission: 28-Jun-21	
	0	000	20-Jun-21	
34.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.506, 5th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi	Legal Manufacturer: Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH	Cable Implants Class C	Deffered the case (last oppotunity) for:  1. justification of the grouping of
		FSC # 00015771 valid	in horas	applied devices according to MDR
	(ELI-00154) [2966]	until 29-Sep-2025	Descri Sh	2017 and RRA with
	25-08-2020	FSC # 00015773 valid until 24-Oct-2025	ptions elf	supporting documents.
		(submitted in Response to	C lif	2. Submission of
		48 <sup>th</sup> MDB Decision Letter)	$\begin{bmatrix} 0 \\ d \end{bmatrix}$ $\begin{bmatrix} e \\ (y \end{bmatrix}$	copy of fee challan.
		FSC # 00015778 valid	e ea	
		until 24-Oct-2025	s rs)	
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35.	Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre,	Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Alinity m CMV WB AMP Kit,  (09N46-092)  Deffered the case for submission of;  1. Form 7A with annexures.

	Hyderabad Road, Landhi, Karachi (ELI-00019	Alodul Oradii Alodul Directo	Shelf life 24 Months Storage Condition 2°C-8°C  Alinity m CMV WB CTRL Kit (09N46-082) Shelf life 12 Months Storage Condition -25°C 15°C  Alinity M CMV WB CAL Kit (09N46-072) Shelf life 12 Months	<ol> <li>Undertaking on stapm paper.</li> <li>calrification of grouping of the applied kits as these have different storage conditions and shelf life.</li> <li>Verification of storage facilities 2°C-8°C and -25°C15°C.</li> </ol>
36	Abbott Laboratorias	A Phott Molacular Inc.	Storage Condition -25°C 15°C  CWV WB  Class C	Doffered the case
36.	Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019	ABbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA	Alinity m EBV WB AMP Kit,  (09N43-092)  Shelf life 12 Months  Storage Condition 2°C-8°C Alinity m EBV WB CTRL Kit,  (09N43-082)  Shelf life 24 Months  Storage Condition -25°C15°C  Alinity m EBV WB CAL Kit  (09N43-072)  Shelf life 12 Months  Storage Condition -25°C15°C	Deffered the case for submission of;  1. Form 7A with annexures.  2. Undertaking on stapm paper.  3. calrification of grouping of the applied kits as these have different storage conditions and shelf life.  4. Verification of storage facilities 2°C-8°C and -25°C15°C.

			Class C	
37.	Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019	Abbott Ireland Diagnostics Division Lisnamuck, longford co. longford, Ireland	Calcium 2 04S9120 04S9130  Shelf Life 15 Months  Storage condition 15-30 °C  Class B	Approved
38.	Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi (ELI-00019	Abbott Ireland Diagnostics Division Lisnamuck, longford co. longford, Ireland	Calcium 2 04T8720 04T8730  Shelf Life 15 Months  Storage condition 15-30 °C  Class B	Approved
39.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	Manufacturer:  Abbott Molecular Inc. 1300 East Touhy Avenue Des Plaines, IL 60018 USA  (Embassy Attested CFG USA Validity: 01.08. 2024) LOA issued on 28.10.2022  Dossier Number: 895 Dossier Submission date: 12-Sep-2023	Vysis FISH Pretreatment Reagent kit 02J03-032  Shelf Life: Not Applicable  Class: C Rs.50,000/-	Deferred for;  1. Clarification that product is not a medical device.  2. How it has been applied in class C.  3. How a non medical device or non-IVD can be enlisted/registered as Medical device
40.	Applicant: Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi	(Legal Manufacturer)  Name: M/s. Abon Biopharm (Hangzhou) Co. Ltd. 198 12th Street East, Hangzhou Economic and Technological Development Area,	Brand Name:  ABON HCV Hepatitis C Virus Rapid Test Device (Whole Blood/Serum/Plasma) Generic:  ABON HCV Hepatitis C	Approved subject to submission of Design Examination.

	(ELI-00019)	Hangzhou, 310018. China	Virus Rapid Test Device (Whole Blood/Serum/Plasma)	
	R& I Date:	Free Sale Certificate	Codes: 38221990, 30829	
	(08-01-2025) Fee details:	Date of Issue: (31-10-2024)	Class-D	1 AM
	Amount paid: PKR 62,000/-	Letter of authorization:	(MS)	
	Paid Slip / challan No.: 64760315	Date of Issue: (19-11-2024)	Shelf life: 24 Months	
	Dated: (03-12-2024)	dul rech	lolls 10, rs	
41.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTEURER Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Contempo Rough Rider (Natural Rubber Latex Male Condoms)	Deferred (last opportunity) for submission of notarized, legal, valid and orginal documents.
42.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTEURER Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Contempo Endurance (Natural Rubber Latex Male Condoms with Benzocaine)	Deferred (last opportunity) for submission of notarized, legal, valid and orginal documents
43.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTEURER Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Skyn Original (Synthetic Polyisoprene Condoms)	Deferred (last opportunity) for submission of notarized, legal, valid and orginal documents.
44.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTEURER Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	Skyn Intense Feel (Synthetic Polyisoprene Male Condoms)	Deferred (last opportunity) for submission of notarized, legal, valid and orginal documents.
45.	Name	LEGAL	Contempo Wet n Wild	Deferred (last

	Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	MANUFACTEURER Suretex Limited 31/1 Moo 4, Suratthani-Thakuapha Road, Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130, Thailand	(Natural Rubber Latex Male Condoms)	opportunity) for submission of notarized, legal, valid and orginal documents.
46.	Ghani Brothers 2nd Floor, karimjee Building, North Napier Road, karachi (ELI-00900)	Shandong Qinkai Medical Industry Co., Ltd (South Section of Quancheng Road in industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze 274200, Shandong, China	Mega Disposable Infusion Set  (Sterile Infusion Set)  Class C	Deferred for following reasons;  1. firm has not submitted fee for class C.  2. FSC is not from concerned regulatory authority  3. FSC is for export only.  4. Form 7A without annexures.  5. WHO prequalification/FS C of RRA/CE certificate, DoC, undertaking on stamp paer not submitted.
47.	Ghani Brothers 2nd Floor, karimjee Building, North Napier Road, karachi (ELI-00900)	Shandong Qinkai Medical Industry Co., Ltd (South Section of Quancheng Road in industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze 274200, Shandong, China	Mega Scalp Vein Set  Scalp Vein Set 20g, 21g, 22g, 23g, 24g, 25g, 27g  Class B	Deferred for following reasons;  1. firm has not submitted fee for class C.  2. FSC is not from concerned regulatory authority  3. FSC is for export only.  4. Form 7A without annexures.  5. WHO prequalification/FS C of RRA/CE certificate, DoC, undertaking on

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48.	Ghani Brothers 2nd Floor, karimjee Building, North Napier Road, karachi (ELI-00900)	Shandong Qinkai Medical Industry Co., Ltd (South Section of Quancheng Road in industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze 274200, Shandong, China	Mega Disposable Infusion Set with Y-Connector  (Disposable Infusion Set with Y-Connector)  Class B	Deferred for following reasons;  1. firm has not submitted fee for class C.  2. FSC is not from concerned regulatory authority  3. FSC is for export only.  4. Form 7A without annexures.  5. WHO prequalification/FS C of RRA/CE certificate, DoC, undertaking on stamp paer not submitted.
49.	Ghani Brothers 2nd Floor, karimjee Building, North Napier Road, karachi (ELI-00900)	Shandong Qinkai Medical Industry Co., Ltd (South Section of Quancheng Road in industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze 274200, Shandong, China	Mega Disposable needle (Blood Collection needle) 21g, 22g, 23g, 24g, 25g, 26g, 27g	Deferred for following reasons;  1. firm has not submitted fee for class C.  2. FSC is not from concerned regulatory authority  3. FSC is for export only.  4. Form 7A without annexures.  5. WHO prequalification/FS C of RRA/CE certificate, DoC, undertaking on stamp paer not submitted.

50.	Ghani Brothers 2nd Floor, karimjee Building, North Napier	Shandong Qinkai Medical Industry Co., Ltd (South Section of	Mega Blood Transfusion Set	Deferred for following reasons;  1. firm has not
	Road, karachi (ELI-00900)	Quancheng Road in industrial Park) Medical Equipment	Blood Transfusion Set	submitted fee for class C.
		Industrial Park, Chengwu County, Heze 274200, Shandong, China	Class B	2. FSC is not from concerned regulatory authority
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51.	Ghani Brothers 2nd Floor, karimjee	Shandong Qinkai Medical Industry Co., Ltd (South Section of	Mega Burette 100ml with Infusion Set	Deferred for following reasons;
	Building, North Napier Road, karachi (ELI-00900)	Quancheng Road in industrial Park) Medical Equipment	(Burette Infusion Set 100ml)	1. firm has not submitted fee for class C.
		Industrial Park, Chengwu County, Heze 274200, Shandong, China	1 (Mis) 9:55	2. FSC is not from concerned regulatory authority
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52.	BAIN Medical SMC- Pvt) Ltd Shop No. 2, Ground	Legal Manufacturer:  Bain Medical Equipment (Guangzhou) Co., Ltd.	BAIN Hollow Fiber Dialyzer	prequalification/FS C of RRA/CE certificate, DoC, undertaking on stamp paer not

	Floor, Plot 58-C, Street No. 24, Touheed Commercial Area, phase 5 DHA karachi (ELI-00614) Evaluator: AD-VI	No. 10 Juncheng Road, Eastern Area, Economic and Technological Devolpment District, Guangzhou 510760, China. FSC: China Valid till: 17-03-2023	Codes & Sizes as per FSC Class: C Shelf Life: 03-Years.  B-14P B-16P B-18P B-20P B-14H B-16H B-18H B-20H	RRA.
53.	Hoora Pharma (pvt.) ltd. WH- 01-20-A7 -A8, korangi Creek Industrial Park, Karachi. (ELI-00037	GE Healthcare GmbH oskar Schlemmer-StraBe 11 80807 Munchen, Germany	Viewpoint 6  Radiology Picture Archiving and Communication System Application Software  Class B	Approved subject to submission of undertaking on stamp paper.
54.	Hoora Pharma (Pvt.) Ltd. Wh- 01-20-A7 -A8, Korangi Creek Industrial Park, Karachi.  ELI-00037 1852-C 23-06-2023	Legal Manufacturer: Terumo BCT, Ltd., Old Belfast Road, Millbrook, Larne BT40 2SH, United Kingdom.  Manufacturing site: Terumo BCT Vietnam Co. Ltd. Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam.  FSC Belgium Issuance 22-11-2025	REVEOS LR SET (Blood Donor set)  Class-C  Shelf life: 2 years  Code: 4FG456S0Y	Deferred for provision of documents/ information as mentioned in 68th meeting:
55.	Glo-Med Technologies, A-21/2B-1, KDA	Legal Manufacturer: Urotronic, Inc. 2495	Optilume Uretheral Drug Coated Balloon catheter	Deferred for provision of

	Scheme 1 (Ext.) National Stadium Road Karachi. (ELI-00712) 4486 02-06-2022	Xenium Lane N Minneapolis, MN 55441 USA FSC: USA Valid Till: 14-12-2023	(Uretheral Drug Coated Balloon Catheter)  Class-D  Shelf life: 12 Months  Codes are not provided. per	documents/ information as mentioned in 62 <sup>nd</sup> meeting.
56.	Biomedical Star Enterprises, Plot E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road SITE Karachi (ELI-01186)	Tianchang City Anrui Medical Equipment Co., Ltd Renhe Industrial District 239331 Tianchang city Anhui Province, China	Biofit Powder Free Latex Surgical Gloves  Powder Free Latex Surgical Gloves  Class B	Deffred for;  1. Submission of Form 7A with annexures.  2. Clarification that FSC spain bears name latex surgical glove (powdered free not mentioned).  FSC china have product name sterile surgical gloves for single use.
57.	Biomedical Star Enterprises, Plot E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road SITE Karachi (ELI-01186)	Tianchang City Annrui Medical Equipment Co., Ltd Renhe Industrial District 239331 Tianchang city Anhui Province, China	Biofit Powdered Latex Surgical Gloves Powdered Latex Surgical Gloves	Deferred for;  1. submission of Form 7A with annexures.  2. clarification that FSC spain bears name latex surgical glove (powdered not mentioned).  FSC china have product name sterile surgical gloves for single use.
58.	Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800, Pakistan. (ELI-000416) Date of issuance:23 <sup>rd</sup>	Legal Manufacturer. PhysIOL Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium	PODEYE Hydrophobic Acrylic lens Class: C Shelf life: 5 years (shelf life or validation study for claimed duration is attached at Annexed at.05)	Approved subject to submission of fee.

	May 2019	Mfg Site:		
	Validity:22nd May 2024	PhysIOL		
	Annexed at.01	Address:Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium		AM
		Embassy attested FSC: Belgium Issuance date:	1 (1/18) 9:55	
		17-11-2023	iolisus 5052,	
		No. of No. of No.	· 6/1	
59.	Ms. Jasani Scientifics SC-45, Marium Square,	Legal Manufacturer.	POD F	Approved subject to submission of fee.
	chandni Chowk, Stadium	PhysIOL	Hydrophilic Acrylic lens	submission of fee.
	road, Karachi, 74800, Pakistan. (ELI-000416)	Liege Science Park, Allee des Noisetiers 4, B-4031 Liege, Belgium	Class: C Shelf life: 5 years	
	Date of issuance:23 <sup>rd</sup> May 2019	Mfg Site:		
	Validity:22nd May 2024	PhysIOL		Na.
	Annexed at.01	Address:Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium	Date of submission: 14-11-2023 Fee Submission: 22-12-2020	17 All
		Embassy attested FSC: Belgium Issuance date: 17-11-2023	Fee Slip no. 2048520 Annexed at.06	
60.	Ms. Jasani Scientifics	Legal Manufacturer.	POD FT	Approved subject
	SC-45, Marium Square,	PhysIOL	Fine vision toric lense	to submission of
	chandni Chowk, Stadium road, Karachi, 74800, Pakistan. (ELI-000416)	Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium	Class: C Shelf life: 5 years	fee.
	Date of issuance:23 <sup>rd</sup> May 2019	Mfg Site:		
	Validity:22nd May 2024	PhysIOL		
	Annexed at.01	Address:Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium		
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		Embassy attested FSC: Belgium Issuance date: 17-11-2023	Date of submission: 14-11-2023 Fee Submission: 22-12-2020 Fee Slip no. 2048519 Annexed at.06	TAM
61.	Elate CC Pvt Ltd. Suite No. 1, 2, 3, ST-3, Block-3, Gulshan-e-Iqbal Karachi (ELI-00294)	Shandong Ande Healthcare Apparatus Co., Ltd. No. 999, Zunxian Road, New & Hi-Tech Zone, Zibo Shandong, P.R.China	Disposable IV Catheter  Class B	Deferred for;  1. submission of Form 7A along with annexures and undertaking on stamp paper.  2. FSC of RRA.  3. Submission of separate application for Dispoable catheter, normal safety type and others as per FSC.
62.	M/s. East Health Care  A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.  ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	Legal Manufacturer:  M/s  Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.  FSC: China Validity: Valid jan 2025  LOA Validity: 31/12/2028	collecting vacuum	Deferred for submission of copy of complete application.
63.	M/s. East Health Care	Legal Manufacturer: M/s	6ml, 8ml, 10ml  Brand Name; KAYO  Purple Cap (ETDA K3)  Vacuum Blood Collection	Deferred for submission of copy of complete

	A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.  FSC: China Validity: Valid 19 sep 2026 FSC: Guatemala Valid up 23Jan 2026	Generic Name; Blood collecting vacuum Tube(vecutanier)  Class A  Shelf Life: 2  Years	application.
		LOA Validity: 31/12/2028	Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	
64.	M/s. East Health Care  A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.  ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	Legal Manufacturer:  M/s  Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.  FSC: China Validity: Valid Jan 2025 FSC: Guatemala Valid up 23Jan 2026  LOA	Brand Name; KAYO Black Cap (ESR) 109m/129m Sodium Citrate Vacuum Blood  Generic Name; Blood collecting vacuum Tube(vecutanier)  Class A  Shelf Life: 2 Years  Sizes 1.6ml & 1.8ml	Deferred for submission of copy of complete application.
65.	M/s. East Health Care  A-17/1 ground floor Gulshan e Iqbal Block 6	Validity: 31/12/2028  Legal Manufacturer: M/s  Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao	Brand Name; KAYO Red Cap (No Additive) Plan Vacuum Blood Collection Tubes	Deferred for submission of copy of complete application.

	Karachi.	Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.	Generic Name; venous blood specimen collection vacuum Tube(vecutanier) Class A	
	ELI-01115		Shelf Life: 2	
	Mfg 09/08/2023	FSC: China	Years	
	Exp 8/08/2028	Validity: Valid jan 2025	16/10 0:20	
		LOA	Sizes	
		Validity: 31/12/2028	0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	
66.	M/s. East Health Care	Legal Manufacturer:	Brand Name; KAYO	Deferred for
		M/s	Blue Cap (Sodium Citrate 3.2%) Coagulation Vacuum	submission of copy of complete
		Hangzhou Rollmed Co.,	Blood Collection	application.
	A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.	Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.	Generic Name; Blood collecting vacuum Tube(vecutanier)	
	ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	FSC: China Validity: Valid jan 2025	Shelf Life: 2 Years Sizes	Ala.
	Fee 6000	LOA Validity: 31/12/2028	1.8ml & 2.7ml	
67.	M/s. East Health Care	Legal Manufacturer: M/s Hangzhou Rollmed Co., Ltd.	Brand Name; KAYO Purple Cap (ETDA K2) Vacuum Blood Collection Tubes	Deferred for submission of copy of complete application.
	A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.	Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.	Generic Name; venous blood specimen collection vacuum Tube(vecutanier) Class A	

	ELI-01115		Shelf Life: 2	
	Mfg 09/08/2023	FSC: China	Years	
	Exp 8/08/2028	Validity: Valid jan 2025		
		LOA	Sizes	1 All
		Validity: 31/12/2028	0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	
68.	M/s. East Health Care	Legal Manufacturer:	Brand Name; KAYO	Deferred for
		M/s	Yellow Cap (SST Clot Activator) Vacuum Blood	submission of copy of complete
	A-17/1 ground floor	Hangzhou Rollmed Co., Ltd.	Collection Tubes	application.
	Gulshan e Iqbal Block 6	Room 913, Yuanmao Mansion, No. 5, Wen'er	, , , , , , , , , , , , , , , , , , , ,	
	Karachi.	West Road, Hangzhou,	blood specimen collection vacuum Tube(vecutanier)	
		Zhejiang Province, P. R		
		China.	Class A	
	Y	0,20	Shelf Life: 2	
	ELI-01115		Years	
	Mfg 09/08/2023	FSC: China		
	Exp 8/08/2028	Validity: Valid jan 2025		
	100.		Sizes	DIN
	160,	LOA	0.5ml, 2ml,3ml,4ml, 5ml,	$\langle 1 \rangle$
		Validity: 31/12/2028	6ml, 8ml, 10ml	
69.	M/s. East Health Care	Legal Manufacturer:	Brand Name; KAYO Green Cap (Heparin)	Deferred for submission of copy
		M/s	Vacuum Blood Collection	of complete
		Hangzhou Rollmed Co., Ltd.	Tubes	application.
	A-17/1 ground floor	Room 913, Yuanmao		
	Gulshan e Iqbal Block 6 Karachi.	Mansion, No. 5, Wen'er		
		West Road, Hangzhou, Zhejiang Province, P. R	blood specimen collection vacuum Tube(vecutanier)	
		China.	, , , , , , , , , , , , , , , , , , ,	
		5,01,00	Class A	
	ELI-01115		Shelf Life: 2	
	Mfg 09/08/2023	FSC: China	Years	
	Exp 8/08/2028	Validity: Valid jan 2025		
	2p 0/00/2020			
	4 adilis	LOA	Sizes	
	Ne	Validity: 31/12/2028	0.5ml, 2ml,3ml,4ml, 5ml,	
L				

			6ml, 8ml, 10ml	
70.	M/s. East Health Care  A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.	Legal Manufacturer:  M/s  Hangzhou Rollmed Co., Ltd.  Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.	Brand Name; KAYO Gray Cap (Glucose) Vacuum Blood Collection Tubes  Generic Name; venous blood specimen collection vacuum Tube(vecutanier)  Class A	Deferred for submission of copy of complete application.
	ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	FSC: China Validity: Valid jan 2025 LOA Validity: 31/12/2028	Shelf Life: 2 Years Sizes 0.5ml, 2ml,3ml,4ml, 5ml,	
71.	M/s. East Health Care	Legal Manufacturer:	6ml, 8ml, 10ml Brand Name; KAYO Flash	Deferred (last
	A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi.	M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er West Road, Hangzhou, Zhejiang Province, P. R China.	back pen needle  Generic Name; Blood collecting Needle Flash back Tube(vecutanier)  Class B  Shelf Life: 5 YEARS	opportunity) for submission of;  1. differential fee challan.  2. CE certificate and stability studies.  3. FSC with correct name.
	ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	FSC: China Validity: Valid 19 sep 2026  LOA Validity: 31/12/2028	Sizes 18G,20G,21G,22G, 23G,24G	
72.	M/s. East Health Care  A-17/1 ground floor Gulshan e Iqbal Block 6	Legal Manufacturer: M/s Hangzhou Rollmed Co., Ltd. Room 913, Yuanmao Mansion, No. 5, Wen'er	Brand Name; KAYO BUTTERFLY NEEDLE Generic Name; Blood collecting Needle Class: B	Deferred for submission of copy of complete application and fee for the family.

	Karachi.	West Road, Hangzhou, Zhejiang Province, P. R China.	Years	
	ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	FSC: China Validity: Valid 19 sep 2026  LOA	Sizes 21G, 22G, 23G, 24G, 26G, 27G	TARM
73.	JF International 4th Floor, 10-C, 6th sunset commercial Lane Phase 2 EXT DHA Karachi Pakistan (ELI-00246) Evaluator: AD-VI	Validity: 31/12/2028  CONTEC MEDICAL Systems., Ltd. No. 112 Qinhuang West Street, Economic & Technical Devolpment Zone, Qinhuangdao, 066004, Hebei Province China FSC: China Valid Till: 26-8-2020	<u> </u>	Deferred for submission of original valid FSC of RRA or Valid CE.
74.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.  ELI-00066 1443-C 04-04-2023	Legal Manufacturer: Guangdong Wondfo Biotech Co., Ltd No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China.  FSC China valid till 21-01-24	Safety One Step HIV I/2 Whole Blood/Serum Test  Class-D  Shelf life: 2 years  Code: W006-C	Deferred (last opportunity) for submission of;  1. Original documents including Credentials, LOA, FSC of China, FSC of any RRA country, ISO 13485, FQA and DE certificates.  2. Labels of applied codes.  3. Copy of fee challan.
75.	A. Feroz & Co  Medicine street No. 1,  Marriot Road Karachi.  ELI-00066	Legal Manufacturer: Guangdong Wondfo Biotech Co., Ltd  No. 8 Lizhishan Road Science City, Luogang District, 510663,	Safety One Step  Dengue IgG/IgM Whole Blood/Serum/Plasma Test cassette  Class-C	Deferred (last opportunity) for submission of;  1. Original documents including Credentials, LOA,

	1521-C	Guangzhou. P.R. China		FSC of China, FSC
	11-04-2023		Shelf life: 2 years	of any RRA country, ISO 13485,
		FSC China valid till		FQA and DE
		21-1-24	Code:	certificates.
		FSC Belgium issuance	W109-C	2. Labels of applied codes.
		23-09-2022	MISI	3. Copy of fee challan.
76.	A. Feroz & Co	Legal Manufacturer:	Safety Combined	Deferred (last
	Medicine street No. 1,	Guangdong Wondfo	Diagnostic kit	opportunity) for submission of;
	Marriot Road Karachi.	Biotech Co., Ltd	Dengue NSI Antigen and IgG/IgM Antibody test	1. Original
		No. 8 Lizhishan Road Science City, Luogang	(Colloidal Gold)	documents
	ELI-00066	District, 510663,	(Conoldar Gold)	including Credentials, LOA,
	1457-C	Guangzhou. P.R. China	Class-C	FSC of China, FSC
	04-04-2023	50000	Clubb C	of any RRA country, ISO 13485,
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	FSC China valid till	Shelf life: 2 years	FQA and DE
		21-1-24	2.1011 1.101 2 yours	certificates.
		FSC Belgium issuance	Code:	2. Labels of applied codes.
		23-09-2022	W111-C	3. Copy of fee
	adine			challan.
77.	A. Feroz & Co	Legal Manufacturer:	Safety One Step	Deferred (last
	Medicine street No. 1, Marriot Road Karachi.	Guangdong Wondfo Biotech Co., Ltd	One Step Malaria HRP2/pLDH (P.f/P.v) test	opportunity) for submission of;
		No. 8 Lizhishan Road	1:6/1001	1. Original documents
	ELI-00066	Science City, Luogang District, 510663,	Class-C	including
	1456-C	Guangzhou. P.R. China	el i	Credentials, LOA, FSC of China, FSC
	04-04-2023	180 a	Shelf life: 2 years	of any RRA
		FSC China valid till		country, ISO 13485, FQA and DE
		21-1-24	Code:	certificates.
	Y	FSC Belgium issuance	W056-C	2. Labels of applied
		23-09-2022		codes.
		197,		3. Copy of fee challan.
78.	A. Feroz & Co	Legal Manufacturer:	Safety One Step	Deferred (last
	Medicine street No. 1,	Guangdong Wondfo		opportunity) for submission of;
	Marriot Road Karachi.	Biotech Co., Ltd	Blood/Serum/Plasma Test	1. Original
L		l .	I .	3115111di

	ELI-00066 1520-C 10-04-2023	No. 8 Lizhishan Road Science City, Luogang District, 510663, Guangzhou. P.R. China FSC China valid till 21-1-24 FSC Belgium issuance 23-09-2022	cassette  Class-C  Shelf life: 2 years  Code: W041-C	documents including Credentials, LOA, FSC of China, FSC of any RRA country, ISO 13485, FQA and DE certificates.  2. Labels of applied codes.  3. Copy of fee challan.
79.	a.feroz & co medicine street no 1, marriot road karachi. (ELI-00066	GUANGZHOU WONDFO BIOTECH CO, LTD NO 8 LIZHISHAN ROAD SCIENCE CITY, LUOGANG CHINA FSC CHINA VALID TILL	SAFETY ONE STEP TROPONIN 1 WHOLE BLOOD/ SERUM / PLASMA TEST Sizes: As per FSC Shelf Life: As per Data	Deferred (last opportunity) for submission of;  1. Original documents including Credentials, LOA, FSC of China, FSC of any RRA country, ISO 13485, FQA and DE certificates.  2. Labels of applied codes.  3. Copy of fee challan.
80.	A&E Medical 323-ATA Turk Block New Garden Town, Lahore ELI-00023 Dossier# 977-C Submission date: 27/12/2022 Evaluator: DD-III	Legal Manufacturer: Fiab S.p.A Via. P. Costoli 4, 50039 Vicchio (FL) Italy  FSC: Italy  Issued on: 16/01/2019	Disposable Electrosurgical Grounding plates with connection cable Codes & Sizes: As per FSC Class-C Shelf Life: 4 years	Deferred for provision of clarification of grouping along with Cartalogue nad valid FSC
81.	A&E Medical 323-ATA Turk Block New Garden Town, Lahore ELI-00023 Dossier# 976-C	Legal Manufacturer: Fiab S.p.A Via. P. Costoli 4, 50039 Vicchio (FL) Italy	Disposable Sterile Hand Switch Electrosurgical Pencils Codes & Sizes: As per FSC Class-C	Deferred for provision of clarification of grouping along with Cartalogue nad valid FSC

	Submission date:		Shelf Life: 4 years	
	27/12/2022	FSC: Italy	Shell Elle. Tyems	
	Evaluator:	•		
		Issued on:		
	DD-III	16/01/2019		
82.	M/s. Maqsood Brothers		LIFE CARE PLUS (Sterile	Approved with
	Office No. 503-B, 5th Floor, Saima Trader	Medical Products Co., Ltd.	Self Destruction Safety Syringe / Auto-Disable	correct sizes 3ml, 5ml, 10ml and 20ml
	Tower, I.I Chundrigar	Yan Tai Industrial Park,	0.5ml & 1ml)	and valid FSC
	Road Karachi.	Ding Tao County (The	5.6.111 62 75117	and valle 1 50
	(ELI-00282)	East of Zhanqian Road)	Class: B.	
		Heze, Shandong Province,	Shelf life: 03-years.	
	Evaluator	China.		
	AD-VI.	FSC China.	100	
	-3766-	70, 10		
83.	Unisa Pvt. Ltd. Main GT Road	UNiViTEX Nitrile Powder Free	Made from synthetic nitrile rubber, offering a latex-free	Approved subject to;
	Adamzai Akora Khattak,	Examination Gloves,	alternative ideal for	,
	Nowshera KPK Pakistan	XS, S, M, L, XL	individuals with	1. verification of the
	(ELM-0002)		latex allergies.	manufacturing facility by area FID.
		Class: A		2. Submission of fee
	[758-6L]	Shelf Life: 5 Years		for family.
	[110 02]	Fee: 6000		
		Fee Slip No. 1514425744		1 1
84.	Unisa Pvt. Ltd.	UNiViTEX	UNiViTEX Latex Pre-	Approved subject
04.	Main GT Road	Latex Pre-Powdered	Powdered Gloves combine	to;
	Adamzai Akora Khattak,	Examination Gloves,	natural rubber elasticity	,
	Nowshera KPK Pakistan	XS, S, M, L, XL	with medical-grade	1. verification of the manufacturing
	(ELM-0002)		cornstarch for reliable	facility by area FID.
		Class: A	barrier protection, tactile precision, and user comfort.	2. Submission of fee
	[758-6L]	Shelf Life: 5 Years	Their formulation balances	for family.
	[,]	Fee: 6000	durability, allergen	
		Fee Slip No. 0585046989	management, and	
		1 55 Shp 110. 050501070707	compliance with global	
	D	2 O V COY	standards, making them versatile for medical and	
	<b>Y</b>	613	industrial applications.	
85.	Unisa Pvt. Ltd.	UNiViTEX	UNiViTEX Latex Powder-	Approved subject
	Main GT Road	Disposable Non-Sterile	Free Examination Gloves	to;
	Adamzai Akora Khattak,	Latex Powder Free	made from natural latex	1. verification of the
	Nowshera KPK Pakistan	Examination Gloves,	rubber for superior	manufacturing
	(ELM-0002)	XS, S, M, L, XL	elasticity, tactile sensitivity, and fit.	facility by area FID.
	"VIQ"		and III.	2. Submission of fee

	[758-6L]	Class: A		for family.
		Shelf Life: 5 Years		
		Fee: 6000 Fee Slip No. 0585046989		
86.	Unisa Pvt. Ltd. Main GT Road Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002)  [758-6L]	UNIVITEX Disposable Latex Powder Free Sterile Single Use Only Surgical Gloves, XS, S, M, L, XL  Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 884032824469	UNIVITEX Disposable Latex Powder-Free Sterile Surgical Gloves are designed for high-precision medical procedures requiring sterility, tactile sensitivity, and durability.  Available in sizes 6.0 to 9.0 (in 0.5 increments), they cater to diverse hand sizes, ensuring optimal fit and performance in critical healthcare environments.	Approved subject to;  1. verification of the manufacturing facility by area FID.  2. Submission of fee for family.
87.	Unisa Pvt. Ltd. Main GT Road Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002)	UNiViTEX Disposable Latex Surgical Gloves (Powdered), Sizes 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0  Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 071765457519	UNIVITEX Latex Surgical Gloves are premium-quality, powdered gloves designed for medical and surgical applications. Available in sizes 6.0 to 9.0, they cater to a wide range of hand sizes, ensuring a secure and comfortable fit for healthcare professionals.	Approved subject to;  1. verification of the manufacturing facility by area FID.  2. Submission of fee for family.
88.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000.  ELI-00415 31,000/-	Legal Manufacturer: Bonree Medical Co., Ltd 1st Floor of Building No. 2, Building No. 4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, People's Republic of China.  FSC: China Validity: 24-10-2025 LOA validity 30-12-2028 ISO 13485 Validity 31- 07-2025	Endotracheal Tubes	Approved subject to submission of fee for family valid original FSC.

extension notification I.D.7.5, letter. I.D.8.0,	
1005	
I.D.8.5, I.D.9.0,	
I.D.9.0, I.D.9.5,	
I.D.10.0,	
89. Cabbot Surgicals, Legal Manufacturer: Bonree Feeding Tubes	Approved subject to
09 Rose Lane 1 Gulberg Bonree Medical Co., Ltd	submission of fee
Avenue New Lalazar 1st Floor of Building No.	for family valid
Rawalpindi 46000. 2, Building No. 4, Class-B	original FSC.
Longzhu Village	
ELI-00415 Economic Estate, Shelf Life: 5 Years	
31,000/- Longzhu Avenue,	
Nanlang, 528451	
Zhongshan, Guangdong, People's Republic of Fr.4	
Chies	
II3,	
FSC: China Fr6, Fr8,	
Validity: 24-10-2025 F18, Fr10,	
LOA validity 30-12-2028 Fr12,	
ISO 13485 Volidity 31 Fr14,	
07 2025	
CE certificate with Fr20,	
extension notification	
letter.	
90. Cabbot Surgicals, <u>Legal Manufacturer:</u> Bonree Ureteral Cathet	ters Approved Bonree
09 Rose Lane 1 Gulberg Bonree Medical Co., Ltd	Ureteral Catheters
Avenue New Lalazar 1st Floor of Building No.	Straight Tip Closed,
Rawalpindi 46000. 2, Building No. 4, Class-B	subject to
Longzhu Village	submission of fee
ELI-00415 Economic Estate, Shelf Life: 5 Years	for family and valid
31,000/- Longzhu Avenue, Nanlang, 528451	original FSC
Zhongshan Guangdong	
Paople's Papublic of Type	Noned Einer
China Straight Tip C	Closed Firm will apply
Straight Tip	Open separately for Bonree Ureteral
FSC: China Size	Catheters Straight
Validity: 24-10-2025 Straight Tip Closed:4	
	7.0FR
ISO 13485 Validity 31- Streight Tip Open 4	OED
07-2025 Straight Tip Open:4	·.0FR,   7.0FR
CE certificate with	
extension notification	

		letter.		
91.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000.  ELI-00415 6040-P 62,000/-	Legal Manufacturer: Changzhou Haida Medical Equipment Co., Ltd Sanhekou Industrial Zone, Zhenglu Town, Tianning Dist., Changzhou City, Jiangsu Province, China.  FSC: Germany Date of Issuance: 11-03- 2024.  FSC: China. Date of Validity: 06-08- 2024.  LOA validity 01-03-2030 ISO 13485 validity 28-02- 2025  FQA certificate validity 26-05-2024		Approved Hygiene Disposable Skin Stapler subject to differential fee
92.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000.  ELI-00415 6041-P 62,000/-	Legal Manufacturer: Changzhou Haida Medical Equipment Co., Ltd Sanhekou Industrial Zone, Zhenglu Town, Tianning Dist., Changzhou City, Jiangsu Province, China.  FSC: Germany Date of Issuance: 11-03- 2024.  FSC: China. Date of Validity: 06-08- 2024.  LOA validity 01-03-2030 ISO 13485 validity 28-02- 2025  FQA certificate validity 26-05-2024	Disposable Linear Cutter Stapler Disposable Linear Cutter Stapler  Class-C Shelf Life: 5 Years  Product Code: HQ-60L/M/H, HQ-80L/M/H, HQZ-60L/M/H, HQZ-80L/M/H, HQZ-100L/M/H, HQZ-100L/M/H, HQZ-100L/M/H, HQZ-60H, HDQ-60H, HDQ-80L,	Approved

			HDQ-/80M,	
			HDQ-80H, HDQ-100L,	
			HDQ-100M, HDQ-100H,	MA
			HDQZ-60L, HDQZ-60M,	17 ARM
		adir	HDQZ-60H, HDQZ-80L,	
		Aul Grado	HDQZ-80M, HDQZ-80H,	
		Programme big	HDQZ-100L, HDQZ-100M,	
		180 V	HDQZ-100H.	
93.	M/s Haji S. Ameer Din	Legal Manufacturer:	Good-Lite	Deferred for;
	& Sons 305-A Upper Mall Lahore.	Good-Lite Company,	Eye Examination Tools	1. Submission of
	(ELI-00059)	1155 Jansen Farm Drive Elgin, IL 60123, USA.	Class-A	separate application for each medical device.
	Fee-5,000/-	187,		2. Justification of
	April 2024 submission	FSC: USA.	Shelf Life: N/A	grouping.
	April 2024 submission	Validity: 09-01-2025.	Models:	3. Submission of brochure and product catalogue.
		adir	Handheld Bagolini striated Lens Set	
		And Gold	Loose individual prism set 22pcs	
		Mod Dire br	GL Horizontal & Vertical Prism Bar	
		"311, 16p	Set	
		sistant Dir Pr	Worth 4 – dot attachment for muscle	
		9 (0, 30.	light with adult red/green glasses	
		201,	GL Retinoscopy Paddles w/Axis	
	C.		Compass	
	Ane		Heavy duty Hertel	
	Medhes		Exophthalmometer	

			CL OWN Days 10	
			GL OKN Drum 10	
			GL expanded Amsler Grid book	
			GL Tangent screen 22.5-degree one	Ma
			meter roll-up	1
94.	M/s Haji S. Ameer Din		HEINE	Approved HEINE
	& Sons 305-A Upper Mall Lahore.	HEINE Optotechnik GmbH & Co. KG. (Dornierstr 6, 82205	LARYNGOSCOPES	LARYNGOSCOPE S
	(ELI-00059)	Gilching, Germany)	Class-A	Classic+ macintosh subject to valid original FSC.
	Fee-5,000/- 2021 submission	FSC: Germany 22-06-2020	Service Life: 7 years	
		sister Wooten	Models:	Firm will submit separate application for HEINE
		5 (0), 80,	Classic+ macintosh	LARYNGOSCOPE
	,		Flex tip+ macintosh	S
		937,		Flex tip+ macintosh.
95.	Haji S. Ameer Din and Sons,305-A Upper Mall Lahore.ELI: 00059 1566- P 10-07-2020	Legal Manufacturer:HAAG- STREIT AG 10 Gartenstadtstrasse, 3098 Koeniz SwitzerlandFSC: Switzerland Valid till: 14.06.2022	HAAG-STREIT Diagnostic (Biometer Lenstar LS 900) Class B	Approved Biometer Lenstar LS 900 Pro subject to valid original FSC.
		11.00.2022	Shelf life: not mentioned	Firm will submit
		About Direction	Models: LENSTAR LS 900 Pro (7220096/1009000) LENSTAR LS 900 Pro T- Cone (7220400/1009000)	separate application for LENSTAR LS 900 Pro T-Cone.
96.	Name	Legal Manufacturer	WAXBIO-CERA PARA OSSO	Deferred for submission of FSC
	Cardio Life	6,19	Bone Wax-Wax Bio Sterile	of RRA/CE
	Address of Importer	Bioline Fios Cirurgicos LTDA	Surgical Hemostates	marking certificate/WHO
	House No. 534, Ground			pre-qualification.
	Floor Lane 1, Main Khayaban e Tanveer,	(Manufacturing site)	Sticks or Tablets containing	_ ^
	Scheme 3 Rawalpindi	AV. Maranhao, N 500, Bairro Jundiai, Cep	2.5g, 3.0g and 5.0g	
	(ELI-00984)	75.110-470 Anapolis –		

		GO Brazil	Class C	
			Shelf life: 05 Years	AN
97.	Name Cardio Life Address of Importer House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi (ELI-00984)	Legal Manufacturer  Bioline Fios Cirurgicos LTDA  (Manufacturing site) AV. Maranhao, N 500, Bairro Jundiai, Cep 75.110-470 Anapolis – GO Brazil	Biofita-Surgical-Tapes  Class C  Shelf life: 05 Years  Codes/Sizes:  Cardiac Biotape in individual and sterile packaging packed into boxes containing 12, 24 or 36 Units, Dimensions	Deferred for submission of FSC of RRA/CE marking certificate/WHO pre-qualification.
98.	M/s. F.W	Legal Manufacturer:	between 1MM and 5 MM in width and 40cmto 120cm in length	Rejected the case
90.	DISTRIBUTOR	CERACARTA SPA	ECG ELECTRODE	because firm has;
	S, F.w building, opposite Poonch house, Adamjee road, saddar, Rawalpindi.	SECONDO CASADEI N*14, Z.I. VILLA SELVA, 47122 FORLI	Class A	Submitted Free Sale Declaration issued by the manufacturer himself.
	ELI:00221.	(FC), ITALY CERACARTA S.p.A. Sede	Claimed Shelf Life:03 years	2. not submitted prescribed fee for
		Legale e Operativa Via Secondo Casadei 47122	Codes / Sizes: ST 50 RFI	the family.
		Forlì Italy	ST 50 RLI	
	P	FSC: ITALY Validity:	RT 50 RFI NP 30 RFI	
	408	Indefinite period LOA Validity: indefinite period		
99.	AA Traders, P-871-B Basement Chen One	LegalManufacturer:SejoyBiomedicalCo.,	Sejoy Easy Check	Deffered for;

	Road, People Colony No.1, District Faisalabad,	Ltd. Address:	Blood Glucose Test Strip	1. submission of revised Form 7A for
	Pakistan ELI: 00836	Area C, Building 2, No. 365, Wuzhou Road, Hangzhou City, 311100	Class-B	class C.  2. Codes as per FSC.
	Fee 31,000/-	Zhejiang, Peoples Republic of China.	.6)	
		FSC: China. Validity: 09-05-2026.	Model: BG-500	
		LOA issuance 03-01-2025 ISO 13458 validity 18-06- 2026	olishe 125,	
		CE validity 26-05-2024 with extension notification letter	lost,	
100.	AA Traders, P-871-B	<b>Legal Manufacturer:</b>	, , ,	Deffered for;
	Basement Chen One Road, People Colony	Sejoy Biomedical Co., Ltd.	Blood Glucose Monitoring System	1. submission of
	No.1, District Faisalabad,	Address:	System	revised Form 7A for
	Pakistan	Area C, Building 2, No.	Class-B	class C.
	ELL 00026	365, Wuzhou Road,	C1-161 'C 2 W	2. Codes as per FSC.
	ELI: 00836	Hangzhou City, 311100 Zhejiang, Peoples	Shelf Life: 3 Years	rsc.
	Fee 31,000/-	Republic of China.	Model:	DU
	Meor	FSC: China. Validity: 09-05-2026.	BG-500	
		LOA issuance 03-01-2025	1/1,9 0:2	
		ISO 13458 validity 18-06-2026	lishe 25.	
		CE validity 26-05-2024 with extension notification letter	ioei, so,	
101.	Opti Med, 2nd Floor	Legal Manufacturer:	CF X-Linker with Kit	1 1
	Hassan Plaza 6A Jail	Iromed Group S.R.L	(RiboFast and Ribocross	Linker subject to
	Road lahore 54000 Pakistan.	Via Tempio del Cielo 3/5 00144 Rome, Italy	TE)	submission of valid original FSC.
		LOA:	Class-B	
		Validity 14-04-2028		Cases of Kit
	ELI-00501	90.7	Ch.161'6 2	(RiboFast and
	25,000/-	FSC: Country of Origin	Shelf life: 2 years for kit	Ribocross TE) will be process
	25,000/-	Validity 30-06-2025		separately as per
	VISO	·	Codes:	submitted
		EC:		

		Validity 30-12-2028		applications.
		ISO 13485: Validity 28-05-2025		
102.	Opti Med, 2nd Floor Hassan Plaza 6A Jail Road lahore 54000 Pakistan.	Legal Manufacturer:  H.P. Braem AG Manufacturing Site; Industriestrasse 4, CH- 9552 Bronschhofen, SWITZERLAND.  LOA: Validity 19-01- 2026 FSC: Validity 06-02- 2026 Country of Origin SWITZERLAND  EC: Validity 07-03-2028 ISO 13485: Validity 03- 07-2025	Phaco Handpiece with tip and sleeve  Class: B  Shelf Life: 5 Years  Code/Sizes: Phaco Handpiece (12300, 12350)  Phaco accessories Set with tip (12306, 12308)  Fragmatome Phaco tip (12333)	Approved Phaco Handpiece (12300, 12350) subject to submission differential fee for family.  Firm will apply separately for Phaco accessories Set with tip & Phaco tip (12333) Silicon sleeve.
		day,	Silicon sleeve (12355, 12356)	A
	Surgi Plast, Plot No.78, Road L-4, Industrial Estate, Gadoon Amazai, Swabi, KPK (ELM-0030 valid till 10- 06-2021, Renewal application submitted dated 02-06-2021) [928-7L] D. No. 13532 dated 19- 05-2025  Additional Sections approved vide letter No.F.4-13/2025-Md (M- 89 dated 13-05-2025.  1. Butterfly Needle Section/Facility 2. IV cannula (Packing, Labelling, Sterilization and Testing) Section/Facility	Clinic IV Cannula with Different Gauge Needle (16G/18G/20G/21G/22G/ 24G/26G)  IV Disposable Cannula with different Gauge needle (16G/18G/20G/21G/22G/ 24G/26G)  Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 2064126991	IV Disposable Cannula	Approved Clinic IV Disposable Cannula with wings and injection port subject to submission of differential fee .

104.	Applicant Name:	Name of Manufacturer:	Brand name:	Deferred the case
		W.C. III	Y Connector Set	for clarification that;
	Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi	medK GmbH, Borkstrasse 10, 48163 Muenster, Germany	Generic Name: Hemostatic Valve and Accessories	<ol> <li>manufacturing site not mentioned on ISO and FSC.</li> <li>justification for applying all codes</li> </ol>
	Kiluliu Society, Karacili	Manufacturing Site:	Class-A	as single.
	ELI-01292	Shanghai Kindly Medical Instruments Co., Ltd.,	Shelf life: 03 years	3. As per all submitted
	Date of R&I 07-04-2025	No. 925, Jin Yuan Yi Road, Jiading District,	Models/ Specification	documents manufacturer is "medK GmbH,
	07-04-2023	201803, Shanghai, China	9822900120	Borkstrasse 10,
	Fee Details:	Stall New	9822905120	48163 Muenster, Germany"
	Paid Fee: 6,000/-	LOA Validity:	9822910110	Germany
	Fee Challan No:	31-12-2025	9822910120	
	0568076152		9822915110	
	Dated: 24-03-2025	FSC: Germany	9822915120	
		<b>Issue date</b> : 27-06-2024	9822915150	
	000		9822903120	'Ell
	dille	ISO Validity:	9822908120	TAM
	Ne	08-10-2024	9822913120	
		1114	9822904120	
		Ost	9822909120	
		1110000	9822914120	
		" Morning	9822900100	
		Bo 'D' A	9822900150	
		sistant Neb septen	9822916110	
		cision is	9822916150	
	D	500	9822900112	
		6,13	9822900116	
			9822900122	
		797,	9822900126	
	C.		9822900156	
	dillo		9822901122	
	Nes		9822901152	

	, Nednes	Issue date: 27-06-2024 ISO Validity:	psi, sterile Push Click Y PTCA Connector, with 25 cm Extension line and STP 45	
	Dated: 25-03-2025	FSC: Germany	Connector, with 25 cm Extension line and STP 45	
	Fee Challan No: 9757711310		Tuohy Borst Y PTCA	
	Paid Fee: 6,000/-	31-12-2025	Push Pull Y PTCA Connector, sterile	4. Brand name
	Fee Details:	LOA Validity:	Connector, sterile Push Click Y PTCA Connector, sterile	48163 Muenster, Germany".
	Date of R&I 07-04-2025	Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China	Models/ Specification: Tuohy Borst Y PTCA Connector, sterile Push Rotate Y PTCA	submitted documents manufacturer is "medK GmbH, Borkstrasse 10,
	Khund Society, Karachi ELI-01292	Manufacturing Site:	Class-A Shelf life: 03 years	<ol> <li>justification for applying various types in single.</li> <li>As per all</li> </ol>
	Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail	Borkstrasse 10, 48163 Muenster, Germany	Generic Name: Hemostatic Valve	1. manufacturing site not mentioned on ISO and FSC.
105.	Applicant Name:	Name of Manufacturer:	Brand name: Y-PTCA Connector	Deferred the case for clarification that;
	<b>V</b>	9,13	9822916152	
	D	35,016,066	9822916116	
		isto William	9822916112	
		"301 180 a	9822915112	
		Mo. Oli bi	9822913122	
		AUI CCC	9822911126	
		, Q.o. *0	9822910136	
		dill	9822910152 9822910156	
			9822910122	
			9822910116	1
			9822910112	V VIII
			9822908122	
			9822905122	
			9822903122	

		08-10-2024	psi, sterile	
			Push Click Y PTCA	
			Connector, with 25 cm	
			Extension line and MP STP	
			500 psi, sterile	
			Push Pull Y PTCA	
			Connector, with 25 cm	
			Extension line and STP 45	
			psi, sterile	<b>*</b>
			Push Pull Y PTCA	
		20.	Connector, with 50 cm	
		. G	Extension line and STP 45	
			psi, sterile	
		70. 480	Tuohy Borst Y PTCA	
		"/O OII O	Connector, with 50cm	
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Extension line and STP 45	
		00	psi, Sterile	
		40, Me. 4	Push Rotate Y Connector	
		19, 7, 40,	with 50 cm Extension line	
		2, 10 00	and STP 45 psi, sterile	
		5 (0), 60,	Push Click Y PTCA	
		(4)	Connector, with 50 cm	
			Extension line and STP 45	
		.03'	psi, sterile	
		0.00	Tuohy Borst Y PTCA	
			Connector, with 50 cm	
	100		Extension line and MP STP	
	1801		500 psi, sterile	
	Ne		Push Rotate Y connector	
		.4.6	with 50 cm Extension line	
			and MP STP 500 psi, sterile	
			Push Click Y PTCA	
		, G- ,0	Connector, with 50 cm	
		i ill cili	Extension line and MP STP	
			500 psi, sterile	
106.	Applicant Name:	Legal Manufacturer:	Introducer set	Deferred the case
		modV CmbII	Vascular catheter	for clarification
		medK GmbH,	Introduction Set	that;
	Global Biotech Medical	Borkstrasse 10, 48163		1
	Devices (Private)	Muenster, Germany	Class-B	1. manufacturing
	Limited, First Floor, Plot	5 01 - 68		site not mentioned
	No. 34-N/3, PECHS	F (0', 50'	Shelf life: 3 Years	on ISO and FSC.
	Block-6, Near Rohail	~.1 ~		2. justification for
	Khund Society, Karachi	Manufacturing Site:		applying various
			Models/ Specification:	types in single.
		Shanghai Kindly Medical	Introducer Set, 5 Fr, 90 cm	
	ELI-01292	Instruments Co., Ltd.,	Sheath / 970 mm Dilator /	3. As per all
	-01	No. 925, Jin Yuan Yi	18 g x 7 cm Needle, sterile	submitted
	Allie	Road, Jiading District,	Introducer Set, 5 Fr, 11 cm	documents
	Date of R&I	201803, Shanghai, China		manufacturer is
	07-04-2025		Sheath / 169 mm Dilator /	"medK GmbH,
1				1

0.038" x 45 cm Guide Wire Borkstrasse / 18g x 7 cm Clear Arterial 48163 Muenster, **Fee Details: LOA Validity:** Needle without Wings, Germany". Paid Fee: 31,000/-31-12-2025 sterile 4. Brand name Introducer Set, 6 Fr, 11 cm Fee Challan No: Sheath / 169 mm Dilator / 0882246092 **FSC:** Germany 0.038" x 45 cm Guide Wire Dated: 25-03-2025 / 18 g x 7 cm Clear Arterial Issue date: 27-06-2024 Needle without Wings, sterile Introducer Set, 7 Fr, 11 cm ISO Validity: Sheath / 169 mm Dilator / 08-10-2024 0.038" x 45 cm Guide Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 6 Fr, 11 cm EC Certificate Validity: Sheath / 169 mm Dilator/ 08-10-2023 0.035 ^ prime prime \*45 cm Gulde Wire / 18 g x 7 cm Arterial Needle Dear without Wings, sterile Introducer Set, 7 Fr, 11 cm Sheath / 169 mm Dilator/ 0.035 ^ prime prime \*45 cm Guide Wire / 18g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 8 Fr, 11 cm Sheath / 169 mm Dilator / 0.038 ^ prime prime \*45 cm Gulde Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile Radial Introducer Set, 5 Fr, 11 cm Sheath /169 mm Dilator / 0.021 ^ prime cm Guide prime \*45 Wire/21 g 1x4 cm Arterial Needle, sterile Radial Introducer Set, 6 Fr, 11 cm Sheath/169 mm Dilator/ 0.021<sup>^</sup> prime prime \* 45c Guide Wire/21 g 1x4 cm Arterial Needle, sterile

107.	Applicant Name:  Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS	Legal Manufacturer:  medK GmbH, Borkstrasse 10, 48163 Muenster, Germany	Radial Introducer Set, 6 Fr, 16 cm Sheath / 219 mm Dilator/ 0.021 ^ prime prime *45 cm Guide Wire/21 g 1 x4 cm Arterial Needle, sterile  Manifold Sets Manifold Sets (Fluid Transfer set general purpose)  Class-B	Deferred the case for clarification that;  1. manufacturing site not mentioned on ISO and FSC.
	Block-6, Near Rohail Khund Society, Karachi	Manufacturing Site:	Shelf life: 3 Years	2. justification for applying various types in single.
	ELI-01292	Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District,	Models/ Specification: Manifold Set, 3 Port, Right, ON, 500 psi / Control	3. As per all submitted documents
	Date of R&I 07-04-2025	201803, Shanghai, China	Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure	manufacturer is "medK GmbH, Borkstrasse 10,
	Fee Details:	<b>LOA Validity:</b> 31-12-2025	Line/120cm Pressure Monitoring Line 500 psi, sterile	48163 Muenster, Germany".
	Paid Fee: 31,000/-	O		4. Brand name
	Fee Challan No: 20130269101 Dated: 25-03-2025	FSC: Germany Issue date: 27-06-2024	Manifold Set, 3 Port, Right, OFF, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber	IT ARV
		<b>ISO Validity:</b> 08-10-2024	Line/120cm Pressure Monitoring Line 500 psi, sterile	
		EC Certificate Validity: 08-10-2023	Manifold Set, 3 Port, Left, OFF, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile	
	Medines	997,	Manifold Set, 3 Port, Right, ON, 500 psi / Control Syringe 12 ml LL / 180cm Vented Spike Line/180cm Vented Drip Chamber Line / 120cm Pressure	

Monitoring Line 500 psi, sterile Manifold Set, 3 Port, Right, ON, 500 psl / 180cm Vented Spike Line / 180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile Manifold Set, 3 Port, Right, ON, 500 psi / 180cm Vented Spike Line / 180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, HP Stopcock, 3 Way, OFF, 500 psi, sterile Manifold Set, 3 Port, Right, ON, 500 psi / Colour Coded Syringe 10 ml, LL, White / 180cm Vented Spike Line/180cm Vented Drip Chamber Line / 120cm Pressure Monitoring Line 500 psl, sterile Manifold Set, 3 Port, Right, ON, 500 psi / 275cm Vented Spike Line/275cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile Manifold Set, 3 Port, Right, OFF, 500 psi / 275cm Vented Spike Line/275cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile Manifold Set, 3 Port, Right, OFF, Green - Soft, 500 psi / Control Syringe 10 ml, Pad/Finger Palm Plate,

			LL/180cm Vented Spike Line/180cm Vented Drip Chamber Line /120cm	
			Pressure Monitoring Line 500 psi, sterile	
108.	Applicant Name:	Legal Manufacturer:	Manifold	Deferred the case
	Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail	medK GmbH, Borkstrasse 10, 48163 Muenster, Germany	Manifold (Non-active devices for anesthesia, emergency and intensive care)  Class-B	for clarification that;  1. manufacturing site not mentioned on ISO and FSC.  2. justification for
	Khund Society, Karachi	Manufacturing Site:	Shelf life: 3 Years	applying various types in single.
	ELI-01292  Date of R&I	Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China	Models/ Specification: HP Manifold, 3 Port, Right, OFF, Blue - Soft, RA, 500	3. As per all submitted documents manufacturer is
	07-04-2025		psi, sterile	"medK GmbH,
	Fee Details:	<b>LOA Validity:</b> 31-12-2025	HP Manifold, 3 Port, Right, ON, Blue - Soft, RA, 500 psi, sterile	Borkstrasse 10, 48163 Muenster, Germany".
	Paid Fee: 31,000/-	903		4. Brand name
	Fee Challan No: 808860841718 Dated: 25-03-2025	FSC: Germany Issue date: 27-06-2024	HP Manifold, 2 Port, Right, OFF, Blue - Soft, RA, 500 psi, sterile	7 AM
		ISO Validity: 08-10-2024	HP Manifold, 2 Port, Right, ON, Blue - Soft, RA, 500 psi, sterile	
		EC Certificate Validity:	HP Manifold, 3 Port, Right, OFF, Green - Soft, RA, 500 psi, sterile	
		08-10-2023	HP Manifold, 3 Port, Right, ON, Blue, RA, 500 psi, sterile	
		0130	HP Manifold, 3 Port, Right, OFF, White, RA, 500 psi, sterile	
	Anes	997	HP Manifold, 3 Port, Right, ON, Blue, with Extension Line, RA, 500 psi, sterile	
	Men		HP Manifold, 3 Port, Left,	

109.	Applicant Name:	Legal Manufacturer:	ON, Blue, RA, 500 psi, sterile  HP Manifold, 3 Port, Left, OFF, White, RA, 500 psi, sterile  HP Manifold, 2 Port, Right, ON, Blue, RA, 500 psi, sterile  HP Manifold, 2 Port, Right, OFF, White, RA, 500 psi, sterile  HP Manifold, 4 Port, Right, ON, Blue, RA, 500 psi, sterile  HP Manifold, 4 Port, Right, ON, Blue, RA, 500 psi, sterile  HP Manifold, 4 Port, Right, OFF, White, RA, 500 psi sterile  Pressure Monitoring Line	Deferred the case
	rr	medK GmbH,	Pressure Monitoring Line	for clarification
	Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail	Borkstrasse 10, 48163 Muenster, Germany	Class-B Shelf life: 3 Years	that; 1. manufacturing site not mentioned on ISO and FSC. 2. justification for
	Khund Society, Karachi	Manufacturing Site:	Models/ Specification: Pressure Monitoring Line,	applying various types in single.
	ELI-01292	Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District,	30 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile	3. As per all submitted documents
	Date of R&I 07-04-2025	201803, Shanghai, China  LOA Validity:	Pressure Monitoring Line, 60 cm, DEHP free PVC, 500 psi, Male/Female LL,	manufacturer is "medK GmbH, Borkstrasse 10,
	Fee Details:	31-12-2025	sterile	48163 Muenster, Germany".
	Paid Fee: 31,000/-	, (O, 20,	Pressure Monitoring Line,	4. Brand name
	Fee Challan No: 5822621260 Dated: 25-03-2025	FSC: Germany Issue date: 27-06-2024	90 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile	
	Medines	ISO Validity: 08-10-2024	Pressure Monitoring Line, 120 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile	

	EC Certificate Validity: 08-10-2023  Legal Manufacturer:	Pressure Monitoring Line, 150 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile  Pressure Monitoring Line 180 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile High Pressure Extension	Deferred the case
Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi  ELI-01292  Date of R&I 07-04-2025  Fee Details: Paid Fee: 31,000/- Fee Challan No: 16400565854 Dated: 25-03-2025	medK GmbH, Borkstrasse 10, 48163 Muenster, Germany  Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China  LOA Validity: 31-12-2025  FSC: Germany Issue date: 27-06-2024  ISO Validity: 08-10-2024  EC Certificate Validity: 08-10-2023	lines  Class-B  Shelf life: 3 Years  Models/ Specification: High Pressure Extension Line, 30 cm, PUR braided, 1200 psi, Male/Female LL, sterile  High Pressure Extension Line, 60 cm, PUR braided, 1200 psi, Male/Female LL, sterile  High Pressure Extension Line, 90 cm, PUR braided, 1200 psi, Male/Female LL, sterile  High Pressure Extension Line, 120 cm, PUR braided, 1200 psi, Male/Female LL, sterile  High Pressure Extension Line, 120 cm, PUR braided, 1200 psi, Male/Female LL, sterile  High Pressure Extension Line, 30 cm, PUR braided, 1200 psi, RA, sterile  High Pressure Extension Line, 60 cm, PUR braided, 1200 psi, RA, sterile  High Pressure Extension Line, 60 cm, PUR braided, 1200 psi, RA, sterile	for clarification that;  1. manufacturing site not mentioned on ISO and FSC.  2. justification for applying various types in single.  3. As per all submitted documents manufacturer is "medK GmbH, Borkstrasse 10, 48163 Muenster, Germany".  4. Brand name
Megli.		1200 psi, RA, sterile	

		O adili	High Pressure Extension Line, 120 cm, PUR braided, 1200 psi, RA, sterile  High Pressure Extension Line, 150 cm, PUR braided, 1200 psi, RA, sterile  High Pressure Extension Line, 150 cm, Balibraided, (Braided, 1200 psi, MRA-MRA, sterile	A AM
111.	M/s Global Biotech	Legal Manufacturer:	AltoSa-XL	Deffered for
	Medical Devices Private Limited	M/s AndraTec GmbH, Simmerner Str. 70, 56075	PTA Balloon Catheter	issuance of show cause notice/personal
	First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI	Koblenz Germany	Class: D	hearing to M/s SES Associates
	(ELI-01292)	LOA/sole agency :09-06- 2025 (copy of LOA)	Shelf life: 6 Years	
		197,	Codes/Sizes as per FSC	
	R&I date: 18-03-2025	FSC (Germany) Issue date:		Ma
	Fee Rs 62000/- vide Challan no. 7929936511	17-03-2024 (Notarized FSC)	MIS)	
		EC Certificate 28-10-2028 (Notarized EC certificate)	ligher) 9.5	
		ISO-13485 Validity:	10. 50	
		13-10-2027(Notarized ISO Certificate)	losi,	
112.	M/s Global Biotech Medical Devices Private	Legal Manufacturer:	Lokum Amplatz Type Guide Wire	Deffered for issuance of show
	Limited	M/s AndraTec GmbH, Simmerner Str. 70, 56075	Guide wife	cause
	First Floor of Plot No: 35-N/3, PECHS Block 6,	Koblenz Germany	Class: D	notice/personal hearing to M/s SES Associates
	Near ROHAIL KHUND SOCIETY KARACHI	0.00	Shelf life: 5 Years	
	(ELI-01292)	LOA/sole agency :09-06-		
	Nev	2025 (copy of LOA)	Codes/Sizes as per FSC	

		Т	Т	
	R&I date: 18-03-2025  Fee Rs 62000/- vide Challan no. 578461584572	FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)  EC Certificate 28-10-2028 (Notarized EC certificate)  ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	Jolisher) 9:55	TAN
112	M/a Clab -1 D: -4 1		The same	Deffered 1
113.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)  R&I date: 18-03-2025  Fee Rs 62000/- vide Challan no. 922023750630	Legal Manufacturer:  M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany  LOA/sole agency :09-06- 2025 (copy of LOA)  FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)  EC Certificate 28-10-2028 (Notarized EC certificate)  ISO-13485 Validity: 13-10-2027 (Notarized	Exeter Retrieval Snare preloaded Class: D Shelf life: 5 Years Codes/Sizes as per FSC	Deffered for issuance of show cause notice/personal hearing to M/s SES Associates
		ISO Certificate)		
114.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI	Legal Manufacturer:  M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany  LOA/sole agency :09-06-	AltoSa-XL Gemini Balloon Catheter PTA Balloon Catheter Class: D	Deffered for issuance of show cause notice/personal hearing to M/s SES Associates
	0 0 = t b 3 5			202122

	(ELI-01292)	2025 (copy of LOA)	Shelf life: 6 Years	
	R&I date: 18-03-2025  Fee Rs 62000/- vide Challan no. 71044293	FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)  EC Certificate 28-10-2028 (Notarized EC certificate)  ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	Codes/Sizes as per FSC	TAM
115.	M/s Global Biotech	Legal Manufacturer:	Optimus	Deffered for
	Medical Devices Private Limited	M/s AndraTec GmbH,	CoCr Stent	issuance of show cause
	First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND	Simmerner Str. 70, 56075 Koblenz Germany	Class: D	notice/personal hearing to M/s SES Associates
	SOCIETY KARACHI		Shelf life: 6 Years	
	(ELI-01292)	LOA/sole agency :09-06- 2025 (copy of LOA)	Codes/Sizes as per FSC	7 AM
	R&I date: 18-03-2025	FSC (Germany) Issue date:	(MI) 0:55	
	Fee Rs 62000/- vide Challan no. 667274866	17-03-2024 (Notarized FSC)	olishen 25, s	
		EC Certificate 28-10-2028 (Notarized EC certificate)	iper,	
		ISO-13485 Validity:		
	P	13-10-2027(Notarized ISO Certificate)		
116.	M/s Global Biotech Medical Devices Private Limited	Legal Manufacturer:  M/s AndraTec GmbH, Simmerner Str. 70, 56075	Optimus-CVS PTFE- Covered Stent	Deffered for issuance of show cause
	First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND	Koblenz Germany	Class: D	notice/personal hearing to M/s SES Associates

	SOCIETY KARACHI		Shelf life: 6 Years	
	(ELI-01292)	LOA/sole agency :09-06- 2025 (copy of LOA)	Codes/Sizes as per FSC	
	R&I date: 18-03-2025	FSC (Germany) Issue date:	.6)	1 AM
	Fee Rs 62000/- vide Challan no. 276311473	17-03-2024 (Notarized FSC)	1 (4)13 9:55	
		EC Certificate 28-10-2028 (Notarized EC certificate)	iolisus 2025,	
		ISO-13485 Validity:	10 <sub>81</sub> .	
		13-10-2027(Notarized ISO Certificate)		
117.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.  ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi- do, Republic of Korea.  Original FSC: Korea Date of Issuance: 30-08- 2024.  LOA validity 18-12-2029 ISO 13485 validity 29-03- 2026	EXTRA I  Sterile Absorbable Hyaluronic Acid Dermal Filler  Class-D  Shelf Life: 30 Months  Model/ codes as per FSC.	Approved.
118.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.  ELI-00673 62,000/-		EXTRA II  Sterile Absorbable Hyaluronic Acid Dermal Filler  Class-D  Shelf Life: 30 Months  Model/ codes as per FSC.	Approved.

		ISO 13485 validity 29-03- 2026		
119.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.  ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi- do, Republic of Korea.  Original FSC: Korea Date of Issuance: 30-08- 2024. LOA validity 18-12-2029 ISO 13485 validity 29-03- 2026	Sterile Absorbable	Approved.
120.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.  ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea.  Original FSC: Korea Date of Issuance: 30-08- 2024.  LOA validity 18-12-2029 ISO 13485 validity 29-03- 2026	EXTRA S Sterile Absorbable Hyaluronic Acid Dermal Filler Class-D Shelf Life: 36 Months Model/ codes as per FSC.	Approved.
121.	Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.  ELI-00673 62,000/-	Legal Manufacturer: Bioplus Co Ltd A-#901, #902, #903, #904, #905, #906, #907, 14, Sagimakgol-ro 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi- do, Republic of Korea.  Original FSC: Korea Date of Issuance: 30-08- 2024.  LOA validity 18-12-2029 ISO 13485 validity 29-03-	EXTRA H  Sterile Absorbable Hyaluronic Acid Dermal Filler  Class-D  Shelf Life: 36 Months  Model/ codes as per FSC.	Approved.

		2026		
122.	M/s Medco, 19-Khyber	Legal Manufacturer:	GEMSS Stationary	Approved subject to
	Bazar Peshawar	M/s Gemss Healthcare Co., Ltd., 822 Bogwang-Ro,	X-Ray System XVision-525	FSC
	ELI-00686	Gwangtan-myeon, Paju-Si Gyeonggi-Do, 10952 Korea	Digital X-Ray Machine	1 AM
	Date of R& I 19-05-2025		Applied as: Single	
	17-03-2023	LOA:	9.	
	Fee: Rs.31000/ through	Valid till: 31-12-2030	Class-C	
	slip no. 09271620709 and	FSC:	Shelf Life:	
		Validity:	100	
	Rs. 31000	icha March		
	70206399529	ISO - Validity Date: 22-01-	Model:	
	P	2026	XVision-525	
		EC Certificate Valid till: 05-06-2024		
123.	M/s Medco, 19-Khyber Bazar Peshawar ELI-00686	Legal Manufacturer:  M/s Gemss Healthcare Co., Ltd., 822 Bogwang-Ro, Gwangtan-myeon, Paju-Si Gyeonggi-Do, 10952 Korea	GEMSS Image Intensified Fluoroscopic X-Ray System (Mobile C-Arm)	Approved Subject To FSC
	Date of R& I	ill Octo	Class-C	
	19-05-2025	LOA:	101. Jo.	
	Fee: Rs.50000/ through	Valid till: 31-12-2030	Shelf Life:	
	slip no. 20521777101	isia Wiel		
	and	FSC:	Code/sizes:	
	Rs. 62000	Validity: Not provided	XPLUS 35	
	7607854166		XPLUS 35FD	
	7.507.55 11.00	ISO - Validity Date: 22-01- 2026		
	Meglue	EC Certificate Valid till: 05-06-2024		

124.	Applicant Name:	Legal Manufacturer:  M/s Ecotron Co. Ltd.,	Ecotron Image Intensified Fluoroscopic X-Ray System	Approved with following codes
	M/s Medco, 19-Kyber Bazar, Peshawar	505Ho, Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-gu, Seoul,	(Mobile C-Arm) Anyview Series Anyview 500DR, Anyview 500R, Anyview 240DR & Anyview 320DR	500DR & 500R
	ELI-00686	08511, Korea.	Mobile C-Arm	
	Date of R&I 19-05-2025	LOA Validity: 14-05-2029	Class-B Shelf life: 10 Years	
	Fee Details: Paid Fee: 50,000/-	ISO Validity: 18-02-2028	Models/specifications:  Anyview 500DR, Anyview 500R, Anyview 240DR	
	Fee Challan No: 7170434627	EC Certificate Validity: N/A	Anyview 320DR	
	408			AN
125.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Brand name:  EDTA K3 Blood Collection Tube Glass  Generic Name:  EDTA K3 Vaccum Blood Collection Tube	Approved.
	(ELI- 01225)	• LOA Type: Copy	eli	
	<b>R&amp;I detail</b> 15-05-2025	Notarization: Not notarized.	Class: A Codes/Sizes:	
	Fee: 25,000/- Slip: 09549959	<b>Validity:</b> 22-03-2027	2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,	
		• FSC Type: Copy Issued By: Govt. Body	Applied as: Family	
	Megli	<b>Legalization:</b> Not legalized	Shelf life: Not mentioned	

		Validity: 28-12-2025		
		• ISO Certificate Type: Original Notarization: Not notarized		AM
		Validity: 26-10-2025	(19)	
126.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan	Clot Activator/Separate Gel Blood Collection Tube Glass	
		Taizhou Zhejiang, China.	Generic Name:	
	(ELI- 01225)	• LOA Type: Copy	Gel + Clot Activator Vaccum Blood Collection Tube	
	<b>R&amp;I detail</b> 15-05-2025	<b>Notarization:</b> Not notarized.	Class: A	
	Fee: 25,000/-	Validity: 22-03-2027		
	<b>Slip:</b> 8114812075	900	Codes/Sizes:	
	dhe	• FSC Type: Copy	3ml, 4ml, 5ml, 6ml, 7ml, 8ml	1 AM
	Ne	Issued By: Govt. Body	(5)	
		<b>Legalization:</b> Not legalized	Applied as: Family	Þ
		<b>Validity</b> : 28-12-2025	"che up	
		1901 1600 E	Shelf life: Not mentioned	
		• ISO Certificate Type: Original	ner,	
		Notarization: Not notarized		
	D	<b>Validity:</b> 26-10-2025		
127.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan	Sodium Citrate Collection Tube PET	
	Ane	Taizhou Zhejiang, China.	Generic Name:	
	(ELI- 01225)	• LOA	Sodium Citrate Collection	

		Type: Copy	Tube	
	<b>R&amp;I detail</b> 15-05-2025	<b>Notarization:</b> Not notarized.	Class: A	
	Fee: 25,000/-	<b>Validity:</b> 22-03-2027	Codes/Sizes:	M
	<b>Slip:</b> 3201664	• FSC Type: Copy	1.28ml, 4.5ml, 1.6ml, 2.4ml, 2.7ml, 3.6ml, 1.8ml, 3.2ml	TA
		Issued By: Govt. Body	Applied as: Family	
		<b>Legalization:</b> Not legalized	isher)5,	
		<b>Validity</b> : 28-12-2025	Shelf life: Not mentioned	
		• ISO Certificate Type: Original	loe,	
	P	Notarization: Not notarized		
		<b>Validity:</b> 26-10-2025		
128.	M/s. Biocept Intl., Co., Office No. 28-29, /E1,	Name of Manufacturer:	Brand name:	Approved.
	Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Clot Activator/Separate Gel Blood Collection Tube PET Generic Name: Gel + Clot Activator Vaccum Blood Collection	TAM
	(ELI- 01225)	• LOA Type: Copy	Tube Concentration	
	<b>R&amp;I detail</b> 15-05-2025	Notarization: Not notarized.	Class: A	
	Fee: 25,000/-	<b>Validity:</b> 22-03-2027	Codes/Sizes:	
	<b>Slip:</b> 307968530145	• FSC Type: Copy	3ml, 4ml, 5ml, 6ml, 7ml, 8ml	
	Y	<b>Issued By:</b> Govt. Body	<b>Applied as:</b> Family	
		<b>Legalization:</b> Not legalized	K K	
	09	<b>Validity</b> : 28-12-2025	Shelf life: Not mentioned	
	1601	• ISO Certificate		

Type: Original Notarization: Not notarized	
Validity: 26-10-2025	
129. M/s. Biocept Intl., Co., Name of Manufacturer: Brand name: Appro	oved.
Office No. 28-29, /E1, Old FCC Guberg III, M/s. Zhejiang SKG EDTA K2 Blood Collection	
Lahore. Let No. 39 Anye Road	
Gaoqiao Street Huangyan Generic Name:	
Taizhou Zhejiang, China. EDTA K2 Vaccum Blood Collection Tube	
(ELI- 01225) • LOA	
Type: Copy Class: A	
R&I detail Notarization: Not	
notarized. Codes/Sizes:	
Fee: 25,000/- Validity: 22-03-2027 2ml, 3ml, 4ml, 5ml, 6ml,	
Slip: 59176081 7ml, 8ml, 9ml, 10ml,	
• FSC	
Type: Copy Applied as: Family	
Issued By: Govt. Body	
Legalization: Not legalized	
Validity: 28-12-2025 Shelf life: Not mentioned	
Valuary, 25 12 2020	
• ISO Certificate	
Type: Original	
Notarization: Not	
notarized	
Validity: 26-10-2025	
130. M/s. Biocept Intl., Co., Name of Manufacturer: Brand name: Appro	oved.
Old FCC Guberg III, Medical Technology Co. Collection Tube Glass	
Ltd., No. 39, Anye Road Congric Name:	
Gaoqiao Street Huangyan	
Taizhou Zhejiang, China. Plain Vaccum Blood Collection Tube	
(ELI- 01225) • LOA	
Type: Copy Class: A	
R&I detail Notarization: Not	
15-05-2025 notarized.	

	Fee: 25,000/-	Validity: 22-03-2027	Codes/Sizes:	
	<b>Slip:</b> 6492402841	• FSC	2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,	
		<b>Type:</b> Copy		
		<b>Issued By:</b> Govt. Body	Applied as: Family	1 2
		<b>Legalization:</b> Not legalized	MIS) SS	
		<b>Validity</b> : 28-12-2025	Shelf life: Not mentioned	
		• ISO Certificate Type: Original	10181,505p	
		Notarization: Not notarized	pel,	
		Validity: 26-10-2025		
131.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	Medical Technology Co.,	EDTA K2 Blood Collection Tube Glass	
			Generic Name:	
	Taizhou Zhejiang, O	Taizhou Zhejiang, China.	EDTA K2 Vaccum Blood Collection Tube	Ma
	(ELI- 01225)	• LOA Type: Copy	Class: A	1 P
	R&I detail	Notarization: Not	(M), (2)	<b>&gt;</b>
	15-05-2025	notarized.	Codes/Sizes:	
	Fee: 25,000/- Slip: 473945571799	Validity: 22-03-2027	2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,	
		• FSC Type: Copy	<b>Applied as:</b> Family	
		Issued By: Govt. Body		
	0	<b>Legalization:</b> Not legalized	CL 16116 N	
		Validity: 28-12-2025	Shelf life: Not mentioned	
	29	• ISO Certificate Type: Original		
	1edne.	Notarization: Not notarized		

		<b>Validity:</b> 26-10-2025		
132.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Clot Activator Blood Collection Tube PET  Generic Name: Clot Activator Vaccum	T AM
	(ELI- 01225) <b>R&amp;I</b> detail	• LOA Type: Copy Notarization: Not	Blood Collection Tube  Class: A	
	15-05-2025 Fee: 25,000/- Slip: 52154302796	notarized.  Validity: 22-03-2027  • FSC	Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml	
	P	<b>Type:</b> Copy <b>Issued By:</b> Govt. Body	Applied as: Family	
		Legalization: Not legalized Validity: 28-12-2025	Shelf life: Not mentioned	
	Meque	• ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025	ingles of the state of the stat	TAR
133.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	Medical Technology Co., Ltd., No. 39, Anye Road	Brand name: Heparin/Sodium Fluoride Blood Collection Tube PET Generic Name:	Approved.
	(ELI- 01225)	Gaoqiao Street Huangyan Taizhou Zhejiang, China.  • LOA Type: Copy	Heparin/Sodium Fluoride Blood Collection Tube  Class: A	
	<b>R&amp;I detail</b> 15-05-2025 <b>Fee: 25,000/- Slip:</b> 33112274401	Notarization: Not notarized.  Validity: 22-03-2027  • FSC	Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml	

		Type: Copy		
		Issued By: Govt. Body	Applied as: Family	
		<b>Legalization:</b> Not legalized		
		<b>Validity</b> : 28-12-2025	Shelf life: Not mentioned	1 AR
		• ISO Certificate Type: Original Notarization: Not notarized	11 (MIS) 9:55	
		Validity: 26-10-2025	10. 10.	
134.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.  (ELI- 01225)  R&I detail 15-05-2025 Fee: 25,000/- Slip: 59504524272	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.  • LOA Type: Copy Notarization: Not notarized.  Validity: 22-03-2027  • FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025  • ISO Certificate Type: Original Notarization: Not notarized  Validity: 26-10-2025	No additive Blood Collection Tube PET  Generic Name: Plain Vaccum Blood Collection Tube  Class: A  Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,  Applied as: Family  Shelf life: Not mentioned	
135.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III,	M/s. Zhejiang SKG Medical Technology Co.,		**

	Lahore.	Ltd., No. 39, Anye Road	Collection Tube Glass	
		Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Generic Name:	
		Tuiznou Zhojiung, China.	Clot Activator Vaccum	
	(ELI- 01225)	• LOA	Blood Collection Tube	No.
		<b>Type:</b> Copy		1 2
	<b>R&amp;I detail</b> 15-05-2025	Notarization: Not notarized.	Class: A	
	Fee: 25,000/-	Validity: 22-03-2027	Codes/Sizes:	
	<b>Slip:</b> 74943844	• FSC Type: Copy	2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml	
		Issued By: Govt. Body	Applied as: Family	
		Legalization: Not legalized		
	P	<b>Validity</b> : 28-12-2025	Shelf life: Not mentioned	
		• ISO Certificate Type: Original		
	08	Notarization: Not notarized		M
	18:011	<b>Validity:</b> 26-10-2025		1
136.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road	Blood Collection Tube	
		Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Generic Name:	
	(ELI- 01225)	• LOA Type: Copy	Heparin/Sodium Fluoride Blood Collection Tube	
	R&I detail	Notarization: Not	Class: A	
	15-05-2025	notarized.		
	Fee: 25,000/-	Validity: 22-03-2027	Codes/Sizes:	
	<b>Slip:</b> 000990568446	• FSC	2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml	
		Type: Copy		
	dine	<b>Issued By:</b> Govt. Body	Applied as: Family	
	100	Legalization: Not		

		legalized		
		Validity: 28-12-2025	Shelf life: Not mentioned	
		• ISO Certificate		Al.
		Type: Original		
		<b>Notarization</b> : Not notarized	WIS)	
		<b>Validity:</b> 26-10-2025	1/1,41 01:20	
137.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Sodium Citrate Collection Tube Glass  Generic Name:	
	(ELI- 01225)	• LOA	Sodium Citrate Collection Tube	
	Y	Type: Copy	Class: A	
	R&I detail	<b>Notarization:</b> Not notarized.		
	15-05-2025	Validity: 22-03-2027	Codes/Sizes:	
	Fee: 25,000/- Slip: 015022500		1.28ml, 4.5ml, 1.6ml, 2.4ml, 2.7ml, 3.6ml, 1.8ml, 3.2ml	Ma
	Medir	• FSC Type: Copy Issued By: Govt. Body	Applied as: Family	
		<b>Legalization:</b> Not legalized	in the state of th	
		<b>Validity</b> : 28-12-2025	Shelf life: Not mentioned	
		• ISO Certificate Type: Original	loer,	
	D.	<b>Notarization</b> : Not notarized		
	X.	<b>Validity:</b> 26-10-2025		
138.	M/s. Biocept Intl., Co.,	Name of Manufacturer:	Brand name:	Approved.
	Office No. 28-29, /E1, Old FCC Guberg III, Lahore.	M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road	EDTA K3 Blood Collection Tube PET	
	Megli	Gaoqiao Street Huangyan Taizhou Zhejiang, China.	Generic Name:	

(ELI- 01225)		EDTA K3 Vaccum Blood
R&I detail	• LOA Type: Copy	Collection Tube
15-05-2025	Notarization: Not notarized.	Class: A
Fee: 25,000/- Slip: 397625294105	Validity: 22-03-2027	Codes/Sizes:
	• FSC Type: Copy	2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,
	Issued By: Govt. Body	Applied as: Family
	<b>Legalization:</b> Not legalized	
	Validity: 28-12-2025	Shelf life: Not mentioned
P	• ISO Certificate Type: Original	
	Notarization: Not notarized	
	Validity: 26-10-2025	

# Item No. IV (a): Deferred Cases of Local Manufacturing

S.No.	Name & Address of Establishment	Name of Medical Devices with Size	Decision of M-93
1.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhupura Road, Muridke,Distt. Sheikhupura ELM-0001	BM Disposable Heparin Cap (Heparin Cap) Class: B Shelf-life:5Years Sizes: Connector: Male Luer Lock Connector Color: Yellow and transparent Length: 18mm 19.32mm	The Board decided for confirmation of manufacturing and testing facilities by panel for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
	16ques	22mm Fee of 20,000 vide Challan No. 07486207625	
2.	NISA.SF Private Limited.	Dosiflow Plus	The Board decided to

	10-Km, Muridke, Sheikhupura Road, Muridke, Distt. Sheikhupura ELM-0001	Disposable flow regulator Extension Line Class: B Shelf-life: 3Years Sizes: 30 cm Types: 1. Dosiflow Plus  (with Y-port injection site). 2. Dosiflow Plus  (with Needle free valve, and side clamp). 3. Dosiflow Plus  (with Needle free Valve, side Clamp, and precision filter)	inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
3.	NISA.SF Private Limited.	Fee of 20,000 vide Challan No. 48643085 HP Disposable Stopcock	The Board decided for
	10-Km, Muridke, Sheikhupura Road, Muridke, Distt. Sheikhupura ELM-0001	with Extension Tube Stopcock Extension Tube (1 Way, 2 Way, 3 Way & 4 Way) Class: B Shelf-life:5Years Length: 10cm, 15cm, 20cm 25cm, 50cm,100cm Fee of 20,000 vide Challan No. 51757256	confirmation of manufacturing and testing facilities by panel for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
4.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhupura Road, Muridke, Distt. Sheikhupura ELM-0001	Super Stopper Disposable Stopcock with Extension Tube Stopcock Extension Tube Class: B Shelf-life:5Years Length: (1 Way, 2 Way, 3 Way & 4 Way) 10cm 15cm 20cm 25cm 50cm 100cm Fee of 20,000 vide Challan	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
5.	NISA S.F. Pvt Ltd. Office No.1, 1st	No. 11296827  BM Disposable Breathing	The Board decided to
	1 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1		

	Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM- 0001) [708-7L] Feb-2025	Bag Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 92330370662	inspect by the panel for confirmation of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
6.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM- 0001) [709-7L] Feb-2025 The firm has following approved sections as per record. 1. Auto Disable Syringes 2. Disposable Syringe 3. I.V. Cannula 4. I.V Products	BM Disposable Anesthetic Circuit Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 9611402310	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
7.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM- 0001) [710-7L] Feb-2025 The firm has following approved sections as per record. 1. Auto Disable Syringes 2. Disposable Syringe 3. I.V. Cannula 4. I.V Products	BM Disposable Oxygen Mask Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 823610502	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
8.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA Phase II, G.T Road, Islamabad (ELM- 0001) [711-7L] Feb-2025	BM Disposable Urine Bag Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 5078076597	The Board decided to inspect by the panel for confirmation of manufacturing and testing facilities and submit a clear and candid opinion regarding confirmation of requirements during manufacturing of applied product in relevant section.
9.	NISA S.F. Pvt Ltd. Office No.1, 1st Floor Maxim Arcade Usman Block Jeddah Town, Phase I, Opp DHA	BM Disposable Anesthetic Mask Class: B	The Board decided to inspect by the panel for confirmation of

	DI HOTED 111 1 1/FIM	Cl 1Cl :C 7 X	C 1
	Phase II, G.T Road, Islamabad (ELM-	Shelf Life: 5 Year	manufacturing and testing
	0001)	Fee: 25000 Fee Slip No.	facilities for the applied
	[712-7L]	89224587	product under aseptic
	Feb-2025		conditions to maintain the
			sterility of the product in
			the packing area.
10.	NISA S.F. Pvt Ltd. Office No.1, 1st	BM Disposable Breathing	The Board decided to
	Floor Maxim Arcade Usman Block	Circuit	inspect by the panel of
	Jeddah Town, Phase I, Opp DHA	Class: B	manufacturing and testing
	Phase II, G.T Road,	Shelf Life: 5 Year	facilities for the applied
	Islamabad (ELM-0001)	Fee: 25000 Fee Slip No.	product under aseptic
	[713-7L]	933019586	conditions to maintain the
	Feb-2025	, "e, "e, "U.S.	sterility of the product in
		100 1011	the packing area.
11.	NISA S.F. Pvt Ltd. Office No.1, 1st	BM Disposable Enteral	The Board decided to
	Floor Maxim Arcade Usman Block	Feeding	inspect by the panel for
	Jeddah Town, Phase I, Opp DHA	Class: B	confirmation of
	Phase II, G.T Road, Islamabad (ELM-	Shelf Life: 5 Year	manufacturing and testing
	0001)	Fee: 25000 Fee Slip No.	facilities and submit a
	[714-7L]	65267853330	clear and candid opinion
	Feb-2025		regarding confirmation of
	, 5.1		requirements during
			manufacturing of applied
	-14		product in relevant section.
	703		product in relevant section.

Accordingly, inspection was conducted by Mr. Muhammad Ansar, Deputy Director DRAP Islamabad.

## RECOMMENDATIONS

Based on the inspection of firm keeping in view of manufacturing, assembly and testing facility following 6 products are recommended-

- 1. BM Disposable Enteral Feeding Syringe/oral feeding syringe.
- 2. BM Disposable Urine Bag.
- 3. BM Disposable Oxygen Mask.
- 4. Super Stopper Disposable Stopcock with Extension Tube Stopcock Extension Tube.
- 5. HP Disposable Stopcock with Extension Tube Stopcock Extension Tube(1 Way, 2 Way, 3 Way, 4 Way).
- 6. Dosiflow Plus Disposable flow regulator Extension Line

The firm has submitted that they are developing manufacturing/assembly facility for the following products hence these products are not recommended till finalization of facility: -

1. BM Disposable Breathing Circuit.

- 2. BM Disposable Anesthetic.
- 3. BM Disposable Anesthetic Circuit.
- 4. BM Disposable Heparin Cap (Heparin Cap
- 5. BM Disposable Breathing Bag

## Decision: MDB decided the cases as follows on the recommendation of inspector;

Sr. No.	Product	Decision of the MDB
1	BM Disposable Heparin Cap	Rejected the case as panel informed that
	(Heparin Cap)	firm don't have the facility for
	Class: B	assembly & packing.
	Shelf-life:5Years	
	Sizes:	
	Connector:	700
	Male Luer Lock Connector	
	Color:	
	Yellow and transparent	
	Length:	
	18mm, 19.32mm, 22mm	
	Fee of 20,000 vide Challan No. 07486207625	
2	Dosiflow Plus	Approved Dosiflow Plus Disposable
	Disposable flow regulator Extension Line	flow regulator Extension Line as per
	Class: B	recommendations of the panel.
	Shelf-life: 3Years	
	Sizes:	1
	30 cm	.6)
	Types:	
	1. Dosiflow Plus	(10, 7 2.10)
	(with Y-port injection site).	
	2. Dosiflow Plus	in the obj
	(with Needle free valve, and side clamp).	115, 012
	3. Dosiflow Plus	10, 00,
	(with Needle free Valve, side Clamp, and precision	0. 4.
	filter)	,001,
	Fee of 20,000 vide Challan No. 48643085	70
3	HP Disposable Stopcock with Extension Tube	Approved as per panel recommendation
	Stopcock Extension Tube (1 Way, 2 Way, 3 Way & 4	subject to fee verification for family.
	Way)	
	Class: B	
	Shelf-life:5Years	
	Length:	
	10cm, 15cm, 20cm, 25cm, 50cm, 100cm	
	Fee of 20,000 vide Challan No. 51757256	
4	Super Stopper Disposable Stopcock with	Approved Super Stopper Disposable
	Extension Tube	Stopcock with Extension Tube
	Stopcock Extension Tube	Stopcock Extension Tube as per panel
	Class: B	recommendations subject to fee

	Shelf-life:5Years	verification.
	<b>Length:</b> (1 Way, 2 Way, 3 Way & 4 Way)	
	10cm, 15cm, 20cm, 25cm, 50cm, 100cm	
	<b>Fee of 20,000</b> vide Challan No. 11296827	
5	BM Disposable Breathing Bag	Rejected as firm don't have facility for
	Class: B	assembly & packing as per panel report.
	Shelf Life: 5 Year	1 1
	Fee: 25000 Fee Slip No. 92330370662	.6)
6	BM Disposable Anesthetic Circuit	Rejected as firm don't have facility for
	Class: B	assembly & packing as per panel report.
	Shelf Life: 5 Year	41 01 0.
	Fee: 25000 Fee Slip No. 9611402310	11 10 -6.
7	BM Disposable Oxygen Mask	Approved as per panel recomendations
	Class: B	10, 00,
	Shelf Life: 5 Year	
	Fee: 25000 Fee Slip No. 823610502	
8	BM Disposable Urine Bag	Approved as per panel recomendations
	Class: B	
	Shelf Life: 5 Year	
	Fee: 25000 Fee Slip No. 5078076597	
9	BM Disposable Anesthetic Mask	Rejected as firm don't have facility for
	Class: B	assembly & packing as per panel report.
	Shelf Life: 5 Year	
	Fee: 25000 Fee Slip No. 89224587	
10	BM Disposable Breathing Circuit	Rejected as firm don't have facility for
	Class: B	assembly & packing as per panel report.
	Shelf Life: 5 Year	
	Fee: 25000 Fee Slip No. 933019586	.41
11	BM Disposable Enteral Feeding	Approved as per panel
	Class: B	recommendations. The oral syringe
	Shelf Life: 5 Year	shall be differentiated from IV syringe
	Fee: 25000 Fee Slip No. 65267853330	with color coding of plunger.

### Case No.1: <u>Deferred case of M/s Hospital Solutions 174-E, Block-2, PECHS Karachi</u>

1.	Hospital	Surgaid Medical (Xiamen) Co.,	Disposable	The product was	Decision:
	Solutions	Ltd.	Laparoscopic Trocar	deferred in 86th meeting	
	174-E, Block-			for provision of Valid	Approved with the site
	2, PECHS	Building 5, No. 18, Shan Bia	Class-B	FSC, LoA, copy of	as mentioned in the
	Karachi	Nhong east Road, haicang		Application form & fee	FSC.
	(ELI-00250)	District, 36 1026, Xiamen	Sizes/codes:	slip.	
	(EEF 00250)	Fujian PR China.	NPVS-100-1-5,		) *
			NPVS-100-1-10,	Now the firm has	
		Sites Address as per FSC:	NPVS-100-1-12,	submitted the following	
		Room No. 5602, Building 5,	NPCS-100-1-5,	documents.	
		No. 18, Shan Bia Nhong East	NPCS-100-1-10,	3.00	
		Road, Haicang District,	NPCS-100-1-12,	1. Copy of Letter of	
		Xiamen city, Fujian province,	NPCS-100-1-15,	Authorization.	
		PR China.	NPCS-100-2-A, NPCS-100-2-B,	2. valid Free Sale	
			NTCS-100-2-B, NTCS-100-1-5,	Certificate.	
		1F Room No. 5101,5102, and	NTCS-100-1-3, NTCS-100-1-10,	3. Copy of CE	
		5104), 2F,3F,5F (Room 5502),:	NTCS-100-1-10, NTCS-100-1-12.	Certificate with	
		Room 102, No. 18, Housxiang	111C5-100-1-12.	extension letter	
		Road, Xiamen city, Fujian	CO	4. Copy of Challan Fee	
		province 361026, PR China.	1	Slip vide No.	
		Zone A, 3 <sup>rd</sup> Floor, No.17-2,		1011760802 dated 31-	
		Hutou Road, Haicang District,		10-2024 (Fee: Rs.	
		Xiamen city, Fujian province,		31000/-)	
		PR China.		5. Clinical Evaluation	
		350		Report	
				6. Scan copy of Form-7A	

## Case No.02: M/S GLOBAL BIOTECH MEDICAL DEVICES (PRIVATE) LIMITED, KARACHI:

The following products were M/s M/s Global Biotech Medical Devices (Private) Limited, Karachi were approved in 77<sup>th</sup> meeting of MDB as per following details:

Sr. No.	Name & Address of the importer	Name & Address of Legal Manufacturer	Name of Medical Devices/ Shelf life /Class & codes / sizes (if any)	Decision
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1.	M/s Global Biotech	Legal	Brand: Xcess Guiding	Approved
	Medical Devices	Manufacturer:	Catheter	· <del>-</del>
	(Private) Limited.	Curatia Medical	Generic:	
	1 <sup>st</sup> floor of Plot	Limited	Guiding Catheter	
	# 35-N/3,	Address: No. 198,	Model: as per FSC	
	# 53-1\(\sigma\), P.E.C.H.S,	Xiangjiang Road,	Class D	.65:17 AM
		New District		
	Block – 06,		Shelf-life: 03 years	
	Near Rohail	Suzhou, China.	Storage Conditions:	
	Khund	Sterilization	Store in a dry, dark and	
	Society,	process:	cool place.	10°
	Karachi.	Name:	QMS - FQA Validity:	
	(ELI-01292)	Goals sterilization	07-01-2029	
	Submission	Co. Ltd.	Design Examination	
	date:	Address:	Certificate Validity:	
	03-12-2024	East of	31-12-2027	
	Fee Challan	Renkangtang, South	LOA: 04-07-2026	
	No:	of 07 provincial		
	02386055134	Road, Xinfeng	ISO 13485 certificate	
		Town, Nanhu	validity: 31-07-2026	
	PKR 62000/-			
	Dated: 26-11-	District, Jiaxing,		
	2024	China.		
	N. 9	FSC (China)		
		Validity: 03-07-		
	· ·	2026		
		CFG USA		
		Dated 14-12-2018.		
				_
	G			
2	M/s Global Riotech	Legal	Rrand:	Approved
2.	M/s Global Biotech	Legal Manufacturer	Brand:	Approved
2.	Medical Devices	Manufacturer:	URSA Angiographic	Approved
2.		Manufacturer: Curatia Medical	URSA Angiographic Catheter	Approved
2.	Medical Devices (Private) Limited.	Manufacturer: Curatia Medical Limited	URSA Angiographic Catheter Generic:	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot	Manufacturer: Curatia Medical Limited Address: No. 198,	URSA Angiographic Catheter Generic: Angiographic	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S,	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road,	URSA Angiographic Catheter Generic: Angiographic Catheter	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC	Approved
2.	Medical Devices (Private) Limited. 1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society,	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China.	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC	Approved
2.	Medical Devices (Private) Limited. 1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society,	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China.	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions:	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi.	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process:	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place.	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd.	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity:	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No:	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address:	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No:	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity:	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing,	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing,	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.  FSC (China)	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.  FSC (China) Validity: 03-07-	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved
2.	Medical Devices (Private) Limited.  1st floor of Plot # 35-N/3, P.E.C.H.S, Block – 06, Near Rohail Khund Society, Karachi. (ELI-01292)  Submission date: 03-12-2024 Fee Challan No: 613828023 PKR 62000/-	Manufacturer: Curatia Medical Limited Address: No. 198, Xiangjiang Road, New District Suzhou, China. Sterilization process: Name: Goals sterilization Co. Ltd. Address: East of Renkangtang, South of 07 provincial Road, Xinfeng Town, Nanhu District, Jiaxing, China.  FSC (China) Validity: 03-07-	URSA Angiographic Catheter Generic: Angiographic Catheter Model: as per FSC Class D Shelf-life: 03 years Storage Conditions: Store in a dry, dark and cool place. QMS - FQA Validity: 07-01-2029 Design Examination Certificate Validity: 31-12-2027 LOA: 04-07-2026 ISO 13485 certificate	Approved

	Dated 14-12-2018.		
		(6)	

The same products are already registered with two different importers as per following details:

Importer Name	Manufacturer	Medical Device Name	Registration No.
M/s A.H Distributors	M/s. Curatia Medical Limited	URSA Angiographic	MDIR-0000443
House No. CB-708, Lane No 5,	198 Xiangjiang Road, New District,	Catheter	
1st Floor, Peshawar Road	Suzhou 215011, China		
Rawalpindi	est Williams		
M/s Al Waali Care Concepts	M/s Curatia Medical Limited	Xcess Guiding	MDIR-0001719
86-Allama Iqbal Road, Chah Baba	198 Xiangjiang Road New District,	Catheter	
Shadiwal Street, Garhi Shahu,	Suzhou, Jiangsu, China, 215011		
District Lahore			
M/s Al Waali Care Concepts	M/s Curatia Medical Limited	Vela RX PTA Balloon	MDIR-0003128
86-Allama Iqbal Road, Chah Baba	198 Xiangjiang Road New District,	Dilatation Catheter	
Shadiwal Street, Garhi Shahu,	Suzhou, Jiangsu, China, 215011		
District Lahore			

Decision: Keeping in view the NOC from the previous Importers & the termination letter via email from the manufacturer abroad, the Board decided to cancell Registration of the below mentioned products as per details below and to issue registration to M/S Global Biotech Medical Devices Pvt. Ltd:

Importer Name	Manufacturer	Medical Device Name	Registration No.
M/s A.H Distributors	M/s. Curatia Medical Limited	URSA Angiographic	MDIR-0000443
House No. CB-708, Lane No	198 Xiangjiang Road, New	Catheter	
5, 1st Floor, Peshawar Road	District, Suzhou 215011, China		
Rawalpindi		0	
M/s Al Waali Care Concepts	M/s Curatia Medical Limited	Xcess Guiding	MDIR-0001719
86-Allama Iqbal Road, Chah	198 Xiangjiang Road New	Catheter	
Baba Shadiwal Street, Garhi	District, Suzhou, Jiangsu,		
Shahu, District Lahore	China, 215011		
M/s Al Waali Care Concepts	M/s Curatia Medical Limited	Vela RX PTA Balloon	MDIR-0003128
86-Allama Iqbal Road, Chah	198 Xiangjiang Road New	Dilatation Catheter	
Baba Shadiwal Street, Garhi	District, Suzhou, Jiangsu,		
Shahu, District Lahore	China, 215011		

### Case No.03: M/S SBK INTERNATIONAL RAWALPINDI

The following products of M/s SBK International, 23, Valley Road, Street 3, Westridge 1, Rawalpindi were approved subject to submission of requisite Fee as per SRO 1324(I)/2024 dated 30th August, 2024. The details are as under:

Importer	Manufacturer	Products details	Decision
Importer  SBK International, 23, Valley Road, Street 3, Westridge 1, Rawalpindi.  ELI-00100	Legal Manufacturer:  M/s FUJIAN BESTWAY MEDICAL POLYMER CORPORATION ADDRESS: Room 02, 17th Floor, West District of Jinyuan Grand Plaza, No 68 Guangda Road, Taijiang District, Fuzhou, Fujian, China Manufacturing Site:  SITE 1: 138, GUANPU ROAD, FUZHOU, FUJIAN, CHINA SITE 2: S2# & S3# BUILDING, MEDICAL DEVICE INDUSTRIAL PARK, INDUSTRIAL PARK, INDUSTRIAL NEW ZONE, NO 66 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN PROVINCE, CHINA  LOA Validity: 31-12-2028  FSC: Country of Origin Validity: 29-12-2025	Medibell IV Cannula with Wings (Straight Type)  IV Cannula with Wings (Straight Type)  Class B  Shelf Life: 05 Years  Codes / Sizes:  1. 10Gx48mm  2. 12Gx48mm  3. 14Gx140mm  4. 14Gx52mm  5. 14Gx50mm  6. 14Gx48mm  7. 14Gx45mm  8. 14Gx32mm  9. 16Gx140mm  10. 16Gx52mm	Approved subject to submission of requisite Fee as per SRO 1324(I)/2024 dated 30 <sup>th</sup> August, 2024.
	FSC: Country of Origin Validity: 29-12-2025  EC Certificate Validity: 26-10-2023 Extended till 31-12-2028 (letter attached) ISO 13485  Validity: 26-10-2027	7. 14Gx45mm 8. 14Gx32mm 9. 16Gx140mm	
	lequesqui,	16. 18Gx50mm 17. 18Gx48mm 18. 18Gx45mm 19. 18Gx33mm 20. 18Gx32mm 21. 18Gx30mm	

	<u></u>		
		22. 18Gx25mm	
		23. 20Gx52mm	
		24. 20Gx50mm	
		25. 20Gx48mm	
		26. 20Gx45mm	1 All
		27. 20Gx33mm	
		28. 20Gx32mm	
		29. 20Gx30mm	
	$^{\prime}G$	30. 20Gx25mm	
	AUI	31. 22Gx32mm	
	Plo Oil	32. 22Gx25mm	
		33. 22Gx19mm	
	i etai Ne	34. 24Gx19mm	
	csl B	35. 26Gx19mm	
	P3 (0), 26	36. 26Gx12.7mm	
SBK International, 23,	Legal Manufacturer:	Medibell IV Cannula Pen Type	Approved subject to
Valley Road, Street 3, Westridge 1,	M/s FUJIAN BESTWAY	IV Cannula Pen Type	submission of requisite Fee as per
Rawalpindi.	MEDICAL POLYMER CORPORATION ADDRESS:		SRO 1324(I)/2024
	Room 02, 17th Floor, West	Class B	dated 30 <sup>th</sup> August, 2024.
ELI-00100	District of Jinyuan Grand Plaza, No 68 Guangda Road, Taijiang	(5)	2024.
	District, Fuzhou, Fujian, China	Shelf Life: 05 Years	
	Manufacturing Site:	30, 11, 31,	
	SITE 1: 138, GUANPU ROAD,	Codes / Sizes:	
	FUZHOU, FUJIAN, CHINA SITE 2: S2# & S3# BUILDING,	1. 10Gx48mm	
	MEDICAL DEVICE	2. 12Gx48mm	
	INDUSTRIAL PARK, INDUSTRIAL NEW ZONE, NO	3. 14Gx140mm	
	66 TINGZHOU AVENUE	4. 14Gx52mm	
	SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY,	5. 14Gx50mm	
	CHANGTING COUNTY, FUJIAN PROVINCE, CHINA	6. 14Gx48mm	
		7. 14Gx45mm	
	LOA Validity: 31-12-2028	8. 14Gx32mm	
	FSC: Country of Origin Validity:	9. 16Gx140mm	
	29-12-2025	10. 16Gx52mm	
	(e)d).	11. 16Gx50mm	
	EC Certificate Validity: 26-10-		

2023 Extended till 31-12-2028 (	12. 16Gx48mm
letter attached ) ISO 13485	
Validity: 26-10-2027	13. 16Gx45mm
	14. 16Gx32mm
	15. 18Gx52mm
	16. 18Gx50mm
	17. 18Gx48mm
	18. 18Gx45mm
	19. 18Gx33mm
, G	20. 18Gx32mm
	21. 18Gx30mm
Plo Oli	22. 18Gx25mm
	23. 20Gx52mm
ista Ne	24. 20Gx50mm
69 18	25. 20Gx48mm
P3 (0), 86	26. 20Gx45mm
	27. 20Gx33mm
	28. 20Gx32mm
	29. 20Gx30mm
	30. 20Gx25mm
adli	31. 22Gx32mm
11/0	32. 22Gx25mm
	33. 22Gx19mm
	34. 24Gx19mm
	35. 26Gx19mm
in do	36. 26Gx12.7mm

Decision: The Board considered the fee submitted for the products & acceded to request of firm and decided to approve the products without additional fee.

### Case No.04: M/S JASSH PHARMA, 20KM, FEROZPUR ROAD, LAHORE

The following products of M/s Jassh Pharma, 20KM, Ferozpur Road, Lahore (Local manufacturer) were approved in 77<sup>th</sup> meeting of MDB as per following details:

S	Firm Name	Product Details	<b>Brief Description</b>	Decision
#			_	
1	Jassh Pharma, 20KM,	Carbosol Plus	Liquid Solution for	Approved.
	Ferozpur Road, Lahore	Hemodialysis Concentrate	Bicarbonate	
	(ELM-0037)		Hemodialysis	
	[470-7L]	Class: C		
	August 2024	Shelf Life: 2 Years		
		Fee: 20000		
		Fee Slip No. 0465176988	.(6)	
2	Jassh Pharma, 20KM,	Citrosol Haemodialysis Concentrate	Liquid Solution for	Approved.
	Ferozpur Road, Lahore	Hemodialysis Concentrate	Bicarbonate	
	(ELM-0037)		Hemodialysis	
	[471-7L]	Class: C	100	
	August 2024	Shelf Life: 2 Years	(1.6), (1.9)	
		Fee: 20000	10112 00 h	
		Fee Slip No. 741755240239		

During processing the case it has been noted the composition of the product is not mentioned in the meeting. The composition is as under:

Sr. No.	Name of Medical Devices With composition & pack size
	Brand name:Carbosol-PLUS Haemodialysis Concentrate
	Generic: Bicarbonate Haemodialysis Concentrate
1	Composition:
	Part A (as per B.P/E.P)
	Sodium: 80 - 110 m.mol
	Potassium: 0 - 3 m.mol
	Calcium: 0 - 2 m.mol
	Magnesium: 0 – 1.2 m.mol Chloride: 90 - 120 m.mol
	Acetic Acid: 2.5 - 10 m.mol
	Glucose: 0 - 12 m.mol
	Part B (as per B.P/E.P)
	Sodium: NMT45m.mol
	Bicarbonate: NMT45m.mol
	100 110 Jo.
	Sizes:
	Part A and Part B
	• For one dialysis session.
	• For two dialysis sessions.
	• For seven dialysis sessions.
	Brand name: Citrosol Hemodialysis Concentrate
	Generic: Bicarbonate Haemodialysis Concentrate
	Composition:
	Part A
2	Sodium: 80 - 110 m.mol
	Potassium: 0 - 3 m.mol
	Calcium: 0 - 2 m.mol
	Magnesium: 0 – 1.2 m.mol
	Chloride: 90 - 120 m.mol

Acetic Acid: 0 - 10 m.mol Citric Acid: 0.5-2.5 m.mol Glucose: 0 - 12 m.mol

Part B

Sodium: NMT45m.mol Bicarbonate: NMT45m.mol

#### Sizes:

Part A and Part B

- For one dialysis session.
- For two dialysis sessions.
- For seven dialysis sessions.

Decision: The Board approved above products with above formulation/composition.

#### Case No.05: M/S INTEK CORPORATION PVT, LTD.

The proprietor of the firm M/s **Intek Corporation Pvt, Ltd.** Office # 501-502, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000 has submitted a clarification wherein he has claimed that he is the sole proprietor of both M/s Intek Corporation and M/s Intek Corporation (Pvt.) Ltd. He authorizes the transfer of the following product portfolio from M/s Intek Corporation (Pvt.) Ltd. For administrative and operational streamlining.

He has also provided the above claim on stamp paper and also provided the copies of ELI of M/s Intek Corporation (Pvt.) Ltd., Rawalpindi ELI-00794 and ELI of M/s Intek Corporation, Rawalpindi ELI-00034 wherein he is the sole proprietor in both of the cases.

The following products of M/s **Intek Corporation Pvt, Ltd.** Office # 501-502, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000 were discussed in different meetings as per following details:-

Sr. No.	Manufacturer	<b>Product Details</b>	Remarks	Decision
1.	Shanghai Shape Memory	MemoPart <sup>TM</sup>	It is submitted that the subject	The board decided to give
	Alloy Co., Ltd Located at	Ventricular Septal	device is registered for Intek	personal hearing to both
	1F and 5F, Tower 41, No.	Defect (VSD)	Corporation, #517, Kohistan	the firms.
	258, Xinzhuan Road,	Occluder	Tower, Mehfooz Road, opposite	(M-72)
	Songjiang High Tech Park,	MemoPart <sup>TM</sup>	AFIC Saddar Rawalpindi. Now,	
	Caohejing Development	Occluder System	the product has been	
	District, Shanghai 201612,		transferred by the Legal	
	China		manufacturer from Intek	
	1801		Corporation, #517, Kohistan	
	Ne		Tower, Mehfooz Road, opposite	

			AFIC Saddar Rawalpindi to	
			Intek Corporation Pvt, Ltd.	
			Office # 501-502, Kohistan	
			Towers, Mehfooz Road, Saddar	
			Rawalpindi-46000 with new	
			agreement. M/s <i>Intek</i>	
			Corporation, #517, Kohistan	
			Tower, Mehfooz Road, opposite	
			AFIC Saddar Rawalpindi also	X \
			applied for deregistration of the	
			subject device.	
2.	Shanghai Shape Memory	MemoPart <sup>TM</sup>	-do-	The board decided to give
	Alloy Co., Ltd Located at	Occluder Delivery	2 4 10 10	personal hearing to both
	1F and 5F, Tower 41, No.	System	40, 481, 0,0,	the firms.
	258, Xinzhuan Road,	MemoPart <sup>TM</sup>	30, 12113 201	(M-72)
	Songjiang High Tech Park,	Delivery System	9 10. 10	,
	Caohejing Development			
	District, Shanghai 201612,		0, 20,	
	China			
3.	Shanghai Shape Memory	MemoPart <sup>TM</sup>	-do-	The board decided to give
	Alloy Co., Ltd Located at	Ventricular Septal		personal hearing to both
	1F and 5F, Tower 41, No.	Defect (VSD)	2	the firms.
	258, Xinzhuan Road,	Occluder	, <del>-</del>	(M-72)
	Songjiang High Tech Park,	MemoPart <sup>TM</sup>		
	Caohejing Development	Occluder System		
	District, Shanghai 201612,	1		
	China			
4.	Shanghai Shape Memory	MemoPart <sup>TM</sup> ASD	-do-	The board decided to give
	Alloy Co., Ltd Located at:	Occluder is a		personal hearing to both
	1F and 5F, Tower 41, No.	percutaneous,		the firms.
	258, Xinzhuan Road,	transcatheter device		(M-72)
	Songjiang High Tech Park,	applied to the	1/2/	
	Caohejing Development	closure of atrial		√,D.
	District, Shanghai 201612,	septal defects	911 1 11 3 0	
	China.	(ASD). It is also		*
		available for the	"O" -10" of 1	
		patient who require	C/2 112, V/2	
		a closure of	3, 10,, 00,	
	0 1 1 C PY 1	fenestrated Fontan.		
5.	Occlutech GmBH Located	Figulla Flex II	-do-	The board decided to give
	at Winzerlaer Straße 2,	ASD Astanial Santal	N 700	personal hearing to both
	07745 Jena, Germany	Arterial Septal		the firms.
		Defect Closure	*0,	(M-72)
	Local Manufacture	device (Migra	It is submitted that the cultive	Doord appealed to the
6.	Legal Manufacturer:	Teleport (Micro	It is submitted that the subject	Board acceded to the
	OrbusNeich Medical B.V.,	Catheter)	device is registered for Intek	request of the M/s Intek
	Drs. W. Van Royenstraat	- A. \	Corporation, #517, Kohistan	Corporation, #517,
	5, 3871 AN Hoevelaken,		Towers, Mehfooz Road,	Kohistan Towers, Mehfooz
	The Netherlands.		opposite AFIC Saddar	Road, Opposite AFIC
	Manufacturing sites:	90,	Rawalpindi. Now, the product	Saddar Rawalpindi for
	OrbusNeich Medical B.V.,		has been transferred by the	deregistration of the
	Drs. W. Van Royenstraat		Legal manufacturer from Intek	product and cancel the
	5, 3871 AN Hoevelaken,		Corporation, #517, Kohistan	product registration and
	The Netherlands. and OrbusNeich Medical Co.,		Towers, Mehfooz Road, opposite AFIC Saddar	approved the product in the name of M/s Intek
		i	CODOSHE AFIL Saddar	rname or M/s intek-l

	Ltd (Shenzhen), No. 1 Jinkui Road, Futian Free Trade Zone, Shenzhen 518038, China.		Rawalpindi to Intek Corporation Pvt, Ltd. Office # 501, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi with new agreement. M/s Intek Corporation, #517, Kohistan Towers, Mehfooz Road, opposite AFIC Saddar Rawalpindi also applied for deregistration of the subject device.	Corporation (Pvt) Ltd, Office # 501, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi as the legal manufacturer abroad has changed the authorization of the product from M/s Intek Corporation, Rawalpindi to Intek Corporation (Pvt) Ltd, Rawalpindi. (M-77)
7.	Legal Manufacturer: Occlutech Tibbi Urunler San.ve Tic.Ltd.Sti AHL Serbest Bolgesi, E-5 Blok 34149, Istanbul Turkey	Occlutech PDA Occluder (Patent Ductus Arteriosus Closure Device)	action is a series of the control of	Approved subject to the deregistration of already issued registration certificate.  Board acceded to the request of the M/s Intek Corporation, #517, Kohistan Towers, Mehfooz Road, Opposite AFIC Saddar Rawalpindi for deregistration of the product and cancel the product registration and approved the product in the name of M/s Intek Corporation (Pvt) Ltd, Office # 501, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi as the legal manufacturer abroad has changed the authorization of the product from M/s Intek Corporation, Rawalpindi to Intek Corporation (Pvt) Ltd, Rawalpindi. (M-77)
8.	Legal Manufacturer: MicroVention, Inc. 35 Enterprise, Aliso Viejo CA 92656 USA.	Traxcess 14 Guidewire	It is submitted that the subject device is registered for M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi.  Now, the product has been transferred by the Legal manufacturer from M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi.  to Intek Corporation Pvt, Ltd. Office # 501-502, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000 with new	The board decided to call both the firms regarding the transfer of registration and updated agreement from the legal manufacturer. (M-89)

9.	Manufacturer/ Manufacturing Site: M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA	Headway 17 Advanced Soft Microcatheter	agreement. M/s. Intek Corporation, Office No. 30, Al- Amin Plaza, The Mall, Rawalpindi also applied for deregistration of the subject device.  Approved. 13th meeting in name of M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034  Transfer of registration to M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.  2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 (M-89)
10.	Manufacturer: M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA Manufacturing Sites: 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica.	Headway 21 Microcatheter	Approved. 13th meeting in name of M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034  Transfer of registration to M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.  2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 (M-89)
11.	Manufacturer: M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA Manufacturing Sites: 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica.	Headway 27 Microcatheter  Headway Duo	Approved.  13th meeting in name of M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034  Transfer of registration to M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794  Approved.	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.  2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 (M-89)

	MicroVention, Inc. 1311 Valencia Ave Tustin, CA 92780, USA Manufacturing Sites: 1. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA, USA 92656 2. MicroVention Costa Rica, S.R.L. Zona Franca coyol Alajuela, Costa Rica. 3. MicroVention, Inc. 1311	Microcatheter	14 <sup>th</sup> meeting in name of M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034	both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.  2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794
13.	<b>Manufacturing Site:</b> M/s	Microplex® Coil System	Approved.  13th meeting in name of M/s.	(M-89)  The board decided to call both the companies to be
	Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA	MCS-CSSR (10) Microplex Cosmos (10 System)	Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034  Transfer of registration to M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794	heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. 2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 (M-89)
14.	Manufacturer/ Manufacturing Site: M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA Contract Manufacturer: (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA	Microplex® Coil System MCS-CS (18) Microplex Cosmos (18 System)	Approved.  13th meeting in name of M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034  Transfer of registration to M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.  2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 (M-89)
15.	Legal Manufacturer Microvention Europe: 30 bis rue du Vieli Abreuvior, 78100 Saint Germain e Laye, France Production Sites MicroVension,Inc. 1311 Valencia Avenue Tustin, California, 92780 USA MicroVension Inc. 35 Enterprise, Aliso Viejo, CA 92656, USA MicroVension Costa Rica S.R.L Edificio B33	SOFIA PLUS Percutaneous Catheter (Distal Access + Aspiration)	Approved. 12th meeting in name of M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034  Transfer of registration to M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794	The board decided to call both the companies to be heard in person. i.e, M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi.  2. M/s. Intek Corporation, (Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall, Rawalpindi. ELI-00794 (M-89)

Zona Franca Coyol Alajuela, Costa Rica				
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Decision: The Board considered the request of proprietor of the firm M/s Intek Corporation Pvt, Ltd. Rawalpindi after confirmation that the proprietor in both of the firm is same as per record, therefore, decided to cancel registration of above products from M/s Intek Corporation and approved same products in the name of M/s Intek Corporation (Pvt.) Ltd. Registration letter will be issued after submission of copy of submitted form and fee challan, valid FSC and with codes/sizes/manufacturer details as per FSC and shelf life and class already approved for M/s Intek corporation.

### **Deputy Director VIII**

### Item No. VI: Cases of Renewal of Registration for Import.

S.#	Importer Name	Manufacturer Name	Product Name	Decision
1.	M/s Easha	Legal Manufacturer:	Cocoon PFO Occluder	Deferred for
	Enterprises, 2B-04,	M/s Vascular	Accessory Set	submission of;
	Third Floor Adyala	Innovations Co., Ltd	(PFO Occluder Delivery	1. Original documents.
	Towers Adyala Road,	88/38 Moo 1, 345 Rd.,	System)	2. Differential fee.
	Rawalpindi	Bangtanai Pakkret,		3. valid Design
		Nonthaburi-11120,	Class D	Examination
	ELI-00203	Thailand.		Λ()
	Renewal application:		Shelf Life: 3 years	
	MDIR-0000504	Attested copy of FSC of		23,
	R & I dated:	Thailand valid till 04-	Codes:	
	29-07-2024	07-2026.	CPF8F	
			CPF9F	
	Fee submitted	FSC of MHRA without	180 1011 00	
	25,000/-	legalization valid till 31-		
	33135598297	01-2028.	in Y all	
			30 300	
	Differential fee	2,0,1		
	32,400/-			
	772190565964	65.010		
	N// E 1	Y 1114	C VID 0 1 1	D 6 16
2.	M/s Easha	Legal Manufacturer: M/s Vascular	Cocoon VSD Occluder	Deferred for
	Enterprises, 2B-04,		Accessory Set II	submission of;
	Third Floor Advala	Innovations Co., Ltd	(VSD Occluder Delivery	1. Original documents.
	Towers Adyala Road,	88/38 Moo 1, 345 Rd.,	System)	2. Differential fee.
	Rawalpindi	Bangtanai Pakkret,	Class D	3. valid Design
	EL 1 00202	Nonthaburi-11120,	Class D	Examination
	ELI-00203	Thailand.	Chalf I ifa. 2am	
	Danassal annliastica	Attacted convertes C - f	Shelf Life: 3 years	
	Renewal application	Attested copy of FSC of		

	MDIR-0000505  R&I date: 29-07-2024  Fee Submitted 25,00/- 3683101218  Differential fee 32,4000/-	Thailand valid till 04- 07-2026.  FSC of MHRA without legalization valid till 31- 01-2028.	Codes: COV116F COV117F	Si'll AM
3.	M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi ELI-00203	Legal Manufacturer: M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand.	Cocoon Duct Occluder Accessory Set (PDA Occluder Delivery System)  Class D  Shelf Life: 3 years	Deferred for submission of; 1. Original documents. 2. Differential fee. 3. valid Design Examination
	Renewal application MDIR-0000506  R&I date: 29-07-2024  Fee Submitted 25,00/- 320968988  Differential fee 32,4000/- 07414530375	Attested copy of FSC of Thailand valid till 04-07-2026.  FSC of MHRA without legalization valid till 31-01-2028.	Codes: COP6F COP7F COP8F COP9F	55:17 AM
4.	M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi  ELI-00203  Renewal application MDIR-0000503  R&I date: 29-07-2024  Fee Submitted	Legal Manufacturer:  M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand.  Attested copy of FSC of Thailand valid till 04- 07-2026.  FSC of MHRA without legalization valid till 31-	Cocoon Septal Occluder Accessory Set (ASD Occluder Delivery System)  Class D  Shelf Life: 3 years  Codes: COA6F COA7F COA8F COA9F COA10F	Deferred for submission of; 1. Original documents. 2. Differential fee. 3. valid Design Examination

	25,00/- 34674009513	01-2028.	COA12F COA14F	
	Differential fee 32,4000/-72535025			AN
The	meeting ended with vo	ote of thanks from and to	the Chair.	
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	N		dir (MS)	22.
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The meeting ended with vote of thanks from and to the C	Chair.
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