

Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

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

97th 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 28th 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) Pathologist, 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 University 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)		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	<p>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.</p> <p>The firm may apply afresh for grant of ELI with correct address.</p>
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

	Tracking ID: 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 Ghona Road, Near Brain School System, Millat Road, Faisalabad Fee: Rs 25000 /- Date of Submission: 26 July 2025 Tracking ID: MDMC-250726-11250	Name: Muhammad Aarsal 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	<p>Rejected as the inspector informed that firm was not ready at the time of inspection.</p> <p>The firm may apply afresh once ready for inspection.</p>

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		
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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

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

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

		<p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date: 2025-05-28</p> <p>Validity Date: 2030-05-27</p> <p>Notarization Status: Yes, by CCPIT</p>		
4	<p>A.M. Distributors.pk</p> <p>37-C, 4th Floor, Lane-8, Bukhari</p> <p>Commercial,Phase-VI, D.H.A. Karachi, Pakistan, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 9355381939</p> <p>Date of submission: 31 July 2025</p> <p>Tracking ID: MDMR-20250731-00010</p>	<p>Manufacturer</p> <p>M/s Anhui Tianrun Medical Packaging Material CO., LTD.</p> <p>Address: Located at No.29 Chaoyang Road, Yixiu District, 246003 Anqing City, Anhui Province, People's of Republic of China</p> <p>ISO 13485</p> <p>Issue Date: 2024-08-24</p> <p>Validity Date: 2027-08-23</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date: 2025-02-28</p> <p>Validity Date: 2027-02-27</p> <p>Issuing Authority:</p> <p>Attestation Status: APOSTILLE</p> <p>Issue Date:</p>	<p>Brand Name:</p> <p>Gussetted Reel</p> <p>Generic Name:</p> <p>Heat Sealing Gussetted Reel</p> <p>Class A</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any):</p> <p>TRHGR075,TRHGR100, TRHGR150,TRHGR200, TRHGR250,TRHGR300, TRHGR350,TRHGR400, TRHGR450,TRHGR500/ 75mm X 100m,100mm X 100m,150mm X 100m,200mm X 100m,250mm X 100m,300mm X 100m,350mm X 100m,400mm X 100m,450mm X 100m,500mm X 100m</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temperature</p>	<p>Deferred for submission of FSC from concerned regulatory authority containing the applied product</p>

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

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

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

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

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

	<p>road, Rawalpindi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 50231683376</p> <p>Date of submission: 25 July 2025</p> <p>Tracking ID: MDMR-20250725-00012</p>	<p>Address: West Side of West Ring Road and North Side of Yongxing Road, Jizhou District, Hengshui City, Hebei Province, China</p> <p>ISO 13485</p> <p>Issue Date: 22024-09-19</p> <p>Validity Date: 2027-09-18</p> <p>Notarization Status: CCPIT</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date: 2025-08-12</p> <p>Validity Date: 2026-07-11</p> <p>Issuing Authority: CCPIT</p> <p>Attestation Status: Apostille</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p>	<p>Manual Hospital Bed</p> <p>Class A</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): SYC-A-(1~1284)/</p> <p>Specify grouping: Single</p> <p>Storage condition: Dry Place</p>	
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10	<p>Chohan & Company 21 BAHADURABAD BLOCK 2, Karachi, Karachi</p> <p>Fee: Rs 6000 /-</p> <p>Challan No.: 7771164790</p> <p>Date of submission: 23 July 2025</p> <p>Tracking ID: MDMR- 20250723-00029</p>	<p>Legal Manufacturer (as per FSC) Jiangsu HXRT MD Co., Ltd</p> <p>Address: No.66 Xingyuan Road, the Modern Science and Technology Industrial Area,Jiangyan District, Taizhou City,225300, Jiangsu, China</p> <p>ISO 13485</p> <p>Issue Date: 2023-09-06</p> <p>Validity Date: 2026-08-12</p> <p>Notarization Status: PAKISTAN APOSTILLE</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date: 2025-03-31</p> <p>Validity Date: 2027-02-14</p> <p>Issuing Authority: Jiangsu Medical Products Administration</p> <p>Attestation Status: PAKISTAN APOSTILLE</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date: 2025-03-31</p> <p>Validity Date: 2027-02-14</p> <p>Issuing Authority: Jiangsu Medical Products Administration</p> <p>Attestation Status: PAKISTAN</p>	<p>Brand Name:</p> <p>TUBER VAC MERUX NYCOTECH</p> <p>Generic Name:</p> <p>Blood collection tube (SODIUM HEPARIN + Separation Gel)</p> <p>Class A</p> <p>Shelf life/service life: 36 Months</p> <p>Codes/Sizes (if any): N/A/1ML, 1.6ML, 2ML, 3ML, 4ML, 5ML, 6ML, 7ML, 8ML, 9ML, 10ML</p> <p>Specify grouping: Single</p> <p>Storage condition: ROOM TEMPERATURE</p>	Approved
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		APOSTILLE LOA Issue Date: 2025-01-01 Validity Date: 2031-12-31 Notarization Status: PAKISTAN APOSTILLE		
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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

		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: 2025-06-16 Validity Date: 2030-06-15 Notarization Status: notarized		
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: Issuing Authority: Attestation Status: LOA Issue Date: Validity Date: Notarization Status:		
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

		<p>Issue Date: 2023-10-25</p> <p>Validity Date: 2025-10-24</p> <p>Issuing Authority: guangdong medical product administration</p> <p>Attestation Status: 10978720</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date: 2025-06-16</p> <p>Validity Date: 2030-06-15</p> <p>Notarization Status: notarized</p>	TEMPERATURE	
4	<p>Abbott Laboratories Pakistan Limited</p> <p>Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi Karachi-75120, Karachi</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.:</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Abbott GmbH</p> <p>Address: Max-Planck-Ring 2 65205, Wiesbaden, Germany</p> <p>ISO 13485</p> <p>Issue Date:</p> <p>Validity Date:</p>	<p>Brand Name:</p> <p>ARCHITECT Pepsinogen II</p> <p>Generic Name:</p> <p>Pepsinogen II</p> <p>Class B</p> <p>ARCHITECT Pepsinogen II Reagent Kit</p> <p>Shelf life/service life: 15</p>	Approved

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

	<p>948494055</p> <p>Date of submission: 29 July 2025</p> <p>Tracking ID: MDMR-20250729-00005 - Deferred</p>	<p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date: 2026-06-15</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p>	<p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): N/A/6, 6.5, 7, 7.5, 8, 8.5, 9</p> <p>Specify grouping: Single</p> <p>Storage condition: Room Temperature Device</p>	
6	<p>HOSPICARE SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e-Faisal,</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel</p>	<p>Brand Name:</p> <p>F&P Flexitrunk Nasal Prong</p> <p>Generic Name:</p> <p>Nasal Prong</p>	approved

	<p>Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 0492161601</p> <p>Date of submission: 28 July 2025</p> <p>Tracking ID: MDMR- 20250728-00043</p>	<p>Place, East Tamaki, Auckland 2013, New Zealand</p> <p>ISO 13485</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p>	<p>Class B</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC3020- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC3520- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC4030- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC4540- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC5040- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC5050- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC5550- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC5560- 10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC6060- 10/</p>	
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			<p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC6070-10/</p> <p>Shelf life/service life: 3 Years</p> <p>Codes/Sizes (if any): BC6570-10/</p> <p>Specify grouping: Family</p> <p>Storage condition: -10 to 50 °C</p>	
7	<p>OPTI MED</p> <p>2nd Floor Hassan Plaza 6-A Jail Road, Lahore</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 04190299711</p> <p>Date of submission: 01 August 2025</p> <p>Tracking ID: MDMR-20250801-00006</p>	<p>Legal Manufacturer (as per FSC)</p> <p>Xuzhou Kaixin Electronic Instrument Co.Ltd</p> <p>Address: Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China.</p> <p>ISO 13485</p> <p>Issue Date: 2023-04-01</p> <p>Validity Date: 2026-03-31</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2024-11-22</p> <p>Validity Date: 2026-11-22</p> <p>Attestation Status: Apostille</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p>	<p>Brand Name:</p> <p>KAIXIN</p> <p>Generic Name:</p> <p>Ophthalmological A/B mode ultrasound scanner</p> <p>Class B</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): ODU5</p> <p>Specify grouping: Single</p> <p>Storage condition: Ambient temperature: -20°C-55°C</p> <p>Relative humidity: 30%-93% (without condensation)</p> <p>Atmospheric pressure: 700hPa-1060hPa</p>	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		
8	JASANI SCIENTIFICS SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi Fee: Rs 31000 /- Challan No.: 2993696009 Date of submission: 04 August 2025 Tracking ID: MDMR- 20250804-00013	Manufacturer (as per FSC) Accutome, 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: Issuing Authority: Attestation Status: 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:		
9	OPTI MED 2nd Floor Hassan Plaza 6-A Jail Road, Lahore Fee: Rs 32400 /- Challan No.: 547018005565 Date of submission: 07 August 2025 Tracking ID: MDMR- 20250807-00013	Legal Manufacturer (as per FSC) INTEROJO INC.KOREA Address: 28 & 25, Sandan-ro 15 beon-gil, Pyeongtaek-si, Gyeonggi-Do, 17744, South Korea ISO 13485 Issue Date: 2023-03-24 Validity Date: 2026-03-24 Notarization Status: Notarized EC Certificate Issue Date: 2025-07-18 Validity Date: 2028-06-18 Issuing Authority: Ministry of Food and Drug Safety Attestation Status: Apostille Issue Date: Validity Date: Issuing Authority: Attestation Status: FSC Issue Date: Validity Date:	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

		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		
10	JASANI 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	Legal Manufacturer (as per FSC) Accutome, INC (Doing Business As) Keeler Ltd Address: 3222 Phoenixville Pike Malvern, PA 19355, USA	Brand Name: 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 Specify grouping: System	Approved

			Storage condition: -20° to -60° C (-4° to -140° F)	
11	<p>JASANI SCIENTIFICS</p> <p>SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 01845089</p> <p>Date of submission: 04 August 2025</p> <p>Tracking ID: MDMR-20250804-00014</p>	<p>Manufacturer (as per FSC)</p> <p>Accutome, INC (Doing Buisness As) Keeler Ltd</p> <p>Address: 3222 Phoenixville Pike Malvern, PA 19355, USA</p> <p>ISO 13485</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p>	<p>Brand Name:</p> <p>B-Scan Plus</p> <p>Generic Name:</p> <p>Ophthalmic ultrasound imaging system</p> <p>Class B</p> <p>Shelf life/service life: 10 Years</p> <p>Codes/Sizes (if any): 24-6100</p> <p>Specify grouping: System</p> <p>Storage condition: -20° to +60° C</p>	Approved

		LOA Issue Date: Validity Date: Notarization Status:		
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: 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

		<p>Attestation Status:</p> <p>LOA</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>Manufacturing Site (as per FSC)</p> <p>Fresenius Medical Care Deutschland GmbH Schweinfurt Plant</p> <p>Address: Hafenstr. 9 97424 Schweinfurt Germany</p> <p>ISO 13485</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p>		
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		Validity Date: Issuing Authority: Attestation Status: LOA Issue Date: Validity Date: Notarization Status:		
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	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:	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

		<p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date: 2025-05-25</p> <p>Validity Date: 2027-05-24</p> <p>Notarization Status: Notarized.</p>		
14	<p>JASANI SCIENTIFICS</p> <p>SC-45 MARIUM SQUARE CHANDNI CHOWK STADIUM ROAD KARACHI, Karachi</p> <p>Fee: Rs 31000 /-</p> <p>Challan No.: 256726134</p> <p>Date of submission: 04 August 2025</p> <p>Tracking ID: MDMR-20250804-00010</p>	<p>Manufacturer (as per FSC)</p> <p>Accutom, INC (Doing Business As) Keeler Ltd</p> <p>Address: 3222 Phoenixville Pike Malvern, PA 19355, USA</p> <p>ISO 13485</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p>	<p>Brand Name:</p> <p>4Sight</p> <p>Generic Name:</p> <p>Ophthalmic ultrasound imaging system</p> <p>Class B</p> <p>Shelf life/service life: 10 Years</p> <p>A-Scan Probe 4SIGHT 24-8000A</p> <p>B-Scan Probe 4SIGHT 24-8000B</p> <p>Pachymeter Probe 4SIGHT 24-8000P</p> <p>UBM Probe 4SIGHT 24-8000U</p> <p>4Sight Ophthalmic ultrasound imaging system 24-8000</p> <p>Specify grouping: System</p> <p>Storage condition: -20° to -60° C (-4° to -140° F)</p>	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:		
15	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

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

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

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

	<p>Date of submission: 12 August 2025</p> <p>Tracking ID: MDMR-20250812-00003</p>	<p>Issue Date: 2025-04-03</p> <p>Validity Date: 2026-03-09</p> <p>Notarization Status: Notarized.</p> <p>EC Certificate</p> <p>Issue Date: 2024-10-31</p> <p>Validity Date: 2028-12-31</p> <p>Issuing Authority: Ministry of Health, Welfare and Sport, the Netherlands.</p> <p>Attestation Status: Embassy off Pakistan, The Hague. Attested.</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p> <p>Issue Date: 2025-05-25</p> <p>Validity Date: 2027-05-24</p> <p>Notarization Status: Notarized.</p>	<p>16G, 17G, 18G, 20G, 22G, 24G & 26G.</p> <p>Specify grouping: Single</p> <p>Storage condition: Temperature < 35°C, Humidity < 70% RH. Keep at Dry place. Protect from Direct Sunlight.</p>	
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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
1	<p>NI Healthcare products (Pvt) Ltd Office #A Unit 10 Survey No. 263 Damlotte Road, District Malir ,Karachi, Karachi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 4589103071</p> <p>Date of submission: 29 July 2025</p> <p>Tracking ID: MDMR-20250729-00002</p>	<p>Manufacturer</p> <p>Günter Bissinger Medizintechnik GmbH</p> <p>Address: Hans-Theisen-Str. 01 79331 Teningen Germany</p> <p>ISO 13485</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p> <p>EC Certificate</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p>	<p>Brand Name:</p> <p>Bipolar Foreceps</p> <p>Generic Name:</p> <p>Bipolar Electrosurgical Forceps</p> <p>Class C</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80520301/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80520306/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80520331/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80520397/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80520398/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any):</p>	<p>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</p>

		<p>Attestation Status:</p> <p>LOA</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Notarization Status:</p>	<p>80522236/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522237/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522301/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522306/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522333/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522334/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522348/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80522349/</p> <p>Shelf life/service life: 7</p>	
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			<p>Years</p> <p>Codes/Sizes (if any): 80580200/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80580201/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80580220/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80580221/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80620301/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80620306/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80620331/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80620397/</p>	
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			<p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80620398/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622301/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622306/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622315/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622336/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622345/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622348/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any):</p>	
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			<p>80622349/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80622351/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80680180/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80680181/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80680200/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 80680201/</p> <p>Shelf life/service life: 7 Years</p> <p>Codes/Sizes (if any): 81522352/</p> <p>Specify grouping: Family</p> <p>Storage condition: Sterilized instruments must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.</p>	
2	HOSPICARE	Legal Manufacturer (as per	Brand Name:	Deferred for provision of

	<p>SYSTEMS</p> <p>Emarah Suites, 9th Floor, Plot# 8-B, Block-A, SMCHS, Shahrah-e-Faisal, Karachi-75350, Pakistan, Karachi</p> <p>Fee: Rs 62000 /-</p> <p>Challan No.: 07625927184</p> <p>Date of submission: 27 July 2025</p> <p>Tracking ID: MDMR-20250727-00001</p>	<p>FSC)</p> <p>Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <p>ISO 13485</p> <p>Issue Date: 2024-11-11</p> <p>Validity Date: 2027-11-13</p> <p>Notarization Status: Notarized</p> <p>EC Certificate</p> <p>Issue Date: 2025-04-15</p> <p>Validity Date: 2030-04-15</p> <p>Issuing Authority: Apostilled</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>FSC</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>Issue Date:</p> <p>Validity Date:</p> <p>Issuing Authority:</p> <p>Attestation Status:</p> <p>LOA</p>	<p>F&P Neopuff T-Piece resuscitator</p> <p>Generic Name:</p> <p>Automatic pneumatic pulmonary resuscitator</p> <p>Class C</p> <p>Shelf life/service life: 5 Years</p> <p>Codes/Sizes (if any): RD900AEU/NA,</p> <p>Specify grouping: Single</p> <p>Storage condition: -10 to 50 C</p>	<p>Free Sale certificate from reference country having applied product.</p>
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		Issue Date: 2025-04-01 Validity Date: 2026-04-01 Notarization Status: Notarized		
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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 Godown Address: N/A Fee: Rs 12000 /- Date of Submission: 11 August 2025 Tracking ID: MDMC-250811-12405		Destination: N/A Name: N/A CNIC No: N/A	Approved renewal of license.

RENEWAL OF PRODUCT CASES

AGENDA FOR CLASS B, C & D MEDICAL DEVICES

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™ 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™ 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	<p>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</p>	<p>Brand Name: PacScan™ 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</p>	Deferred for submission of differential fee of Rs 10400 for system
6	<p>MEDEQUIPS SMC PVT. LTD 30-SHAHRAH E QAUID E AZAM, LAHORE PAKISTAN, Lahore Fee: Rs 15000 /- Challan No.: 74591116292 Date of submission: 05 August 2025 Tracking ID: MDMR-20250805-00022</p>	<p>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</p>	Approved
7	<p>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</p>	<p>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</p>	Approved
8	<p>HAJI S. AMEER DIN & SONS</p>	<p>Brand Name:</p>	Deferred for submission of differential fee of Rs

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

Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan

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

97th 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 28th 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) Pathologist, 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, Islamabad.	Member-cum-Secretary

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): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

FRESH CASES

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s A V Hearing, Office no 120, First Floor, Rafay Mall, Peshawar Road, Rawalpindi	Waleed DMLS 03161010	Approved
2.	M/s Home Land, House # 413-A, Street# 1, Gulraiz II, Rawalpindi	Farrah Bashir CNIC82101-5852172-8	Approved
3.	M/s Advance Medical Devices, Apartment # 1 3rd floor Plaza 01 linear commercial phase 8 Bahria town Rawalpindi.	Mubashar Abbas CNIC37405-3758089-9 BS Computer Science	Deferred for appointment of qualified person in accordance with requirement of medical 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 Regd. No. 9250-A/2024	Approved
5.	M/s Quick Start International, Plaza No. 19 1st Floor, Ali Commercial Phase -8 Behria Town Rawalpindi.	Muhammad Irfan CNIC17101-3761954-3	Approved
6.	M/s Allied Distributors, 1 st 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 st 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 nd 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. 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)	Rejected. The Board decided to reject the

	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., 203-B, Gate No. 3, Sector F-10/3, Islamabad		Rejected. The Board decided to reject the application for establishment license to import of medical devices in light of findings and recommendations of inspector.
13.	M/s ASK Associates, 17/11-N, Industrial Area, Opp Dawn News Paper Office, Gulberg-II, Lahore		Rejected. The Board decided to reject the application for establishment license to import of medical devices in light of findings and recommendations of inspector.
14.	M/s Diazone, 14,16 Saith Center Moj Darya Road, Lahore. Godown: Shop No LG 7, 1st Basement, Arooj Centre, Fardi Court Road, Lahore		Rejected. The Board observed that the firm was not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.
15.	M/s Jahangir Plastic Surgery Clinic, House number 2, street number 1, block number 1, Khanewal.		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.
16.	M/s Ethos Derma, 65-C, Punjab Small Industrial Estate II, Sundar- Raiwind Road,		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.
17.	M/s Standard Technology, H 77, St 02 Kamboh Colony Near		Rejected. The Board observed that the firm was

	Kamboh Mosque Chung Multan Road, Lahore		not ready for inspection therefore decided to reject the application for establishment license for import of medical devices.
18.	Noor Medicine Company, Gulshan -e- Rehman, Street No. 2, Tabindah Model High School for Boys (Shaheen Campus) Tehsil Burewala, District Vehari.		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.

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. Godown Address: H3B9, Street 49, Millat Road, Paki Thati Samanabad, Lahore	Ms. Asma Rabail d/w/o Ghulam Abbas Reg. No. 19338-A/18 CNIC:35202-4883859-0	Approved

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: -

S.#	Name and Address of Establishment	Decision
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 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: I. Disposable Syringes Section II. IV Cannula Section

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)	Existing Office & Godown Address WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi	Existing Office & Godown Address Office: 3 rd Floor: FD-49, 50, 51 & 54, Korangi Creek Industrial Park, Karachi. Godown: Ground Floor, WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi	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.	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
		Accordingly, Mr. Hira Bhutto, Deputy Director, CDL, Karachi was nominated for the inspection of proposed office and godown address. The panel recommended the proposed office and storage facility of medical devices under MDR, 2017.			
2.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No, 806, 8th Floor Horizon Towers, Block 3, Scheme No 5,	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No, 806, 8th Floor Horizon Towers, Block 3, Scheme No 5, Clifton, Karachi.	M/s Johnson & 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, Karachi.	Godown address: 208 & 208/1, Sector-23 Korangi Industrial Area, Karachi.	Godown 1 address: 208 & 208/1, Sector- 23 Korangi Industrial Area, Karachi. Godown 2 Address: Second Floor, WH- 01, 20-A-7A, Korangi Creek Industrial Park, Karachi.	Korangi Creek Industrial Park, Karachi.	Godown 2 Address: Second Floor, WH- 01, 20-A-7A, Korangi Creek Industrial Park, Karachi.
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Item No. II: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT.

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

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

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy of notarized Notarization: Notarized 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	
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. <ul style="list-style-type: none"> • 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; <ul style="list-style-type: none"> • 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.

		Validity: 06-11-2026		
3.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Shahrah-e-Faisal, Karachi. (ELI- 00010) R&I detail 22-05-2025 Fee: 6,000/- Slip: 45005876 Fee: 20,000/- Slip: 525023829	Name of Manufacturer: M/s DiaSorin Italia S.p.A., Via Crescentino, snc 13040 Saluggia (VC), Italy. <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 02-04-2029 • FSC Type: Original Issued By: MoH Legalization: Apostilled Validity: 24-03-2026 • ISO Certificate Type: Original Notarization: Notarized Validity: 06-02-2028 	Brand name: ETI-MAX 3000 Generic Name: Microtiter plate analyzer Applied as: System Class: A Model/Codes/Sizes: 10020 Service life: 10 Years	The Board approved the case.
4.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Shahrah-e-Faisal, Karachi. (ELI- 00010) R&I detail 22-05-2025 Fee: 6,000/- Slip: 2500742830 Fee: 20,000/- Slip: 651384932857	Name of Manufacturer: M/s DiaSorin Italia S.p.A., Via Crescentino, snc 13040 Saluggia (VC), Italy. <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 02-04-2029 • FSC Type: Original Issued By: MoH Legalization: Apostilled Validity: 24-03-2026 • ISO Certificate 	Brand name: LIAISON® XS Generic Name: Chemiluminescence Immunoassay analyzer Applied as: System Class: A Model/Codes/Sizes: 10090 Service life: 10 Years	The Board approved the case.

		Type: Original Notarization: Notarized Validity: 06-02-2028		
5.	M/s. Sindh Medical Stores, 13-B, Block 6, PECHS, Shahrah-e-Faisal, Karachi. (ELI- 00010) R&I detail 22-05-2025 Fee: 6,000/- Slip: 667015673855 Fee: 20,000/- Slip: 0132344965	Name of Manufacturer: M/s DiaSorin Italia S.p.A., Via Crescentino, snc 13040 Saluggia (VC), Italy. • LOA Type: Original Notarization: Notarized Validity: 02-04-2029 • FSC Type: Original Issued By: MoH Legalization: Apostilled Validity: 24-03-2026 • ISO Certificate Type: Original Notarization: Notarized Validity: 06-02-2028	Brand name: LIAISON® XL Generic Name: Chemiluminescence Immunoassay analyzer Applied as: System Class: A Model/Codes/Sizes: 10050 Service life: 10 Years	The Board approved the case.
6.	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3- A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 6,000/- Slip # 14591733201	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • FSC Type: Copy Issued By: Govt Body Legalization: Not legalized	Brand name: Cam Source® LED Generic Name: Camera & Light Source System Applied as: Single Class: A Model/Codes/Sizes: 1. CSFHD01-Camsource® LED Control Unit 2. CSFHD01CC-Camera Head	Deferred due to following deficiencies in application; • Application has been submitted as single while it should be submitted as system since FSC mentions different devices with unique codes that will be combined to perform function as system. Accordingly, Fee of Rs. 25000/- should be deposited by the applicant. • 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 style="list-style-type: none"> • 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.
7.	M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi ELI-00415 Date of R& I 22-05-2025 Fee: PKR 6,000/- Slip # 452409000328	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany. LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025 • 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	Brand name: Vitegra® Generic Name: Visual Integration System Applied as: Single Class: A 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	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Application has been submitted as single while it should be submitted as system since FSC mentions different devices with unique codes that will be combined to perform function as 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, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar,	Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41,	Brand name: Intralaminar Endoscopic Surgical System (ILESSYS)	Deferred due to following deficiencies in application;

	<p>Rawalpindi</p> <p>ELI-00415</p> <p>Date of R& I 22-05-2025</p> <p>Fee: PKR 6,000/- Slip # 2960963069</p>	<p>RaumFabrik 61, 76227 Karlsruhe, Germany.</p> <p>LOA</p> <p>Type: Copy of Notarized</p> <p>Notarization: Notarized</p> <p>Validity: 17-03-2025</p> <p>• FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027</p>	<p>Transforaminal Endoscopic Surgical System (TESSYS)</p> <p>Cervical Endoscopic Surgical System (CESSYS)</p> <p>Generic Name:</p> <p>Intralaminar Endoscopic Surgical System (ILESSYS)</p> <p>Transforaminal Endoscopic Surgical System (TESSYS)</p> <p>Cervical Endoscopic Surgical System (CESSYS)</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes:</p> <p>Not mentioned in application.</p> <p>Service life:</p> <p>Not mentioned</p>	<ul style="list-style-type: none"> • The applicant has applied three different endoscopic surgical systems in a single application. One system should be selected by the applicant. Fee of Rs. 25000/- should be deposited by the applicant. • The relevant devices to be combined in selected system along with their codes, should be mentioned in the application. • 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.
9.	<p>M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi</p> <p>ELI-00415</p> <p>Date of R& I 22-05-2025</p> <p>Fee: Not submitted</p>	<p>Name of Manufacturer:</p> <p>M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany.</p> <p>LOA</p> <p>Type: Copy of Notarized</p> <p>Notarization: Notarized</p> <p>Validity: 17-03-2025</p> <p>• FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024</p>	<p>Brand name:</p> <p>Intracs® EM Sytem</p> <p>Generic Name:</p> <p>Integrated Navigation Tracking & Control System</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Model/Codes/Sizes:</p> <p>1. JINT01S-Intracs EM System. Integrated Navigation Track & Control. 2. JINTCU1115-Intracs EM</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • Evidence of payment of fee has not been submitted. • Application has been submitted as single while it should be submitted as system since FSC mentions different devices with unique codes that will be combined to perform function as system. Accordingly, Fee of Rs. 50,000/- should be deposited by the applicant.

		<p>Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2029 	<p>Control Unit</p> <p>3. JINTFG1125-Intracs EM Field Generator.</p> <p>4. JINTPM2245-AP-Intracs EM Patient Mapper-AP</p> <p>5. JINTPM2245-LAT-Intracs EM Patient Mapper-LAT</p> <p>6. JINTSC2205-Intracs EM Sensor Clip</p> <p>7. JINTPT2235-Intracs EM Patient Tracker.</p> <p>Service life: 3 Years</p>	<ul style="list-style-type: none"> • LOA is copy and has expired. • Copy of FSC submitted has not been legalized. • Copy of ISO certificate has not been notarized. • Copy of EU QMS certificate has not been notarized. • Service life data has not been submitted.
10.	<p>M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi</p> <p>ELI-00415</p> <p>Date of R& I 22-05-2025</p> <p>Fee: PKR 31,000/- Slip # 4337260846</p>	<p>Name of Manufacturer:</p> <p>M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany.</p> <p>LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025</p> <ul style="list-style-type: none"> • 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 • EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2029 	<p>Brand name: Versicon® Spine Pump</p> <p>Generic Name: Irrigation Pump</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Model/Codes/Sizes: JISP3000</p> <p>Service life: 3 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • LOA is copy and has expired. • Copy of FSC submitted has not been legalized. • Copy of ISO certificate has not been notarized. • Copy of EU QMS certificate has not been notarized. • Service life data has not been submitted.

11.	<p>M/s Cabbot Surgicals, Ho. No. CB 6060 Rose Lane 3-A, New Lalazar, Rawalpindi</p> <p>ELI-00415</p> <p>Date of R& I 22-05-2025</p> <p>Fee: PKR 62,000/- Slip # 476366701</p>	<p>Name of Manufacturer: M/s Joimax GmbH, Amalienbadstrabe 41, RaumFabrik 61, 76227 Karlsruhe, Germany.</p> <p>LOA Type: Copy of Notarized Notarization: Notarized Validity: 17-03-2025</p> <p>• FSC Type: Copy Issued By: Govt Body Legalization: Not legalized Issue Date: 26-11-2024 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2027</p> <p>• EU QMS Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2029</p>	<p>Brand name: Endovapor® 2</p> <p>Generic Name: Multi Radio Frequency System</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Model/Codes/Sizes: 1. JEVD0201-Endovapor 2 Device (Power rating 220-240V) 2. JEVD0202-Endovapor 2 Device (Power rating 100-127V) 3. REFUSS01-Footswitch Endovapor 2</p> <p>Service life: 3 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • Application has been submitted as single while it should be submitted as system since FSC mentions different devices with unique codes that will be combined to perform function as system. Accordingly, Fee of Rs. 100,000/- 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. • Copy of EU QMS certificate has not been notarized. • Service life data has not been submitted.
12.	<p>M/s. Med Lab Services, Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.</p> <p>(ELI- 00056)</p> <p>R&I detail 27-05-2025</p> <p>Fee: 31,000/-</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples</p>	<p>Brand name: Vircell Mumps ELISA IgG/IgM Kit</p> <p>Generic Name: Mumps ELISA IgG/IgM Kit</p> <p>Applied as: Kit</p> <p>Class: B</p>	<p>The Board approved the case.</p>

	Slip: 440352963	1+2 ELISA IgG/ IgM Kit Dossier) <ul style="list-style-type: none"> • FSC Type: Copy of legalized 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) 	Model/Codes/Sizes: G/M1014 Shelf life: 21 Months (2-8°C)	
13.	M/s. Med Lab Services, Office No. 1, 1 st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi. (ELI- 00056) R&I detail 27-05-2025	Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain. <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 	Brand name: Vircell Chikungunya ELISA IgM Kit Generic Name: Chikungunya ELISA IgM Kit Applied as: Kit	The Board approved the case.

	Fee: 31,000/- Slip: 23898265	<p>(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <ul style="list-style-type: none"> • FSC Type: Copy of legalized 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) 	Class: B Model/Codes/Sizes: M1010 Shelf life: 21 Months (2-8°C)	
14.	M/s. Med Lab Services, Office No. 1, 1 st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi. (ELI- 00056)	Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain. <ul style="list-style-type: none"> • LOA Type: Copy of notarized 	Brand name: Vircell Chikungunya ELISA IgG Kit Generic Name: Chikungunya ELISA IgG Kit	The Board approved the case.

	R&I detail 27-05-2025 Fee: 31,000/- Slip: 212563640183	Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier) <ul style="list-style-type: none"> • FSC Type: Copy of legalized 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) 	Applied as: Kit Class: B Model/Codes/Sizes: G1010 Shelf life: 21 Months (2-8°C)	
15.	M/s. Med Lab Services, Office No. 1, 1 st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.	Brand name: Vircell Measles ELISA IgG/IgM Kit Generic Name:	The Board approved the case.

	<p>(ELI- 00056)</p> <p>R&I detail 27-05-2025 Fee: 31,000/- Slip: 9280427983</p>	<p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• FSC Type: Copy of legalized 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)</p> <p>• 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)</p> <p>• 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)</p>	<p>Measles ELISA IgG/IgM Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: G/M1001</p> <p>Shelf life: 21 Months (2-8°C)</p>	
16.	M/s. Med Lab Services, Office No. 1, 1 st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada,</p>	<p>Brand name: Vircell Cytomegalovirus ELISA IgM Capture Kit</p>	The Board approved the case.

	<p>(ELI- 00056)</p> <p>R&I detail 27-05-2025 Fee: 62,000/- Slip: 1333281656</p>	<p>Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier) • FSC Type: Copy of legalized 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) 	<p>Generic Name: Cytomegalovirus ELISA Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: M1004</p> <p>Shelf life: 21 Months (2-8°C)</p>	
17.	M/s. Med Lab Services, Office No. 1, 1 st Floor	<p>Name of Manufacturer: M/s Vircell, S.L., Parque</p>	<p>Brand name: Vircell Cytomegalovirus</p>	The Board approved the case.

	<p>ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.</p> <p>(ELI- 00056)</p> <p>R&I detail 27-05-2025 Fee: 62,000/- Slip: 4228202157</p>	<p>Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier) • FSC Type: Copy of legalized 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) 	<p>ELISA IgG Kit</p> <p>Generic Name: Cytomegalovirus ELISA Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: G1004</p> <p>Shelf life: 21 Months (2-8°C)</p>	
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18.	<p>M/s. Med Lab Services, Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.</p> <p>(ELI- 00056)</p> <p>R&I detail 27-05-2025 Fee: 62,000/- Slip: 269130426</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Issue Date: 27-06-2022 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: Vircell Syphilis ELISA IgG + IgM Kit</p> <p>Generic Name: Syphilis ELISA IgG + IgM Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: T1060</p> <p>Shelf life: 21 Months (2-8°C)</p>	<p>The Board approved the case.</p>
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19.	<p>M/s. Med Lab Services, Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.</p> <p>(ELI- 00056)</p> <p>R&I detail 27-05-2025 Fee: 62,000/- Slip: 9650841683</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Issue Date: 27-06-2022 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: Vircell Toxoplasma ELISA IgG Kit</p> <p>Generic Name: Toxoplasma ELISA IgG Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: G1027</p> <p>Shelf life: 21 Months (2-8°C)</p>	The Board approved the case.
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20.	<p>M/s. Med Lab Services, Office No. 1, 1st Floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.</p> <p>(ELI- 00056)</p> <p>R&I detail 27-05-2025 Fee: 62,000/- Slip: 00774078</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy Issued By: Regulatory Body Legalization: Not Legalized Issue Date: 27-06-2022 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: Vircell Toxoplasma ELISA IgM Capture Kit</p> <p>Generic Name: Toxoplasma ELISA IgM Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: M1027</p> <p>Shelf life: 21 Months (2-8°C)</p>	<p>The Board approved the case.</p>
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21.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 14-07-2025 Fee: 62,000/- Slip: 183147898806</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: Herpes Simplex 1+2 Virclia® IgM Monotest Kit</p> <p>Generic Name: Herpes Simplex IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: VCM036</p> <p>Shelf life: 15 Months (2-8oC)</p>	<p>Approved subject to submission of Original Notarized LOA.</p>
22.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud,</p>	<p>Brand name: Measles Virclia® IgG Monotest Kit</p>	<p>Approved subject to submission of Original Notarized</p>

	<p>Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 04-07-2025 Fee: 31,000/- Slip: 551120567</p>	<p>Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled 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 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) 	<p>Generic Name: Measles IgG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM054</p> <p>Shelf life: 15 Months (2-8oC)</p>	LOA.
23.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p>	<p>Brand name: Toxoplasma Virclia® IgM Monotest Kit</p> <p>Generic Name: Toxoplasma IgM Monotest Kit</p>	Approved subject to submission of Original Notarized LOA.

	<p>(ELI- 00496)</p> <p>R&I detail</p> <p>04-07-2025</p> <p>Fee: 62,000/-</p> <p>Slip: 816123169047</p>	<ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled 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 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) 	<p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: VCM088</p> <p>Shelf life: 15 Months (2-8oC)</p>	
24.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized 	<p>Brand name: Toxoplasma Virclia® IgG Monotest Kit</p> <p>Generic Name: Toxoplasma IgG Monotest Kit</p> <p>Applied as: Kit</p>	<p>Approved subject to submission of Original Notarized LOA.</p>

	<p>R&I detail</p> <p>04-07-2025</p> <p>Fee: 62,000/-</p> <p>Slip: 4688828663</p>	<p>Validity: 31-12-2025</p> <ul style="list-style-type: none"> • FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled 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 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) 	<p>Class: C</p> <p>Model/Codes/Sizes: VCM087</p> <p>Shelf life: 15 Months (2-8oC)</p>	
25.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail</p> <p>04-07-2025</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via 	<p>Brand name: Cytomegalovirus Virclia® IgM Monotest Kit</p> <p>Generic Name: Cytomegalovirus IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: C</p>	<p>Approved subject to submission of Original Notarized LOA.</p>

	<p>Fee: 62,000/- Slip: 14172168</p>	<p>Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Model/Codes/Sizes: VCM022</p> <p>Shelf life: 15 Months (2-8oC)</p>	
26.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 14-07-2025 Fee: 31,000/- Slip: 511251287562</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled</p>	<p>Brand name: Parvovirus Virclia® IgG Monotest Kit</p> <p>Generic Name: Parvovirus IgG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM075</p>	<p>Approved subject to submission of Original Notarized LOA.</p>

		<p>Issued By: Regulatory Body</p> <p>Legalization: Apostilled</p> <p>Issue Date: 14-03-2025</p> <p>Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Shelf life: 15 Months (2-8oC)</p>	
27.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 14-07-2025 Fee: 31,000/- Slip: 086804456073</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnologico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled</p>	<p>Brand name: Diphtheria Virclia® IgG Monotest Kit</p> <p>Generic Name: Diphtheria IgG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM006</p> <p>Shelf life: 15 Months (2-8oC)</p>	<p>• Approved subject to submission of Original Notarized LOA.</p>

		<p>Issue Date: 14-03-2025</p> <p>Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>		
28.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 14-07-2025 Fee: 31,000/- Slip: 2036641088</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p>	<p>Brand name: Coxiella Burnetii Virclia® IgM Monotest Kit</p> <p>Generic Name: Coxiella Burnetii IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM020</p> <p>Shelf life: 15 Months (2-8oC)</p>	<p>• Approved subject to submission of Original Notarized LOA.</p>

		<ul style="list-style-type: none"> • 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) 		
29.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 14-07-2025 Fee: 31,000/- Slip: 720406673367</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned • ISO Certificate Type: Copy of notarized 	<p>Brand name: Chagas Virclia® IgG + IgM Monotest Kit</p> <p>Generic Name: Chagas IgG + IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM008</p> <p>Shelf life: 15 Months (2-8oC)</p>	<p>Approved subject to submission of Original Notarized LOA.</p>

		<p>Notarization: Notarized</p> <p>Validity: 06-02-2027</p> <p>(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)</p> <p>• 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)</p>		
30.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 14-07-2025 Fee: 62,000/- Slip: 85900923742</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been</p>	<p>Brand name: Syphilis Virclia® IgG + IgM Monotest Kit</p> <p>Generic Name: Syphilis IgG + IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: VCN086</p> <p>Shelf life: 15 Months (2-8oC)</p>	<p>Approved subject to submission of Original Notarized LOA.</p>

		<p>submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <ul style="list-style-type: none"> • 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) 		
31.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025 Fee: 31,000/- Slip: 33354062711</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • 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) 	<p>Brand name: Chickengunya Virclia® IgG Monotest Kit</p> <p>Generic Name: Chickengunya IgG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM059</p> <p>Shelf life: 15 Months (2-8°C)</p>	<ul style="list-style-type: none"> • Approved subject to submission of Original Notarized LOA.

		<ul style="list-style-type: none"> • 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) 		
32.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025</p> <p>Fee: 31,000/- Slip: 027670024181</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 06-02-2025 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) • EU QMS Certificate Type: Copy of notarized Notarization: Notarized 	<p>Brand name: Hepatitis E Virclia® IgG Monotest Kit</p> <p>Generic Name: Hepatitis E IgG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM066</p> <p>Shelf life: 15 Months (2-8°C)</p>	<ul style="list-style-type: none"> • Approved subject to submission of Original Notarized LOA.

		Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)		
33.	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: 5380710965	Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico 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 of Apostilled 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 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	Brand name: Hydatidosis Virclia® IgG Monotest Kit Generic Name: Hydatidosis IgG Monotest Kit Applied as: Kit Class: B Model/Codes/Sizes: VCM040 Shelf life: 15 Months (2-8°C)	<ul style="list-style-type: none"> • Approved subject to submission of Original Notarized LOA.

		Dossier)		
34.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025</p> <p>Fee: 31,000/- Slip: 720989986</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: Mumps Virclia® IgM Monotest Kit</p> <p>Generic Name: Mumps IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM061</p> <p>Shelf life: 15 Months (2-8°C)</p>	<p>• Approved subject to submission of Original Notarized LOA.</p>
35.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud,</p>	<p>Brand name: Aspergillus Galactomannan</p>	<p>• Approved subject to submission of Original Notarized</p>

	<p>Small Industrial Corporation, Punjab State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025 Fee: 62,000/- Slip: 83615382509</p>	<p>Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled 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 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) 	<p>AG Virclia® Monotest Kit</p> <p>Generic Name: Aspergillus Galactomannan AG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: VCM073</p> <p>Shelf life: 15 Months (2-8°C)</p>	<p>LOA.</p>
36.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab State, Taxila, Rawalpindi.</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • LOA 	<p>Brand name: Mumps Virclia® IgG Monotest Kit</p> <p>Generic Name: Mumps IgG Monotest Kit</p>	<ul style="list-style-type: none"> • Approved subject to submission of Original Notarized LOA.

	<p>(ELI- 00496)</p> <p>R&I detail 26-06-2025 Fee: 31,000/- Slip: 218984870694</p>	<p>Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p> <p>• 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)</p> <p>• 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)</p>	<p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM060</p> <p>Shelf life: 15 Months (2-8°C)</p>	
37.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p>	<p>Brand name: Measles Virclia® IgM Monotest Kit</p> <p>Generic Name: Measles IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p>	<p>• Approved subject to submission of Original Notarized LOA.</p>

	26-06-2025 Fee: 31,000/- Slip: 4357667981	<ul style="list-style-type: none"> • FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 06-02-2025 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) • 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) 	Model/Codes/Sizes: VCM057 Shelf life: 15 Months (2-8°C)	
38.	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: 36447614	Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain. <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 • FSC (Verified Via Website of Regulatory Body) 	Brand name: Chickengunya Virclia® IgM Monotest Kit Generic Name: Chickengunya IgM Monotest Kit Applied as: Kit Class: B Model/Codes/Sizes:	<ul style="list-style-type: none"> • Approved subject to submission of Original Notarized LOA.

		<p>Type: Copy of Apostilled</p> <p>Issued By: Regulatory Body</p> <p>Legalization: Apostilled</p> <p>Issue Date: 14-03-2025</p> <p>Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simplex 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simplex 1+2 ELISA IgG/IgM Kit Dossier)</p>	<p>VCM063</p> <p>Shelf life: 15 Months (2-8°C)</p>	
39.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025 Fee: 31,000/- Slip: 59174230158</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled Issued By: Regulatory Body Legalization: Apostilled</p>	<p>Brand name: Brucella Virclia® IgM Monotest Kit</p> <p>Generic Name: Brucella IgM Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes: VCM007</p> <p>Shelf life: 15 Months (2-8°C)</p>	<p>• Approved subject to submission of Original Notarized LOA.</p>

		<p>Issue Date: 14-03-2025</p> <p>Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027 (Original has been submitted in Vircell Herpes Simplex 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027 (Original has been submitted in Vircell Herpes Simplex 1+2 ELISA IgG/IgM Kit Dossier)</p>		
40.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 04-07-2025</p> <p>Fee: 62,000/- Slip: 91433298425</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of Apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 14-03-2025 Validity: Not mentioned</p>	<p>Brand name: Herpes Simplex 1+2 Virclia® IgG Monotest Kit</p> <p>Generic Name: Herpes Simplex IgG Monotest Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: VCM034</p> <p>Shelf life: 15 Months (2-8°C)</p>	<p>• Approved subject to submission of Original Notarized LOA.</p>

		<ul style="list-style-type: none"> • 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) 		
41.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025 Fee: 6,000/- Slip: 5295254096</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <ul style="list-style-type: none"> • 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: 29-06-2022 Validity: Not mentioned • ISO Certificate Type: Copy of notarized Notarization: Notarized 	<p>Brand name: Virclia® Lotus</p> <p>Generic Name: In Vitro Chemiluminescent Immunoassay Analyzer.</p> <p>Applied as: Kit</p> <p>Class: A</p> <p>Model/Codes/Sizes: VCLTS-CL</p> <p>Service life: Not Mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

		<p>Validity: 06-02-2027</p> <p>(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit Dossier)</p> <p>• EU QMS Certificate Type: Copy of notarized Notarization: Notarized Validity: 17-10-2027</p> <p>(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/IgM Kit Dossier)</p>		
42.	<p>M/s. Lab Diagnostic Systems (SMC) Pvt. Ltd., Plot No. 36-A, Punjab Small Industrial Corporation, Punjab Industrial State, Taxila, Rawalpindi.</p> <p>(ELI- 00496)</p> <p>R&I detail 26-06-2025 Fee: 25,000/- Slip: 7996184219</p>	<p>Name of Manufacturer: M/s Vircell, S.L., Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain.</p> <p>• LOA Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC (Verified Via Website of Regulatory Body) Type: Copy of apostilled Issued By: Regulatory Body Legalization: Apostilled Issue Date: 06-02-2025 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 06-02-2027</p> <p>(Original has been submitted in Vircell Herpes Simples 1+2 ELISA IgG/ IgM Kit</p>	<p>Brand name: Virclia® Auxiliary Reagents</p> <p>Generic Name: Auxiliary Reagents for washing, decontamination and dilution steps of Virclia Kits.</p> <p>Applied as: Family</p> <p>Class: A</p> <p>Model/Codes/Sizes:</p> <ol style="list-style-type: none"> 1. VCMAR (Virclia Auxiliary Reagent) 2. VCMAR-DS (Virclia Auxiliary Reagent-DS)-30 Months 3. VCMAR-EDB (Virclia Auxiliary Reagent-EDB) 4. VCMAR-EDP (Virclia Auxiliary Reagent-EDP) 5. VCMAR-W1 (Virclia Auxiliary Reagent-W1) <p>Shelf life:</p> <ol style="list-style-type: none"> 1. VCMAR (Virclia Auxiliary 	<p>• Approved subject to submission of Original Notarized LOA.</p>

		Dossier) <ul style="list-style-type: none"> 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) 	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	
43.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail 16-06-2025 Fee: 6,000/- Slip: 6294763510	Name of Manufacturer: M/s Intrumentation Laboratory Company, 180 Hartwell Road, Bedford Massachusetts, USA 01730. <ul style="list-style-type: none"> 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 	Brand name: 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	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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; <ul style="list-style-type: none"> Coagulation analyzer and its reagents have been applied in single application as cluster. The analyzer should be applied separately

	Fee: 6,000/- Slip: 495960806824	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	Applied as: Cluster Class: A Model/Codes/Sizes: Not clear Service life: Not clear	as system with a fee of Rs. 25000/- while reagents should be applied separately as cluster with a fee of Rs. 25000/-. <ul style="list-style-type: none"> Codes applied have not been specified. Service life data has not been submitted.
45.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail 16-06-2025 Fee: 62,000/- Slip: 031845124	Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK. • LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned • FSC Not submitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025	Brand name: Anti-A Monoclonal Generic Name: Blood Grouping Reagent Kit Applied as: Kit Class: C Model/Codes/Sizes: BG-A10 (as per DOC) Shelf life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> Valid legalized FSC from regulatory body of country of origin, has not been submitted. Shelf life data has not been submitted.

46.	<p>M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.</p> <p>(ELI- 00244)</p> <p>R&I detail 16-06-2025 Fee: 62,000/- Slip: 416173331</p>	<p>Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.</p> <p>• LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned</p> <p>• FSC Not submitted.</p> <p>• ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027</p> <p>• CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025</p>	<p>Brand name: Anti-D Monoclonal (IgG + IgM)</p> <p>Generic Name: Blood Grouping Reagent Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes: BG-D10 (as per DOC)</p> <p>Shelf life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> Valid legalized FSC from regulatory body of country of origin, has not been submitted. Shelf life data has not been submitted.
47.	<p>M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.</p> <p>(ELI- 00244)</p> <p>R&I detail 16-06-2025 Fee: 62,000/- Slip: 70654835</p>	<p>Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.</p> <p>• LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned</p>	<p>Brand name: ABOD Blood Grouping Kit</p> <p>Generic Name: Blood Grouping Reagent Kit</p> <p>Applied as: Kit</p> <p>Class: C</p> <p>Model/Codes/Sizes:</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> Valid legalized FSC from regulatory body of country of origin, has not been submitted. Shelf life data has not been submitted.

		<ul style="list-style-type: none"> • FSC Not submitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025 	BG-ABOD10 (as per DOC) Shelf life: Not mentioned	
48.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail 16-06-2025 Fee: 62,000/- Slip: 3695108471	Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK. <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned • FSC Not submitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025 	Brand name: Anti-B Monoclonal Generic Name: Blood Grouping Reagent Kit Applied as: Kit Class: C Model/Codes/Sizes: BG-B10 (as per DOC) Shelf life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Valid legalized FSC from regulatory body of country of origin, has not been submitted. • Shelf life data has not been submitted.

49.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 55009983465</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p> <p>• LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Not legalized Issue Date: 02-05-2023 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027</p>	<p>Brand name: HistoCore Water Bath M</p> <p>Generic Name: Tissue Flotation Bath</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: 140607020C1 (as per DOC letter)</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.
50.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>Manufacturing Site: M/s Leica Microsystems Ltd., Shanghai, Floor 1, 2,</p>	<p>Brand name: HistoCore Pegasus Plus</p> <p>Generic Name: Tissue Processor</p> <p>Applied as: Single</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • LOA is copy and not notarized. • Valid legalized FSC, has not been submitted. • Service life has not been mentioned in application.

	Fee: 6,000/- Slip: 617643639	3A, 4A and 6, Building T20-1 & Room 301, Building T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	Class: A Model/Codes/Sizes: Not mentioned Service life: Not mentioned	<ul style="list-style-type: none"> • ISO certificate of manufacturing site is copy and not notarized. • Codes have not been mentioned.
51.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 6,000/- Slip: 7887774539	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. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted 	Brand name: HistoCore Biocut Generic Name: Rotary Microtome Applied as: Single Class: A Model/Codes/Sizes: Not mentioned Service life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • 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.

		• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027		
52.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 6,000/- Slip: 7887774539	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. • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027	Brand name: Leica RM2125 RTS Generic Name: Rotary Microtome Applied as: Single Class: A Model/Codes/Sizes: Not mentioned Service life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • 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. • Codes have not been mentioned.
53.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 6,000/-	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	Brand name: HistoCore Pegasus Generic Name: Tissue Processor Applied as: Single	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • 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

	<p>Slip: 45180735953</p>	<p>T20-5, 258 Jinzang Road (Shanghai) Pilot Free Trade Zone, Shanghai, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	<p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>is copy and not notarized.</p> <ul style="list-style-type: none"> • Codes have not been mentioned.
54.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 02704225</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy 	<p>Brand name: Leica ST4020</p> <p>Generic Name: Automated Slide Stainer</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

		Notarization: Not Notarized Validity: 31-01-2027		
55.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 99149517</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p> <p>• LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026</p> <p>• FSC Not submitted</p> <p>• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027</p>	<p>Brand name: Leica TP1020</p> <p>Generic Name: Tissue Processor</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.
56.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 10-06-2025 Fee: 6,000/- Slip: 19921913067</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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</p>	<p>Brand name: Leica CV5030</p> <p>Generic Name: Automated Coverslipper</p> <p>Applied as: Single</p> <p>Class: A</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

		<p>Zone, Shanghai, China.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	<p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<ul style="list-style-type: none"> • Codes have not been mentioned.
57.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 10-06-2025 Fee: 6,000/- Slip: 0443243367</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized 	<p>Brand name: Leica CM3050S</p> <p>Generic Name: Crystat Microtom</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

		Validity: 31-01-2027		
58.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 10-06-2025 Fee: 6,000/- Slip: 00840557577</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	<p>Brand name: Leica CM1950</p> <p>Generic Name: Crystat Microtom</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.
59.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 8129682709</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p>	<p>Brand name: HistoCore Pearl</p> <p>Generic Name: Tissue Processor</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes:</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

		<ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	<p>Not mentioned</p> <p>Service life: Not mentioned</p>	
60.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 14560793704</p>	<p>Legal Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <p>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.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	<p>Brand name: HistoCore Multicut</p> <p>Generic Name: Rotary Microtome</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

61.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 955889808830</p>	<p>Name of Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Type: Original Legalization: Not legalized Issue Date: 16-01-2025 Validity: Not mentioned • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 23-12-2026 	<p>Brand name: HistoCore Chromax CV</p> <p>Generic Name: Automated Coverslipper</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • LOA is copy and not notarized. • FSC has not been legalized. • Service life has not been mentioned in application. • ISO certificate is copy. • Codes have not been mentioned.
62.	<p>M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi.</p> <p>(ELI- 00109)</p> <p>R&I detail 02-06-2025 Fee: 6,000/- Slip: 427259757</p>	<p>Name of Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Type: Original Legalization: Not legalized Issue Date: 16-01-2025 Validity: Not mentioned • ISO Certificate 	<p>Brand name: HistoCore Chromax ST</p> <p>Generic Name: Automated Slide Stainer</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: Not mentioned</p> <p>Service life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • LOA is copy and not notarized. • FSC has not been legalized. • Service life has not been mentioned in application. • ISO certificate is copy. • Codes have not been mentioned.

		Type: Copy of notarized Notarization: Notarized Validity: 23-12-2026		
63.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 10-06-2025 Fee: 6,000/- Slip: 5376278944	Name of Manufacturer: M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-05-2026 • FSC Not submitted • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 31-01-2027 	Brand name: Leica CM1860 UV Generic Name: Crystat Microtom Applied as: Single Class: A Model/Codes/Sizes: Not mentioned Service life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • 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.
64.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 12-06-2025 Fee: 25,000/- Slip: 8052760298	Name of Manufacturer: M/s Leica Biosystems Melbourne Pty Ltd., 495 Blackburn Road, Mount Waverley, Victoria 3149, Australia. <ul style="list-style-type: none"> • LOA Not submitted. • FSC Type: Copy of legalized Issue By: TGA Legalization: legalized Issue Date: 20-06-2022 Validity: Not mentioned. • ISO Certificate 	Brand name: HistoCore Peloris 3 Generic Name: Tissue processor Applied as: System Class: A Model/Codes/Sizes: 45.0001 Service life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Copy of LOA submitted is from M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany while FSC mentions M/s Leica Biosystems Melbourne Pty Ltd., 495 Blackburn Road, Mount Waverley, Victoria 3149, Australia as MAH. • Original FSC has not been submitted. • Original ISO certificate has not been submitted.

		Type: Copy of notarized Notarization: Notarized Validity: 30-11-2027		<ul style="list-style-type: none"> Service life has not been mentioned in application.
65.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 6,000/- Slip: 820555297385	Name of Manufacturer: M/s Leica Biosystems Imaging Inc., 1360 Park Center Drive Vista, CA 92081, USA. <ul style="list-style-type: none"> LOA Not submitted. FSC (Netherlands) Type: Copy of legalized Issued By: MOH Netherlands Legalization: legalized Validity: 30-05-2027 ISO Certificate Type: Copy Notarization: Not Notarized Validity: 27-03-2028 	Brand name: Aperio WebViewer DX Generic Name: Web-based digital slide viewing software Applied as: Single Class: A Model/Codes/Sizes: 23WVROWIVD Service life: Not mentioned	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> Copy of LOA submitted is from M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany while FSC mentions M/s Leica Biosystems 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. (ELI- 00109) R&I detail 02-06-2025 Fee: 6,000/- Slip: 714441074718	Name of Manufacturer: M/s Leica Biosystems Imaging Inc., 1360 Park Center Drive Vista, CA 92081, USA. <ul style="list-style-type: none"> LOA Not submitted. FSC (Netherlands) Type: Copy of legalized Issued By: MOH Netherlands Legalization: legalized Validity: 30-05-2027 ISO Certificate 	Brand name: Aperio GT450 DX Generic Name: Digital Pathology Scanner Applied as: Single Class: A Model/Codes/Sizes: 23GT450DXIVD Service life:	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> Copy of LOA submitted is from M/s Leica Biosystems Nussloch GmbH, Heidelberger Str. 17-19, 69226 Nussloch, Germany while FSC mentions M/s Leica Biosystems Imaging Inc., 1360 Park Center Drive Vista, CA 92081, USA as MAH. Original FSC has not been submitted. Original notarized ISO certificate has

		Type: Copy Notarization: Not Notarized Validity: 27-03-2028	Not mentioned	not been submitted. • Service life has not been mentioned in application.
67.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 62,000/- Slip: 367485449521	Name of Authorized Representative: M/s bioMerieux SA, 376 Chemin de l'Orme, 69280 Marcy l'Etoile, France. Legal Manufacturer: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. • LOA Type: Copy of Notarized Notarization: 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	Brand name: BacT/ALERT® FA Plus Generic Name: Culture Bottles Applied as: Single Class: C Model/Codes/Sizes: 410851 (as per FSC) Shelf life: 12 Months	Deferred due to following deficiencies in application; • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted and has expired.
68.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109)	Name of Authorized Representative: M/s bioMerieux SA, 376 Chemin de l'Orme, 69280 Marcy l'Etoile, France. Legal Manufacturer: M/s bioMerieux Inc., 100	Brand name: BacT/ALERT® SA Generic Name: Culture Bottles	Deferred due to following deficiencies in application; • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized

	R&I detail 02-06-2025 Fee: 62,000/- Slip: 7807289208	Rodolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. • LOA Type: Copy of Notarized Notarization: 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	Applied as: Single Class: C Model/Codes/Sizes: 259789 (as per FSC) Shelf life: 12 Months	ISO certificate has not been submitted and has expired.
69.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 62,000/- Slip: 973342622	Name of Authorized Representative: M/s bioMerieux SA, 376 Chemin de l'Orme, 69280 Marcy l'Etoile, France. Legal Manufacturer: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. • LOA Type: Copy of Notarized Notarization: Notarized	Brand name: BacT/ALERT® SN Generic Name: Culture Bottles Applied as: Single Class: C Model/Codes/Sizes: 259790 (as per FSC) Shelf life: 12 Months	Deferred due to following deficiencies in application; • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted and has expired.

		Validity: 31-03-2026 <ul style="list-style-type: none"> • 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 		
70.	M/s. Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. (ELI- 00109) R&I detail 02-06-2025 Fee: 62,000/- Slip: 6031378879	Name of Authorized Representative: M/s bioMerieux SA, 376 Chemin de l'Orme, 69280 Marcy l'Etoile, France. Legal Manufacturer: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. <ul style="list-style-type: none"> • LOA Type: Copy of Notarized Notarization: Notarized Validity: 31-03-2026 • FSC Type: Copy of legalized Issued By: CCI Legalization: legalized Issue Date: 22-12-2016 Validity: Not mentioned 	Brand name: BacT/ALERT® FN Plus Generic Name: Culture Bottles Applied as: Single Class: C Model/Codes/Sizes: 410852 (as per FSC) Shelf life: 12 Months	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted and has expired.

		• 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. (ELI- 00109) R&I detail 02-06-2025 Fee: 62,000/- Slip: 2822532428	Name of Authorized Representative: M/s bioMerieux SA, 376 Chemin de l'Orme, 69280 Marcy l'Etoile, France. Legal Manufacturer: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. Manufacturing Site: M/s bioMerieux Inc., 100 Rodolphe Street, Durham, North Carolina 27712, USA. • LOA Type: Copy of Notarized Notarization: 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	Brand name: BacT/ALERT® PF Plus Generic Name: Culture Bottles Applied as: Single Class: C Model/Codes/Sizes: 410853 (as per FSC) Shelf life: 12 Months	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted and has expired.
72.	M/s. Total Technologies (Pvt.) Ltd., 696, J-2 Johar Town, District Lahore. (ELI- 00129)	Name of Manufacturer: M/s MMM Munchener Medizin Mechanik GmbH, Semmelweisstrabe 6 82152 Planegg Deutschland, Germany.	Brand name: Hyper LTS 150 Generic Name: Medical Low temperature	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • The model applied by the applicant is Hyper LTS 150 while FSC

	<p>R&I detail 03-06-2025 Fee: 31,000/- Slip: 707293557906</p>	<p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: 18-02-2030</p> <p>• FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 19-02-2025 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 30-11-2027</p> <p>• EU QMS/CE Certificate Type: Copy of Notarized Notarization: Notarized Validity: 24-04-2027</p>	<p>Sterilizer</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Model/Codes/Sizes: Hyper LTS 150-1 (Single Door) Hyper LTS 150-2 (Double Door) (as per technical documents)</p> <p>Service life: 10 Years</p>	<p>mentions Hyper LTS (all models). Moreover, there are two variants mentioned in documents i.e., Single Door & Double Door. The applied variant should be specified by the applicant.</p> <ul style="list-style-type: none"> • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted.
73.	<p>M/s. Total Technologies (Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.</p> <p>(ELI- 00129)</p> <p>R&I detail 03-06-2025 Fee: 31,000/- Slip: 6981381120</p>	<p>Name of Manufacturer: M/s MMM Munchener Medizin Mechanik GmbH, Semmelweisstrabe 6 82152 Planegg Deutschland, Germany.</p> <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: 18-02-2030</p> <p>• FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized</p>	<p>Brand name: Selectomat PL CL 6612</p> <p>Generic Name: Steam Sterilizer</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Model/Codes/Sizes: Not mentioned in FSC or other documents</p> <p>Service life: 10 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • The model applied by the applicant is Selectomat PL CL 6612 while FSC mentions Selectomat PL (all models). Moreover, there model applied by the applicant has not been mentioned in technical documents submitted. • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has

		Issue Date: 19-02-2025 Validity: Not mentioned • ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 30-11-2027 • EU QMS/CE Certificate Type: Copy of Notarized Notarization: Notarized Validity: 24-04-2027		not been submitted.
74.	M/s. Total Technologies (Pvt.) Ltd., 696, J-2 Johar Town, District Lahore. (ELI- 00129) R&I detail 03-06-2025 Fee: 31,000/- Slip: 11309961462	Name of Manufacturer: M/s MMM Munchener Medizin Mechanik GmbH, Semmelweisstrabe 6 82152 Planegg Deutschland, Germany. • LOA Type: Copy of Notarized Notarization: Notarized Validity: 18-02-2030 • FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 19-02-2025 Validity: Not mentioned • ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 30-11-2027 • EU QMS/CE Certificate Type: Copy of Notarized	Brand name: Unisteri SL 336 Generic Name: Steam Sterilizer Applied as: Single Class: B Model/Codes/Sizes: Not mentioned in FSC Service life: 10 Years	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • The device applied by the applicant has not been mentioned in FSC submitted. • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted.

		Notarization: Notarized Validity: 24-04-2027		
75.	<p>M/s. Total Technologies (Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.</p> <p>(ELI- 00129)</p> <p>R&I detail 03-06-2025 Fee: 31,000/- Slip: 00626251946</p>	<p>Name of Manufacturer: M/s MMM Munchener Medizin Mechanik GmbH, Semmelweisstrabe 6 82152 Planegg Deutschland, Germany.</p> <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: 18-02-2030</p> <p>• FSC Type: Copy of legalized Issued By: Govt. Body Legalization: Legalized Issue Date: 19-02-2025 Validity: Not mentioned</p> <p>• ISO Certificate Type: Copy of Notarized Notarization: Notarized Validity: 30-11-2027</p> <p>• EU QMS/CE Certificate Type: Copy of Notarized Notarization: Notarized Validity: 24-04-2027</p>	<p>Brand name: Unisteri SL 636</p> <p>Generic Name: Steam Sterilizer</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Model/Codes/Sizes: Not mentioned in FSC</p> <p>Service life: 10 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • The device applied by the applicant has not been mentioned in FSC submitted. • Original LOA has not been submitted. • Original FSC has not been submitted. • Original notarized ISO certificate has not been submitted.
76.	<p>M/s. Total Technologies (Pvt.) Ltd., 696, J-2 Johar Town, District Lahore.</p> <p>(ELI- 00129)</p> <p>R&I detail 03-06-2025</p>	<p>Name of Manufacturer: M/s MELAF Medizintechnik GmbH & Co. KG Geneststr. 6-10 10829 Berlin, Germany.</p> <p>• LOA Type: Original Notarization: Notarized</p>	<p>Brand name: Vacuclave 105</p> <p>Generic Name: Steam Sterilizer</p> <p>Applied as: Single</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • Original notarized ISO certificate has not been submitted. • Service life and data has not been submitted

	Fee: 31,000/- Slip: 273039579	Validity: 25-02-2030 <ul style="list-style-type: none"> • FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 19-02-2025 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 03-12-2027 • EU QMS/CE Certificate Type: Copy Notarization: Not Notarized Validity: 23-12-2026 	Class: B Model/Codes/Sizes: ME10105 (as per FSC) Service life: Not submitted	
77.	M/s. Opti Med, 2 nd Floor Hassan Plaza 6-A Jail Road, Lahore. (ELI- 00501) R&I detail 25-06-2025 Fee: 100,000/- Slip: 2375554809 (62,000/-) 38576998363 (38,000/-)	Name of Manufacturer: M/s AJL Ophthalmic SA., Parque Tecnologico de Alava, Ferdinand Zeppelin, 1, 01510 Minano (Alava), Spain. <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 13-05-2030 • FSC Type: Original Issued By: Spanish Agency Legalization: Apostilled Issue Date: 14-07-2023 Validity: Not mentioned • ISO Certificate 	Brand name: AJL Ring Generic Name: Intrastromal Ring Applied as: Family Class: C Codes (Sizes): Are mentioned in FSC and same are applied by the applicant. AFR15140 AFR15180 AFR20120 AFR20150 AFR20180 AFR20210	The Board approved the case.

		Type: Original Notarization: Notarized Validity: 20-08-2027	AFR25120 AFR25140 AFR25160 AFR25180 AFR25210 AFR25300 AFR30120 AFR30160 AFR620090 AFR620120 AFR620160 AFR620320 AFR630150 AFR630210 Shelf life: 4.5 Years	
78.	M/s. Opti Med, 2 nd Floor Hassan Plaza 6-A Jail Road, Lahore. (ELI- 00501) R&I detail 04-03-2024 Fee: 25,000/- Slip: 0562765635	Name of Manufacturer: M/s Iromed Group S.R.L., Via Tempio del Cielo, 3/5- 00144 Roma (RM), Italy. • LOA 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 Issue Date: 20-01-2023 Validity: Not mentioned (Original in CFX Linker Device)	Brand name: Ribofast Generic Name: Dextran –Free Ophthalmic Solution for Corneal Cross- Linking Applied as: Kit Class: B Model as per FSC & Label: 1.5ml Single Use Sterile Syringe Shelf life: 2 Years	The Board approved the case.

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

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

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

		<p>Validity: 18-11-2026</p> <p>• ISO Certificate</p> <p>Type: Copy</p> <p>Notarization: Not Notarized</p> <p>Validity: 08-08-2026</p>	<p>vi. ROB10013-Real Intelligence Robotics Drill</p> <p>vii. ROB10014-Real Intelligence Robotics Drill Tracker</p> <p>viii. ROB10010-Real Intelligence Robotics Bone Pins 4.0mm x 127mm</p> <p>ix. ROB10011-Real Intelligence Robotics Bone Pins 4.0mm x 152mm</p> <p>x. ROB00032-Navio Bone Pin 3.5mm x 127mm</p> <p>xi. ROB10002-Real Intelligence Robotics Cart Column.</p> <p>xii. ROB10003-Real Intelligence 24" Touch Screen.</p> <p>xiii. ROB10031-Real Intelligence Tubing Set.</p> <p>xiv. ROB10024S-Real Intelligence CORI.</p> <p>xv. ROB10025S-Real Intelligence Tracking Camera.</p> <p>xvi. ROB10027S-Real Intelligence Tablet.</p> <p>xvii. ROB10013S-Real Intelligence Robotic Drill.</p> <p>xviii. ROB10003S-Real Intelligence 24" Touch Screen.</p> <p>xix. ROB10028-Real Intelligence Transportation Case.</p> <p>xx. ROB10015-Real Intelligence Robotics Drill Attachment.</p> <p>xxi. ROB10017-Real Intelligence Point Probe.</p> <p>xxii. ROB10086-Real Intelligence Plane Visualizer.</p> <p>xxiii. ROB10020-Real Intelligence Tracker Clamp.</p>	
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			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. xxviii. ROB10012-Real Intelligence Check Point Pins Qty:4. xxix. ROB10023-Real Intelligence Z-Retractor. xxx. ROB10050-Real Intelligence Robotics Intrument Tray. xxxi. ROB10016-Real Intelligence Robotics Drill Guard. xxxii. ROB10000-CORI Starter Kit. xxiii. ROB10051-Real Intelligence Robotics Pin Caddy. xxxiv. ROB10052-Real Intelligence Robotics Pin Caddy Lid. xxxv. ROB10053-JOURNEY II Uni Robotics Finishing Insert(F). xxxvi. ROB10054-Universal Insert Lid(F) xxvii. ROB10055-Real Intelligence Shipping Inser(A). xxviii. ROB10056-Real Intelligence Shipping Inser(B). xxxix. ROB10057-Real Intelligence Shipping Inser(C). xl. ROB10058-Real Intelligence Shipping Inser(F). xli. ROB10087-Universal Base Tray Lid. xlii. ROB100022-Real Intelligence Robotics
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			<p>Cart Base 220.</p> <p>xlili. ROB10014S-Real Intelligence Robotic Drill Tracker.</p> <p>xliv. ROB10015S-Real Intelligence Robotic Drill Attachment.</p> <p>xliv. ROB10400-Real Intelligence Implant Database V2.88.</p> <p>xlvi. ROB00025-TKA Left Tibbia Twin Peg Cut Guide.</p> <p>xlvi. ROB00026-KA Right Tibbia Twin Peg Cut Guide</p> <p>xlvi. ROB00060-TKA Distal FMR Punches-38mm</p> <p>xlvi. ROB00061-TKA Distal FMR Punches-45mm</p> <p>1. ROB10300-Welcome Box 1</p> <p>li. PFSDV0016-Navio Flat Markers (Case of 18)</p> <p>lii. ROB10033-Real Intelligence 6mm Bullet Bur.</p> <p>liii. ROB10035-Real Intelligence 5mm Cylindrical Bur.</p> <p>liv. ROB10036-Real Intelligence 6mm Cylindrical Bur.</p> <p>lv. ROB10034-Real Intelligence 6mm Chip Breaker Bullet Bur.</p> <p>Service life: Not mentioned</p>	
83.	<p>M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>(ELI-00416)</p> <p>Date of R& I 02-07-2025</p> <p>Fee: PKR 6,000/-</p>	<p>Name of Manufacturer: Micro Medical Devices Inc., 23945 Calabasas Rd., Suit 110 Calabasas, CA USA 91302.</p> <p>• LOA Type: Original (PalmScan K2000) Notarization: Notarized</p>	<p>Brand name: PalmScan K2000</p> <p>Generic Name: Portable Keratometer</p> <p>Applied as: Single</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • Application form submitted is unfilled & unsigned. • FSC submitted has expired. • Notarized ISO Certificate of the manufacturer, has not been submitted.

	Slip # 675176810	Issue Date: 03-04-2025 Validity: May-2027 • FSC 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	Class: A Model/Codes/Sizes (as per FSC & Challan): PalmScan K2000 Service life: Not mentioned.	<ul style="list-style-type: none"> • Notarized DOC has not been submitted. • Service life and data has not been submitted.
84.	M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi. (ELI-00416) Date of R& I 02-07-2025 Fee: PKR 31,000/- Slip # 1273281242	Name of Manufacturer: Micro Medical Devices Inc., 23945 Calabasas Rd., Suit 110 Calabasas, CA USA 91302. • LOA Type: Original (PalmScan K2000) Notarization: Notarized Issue Date: 03-04-2025 Validity: May-2027 • FSC 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	Brand name: PalmScan A2000, P2000, AP2000, P2000FP Generic Name: Ophthalmic Ultrasound Applied as: Single Class: B Model/Codes/Sizes (as per FSC & Challan): PalmScan A2000 PalmScan P2000 PalmScan AP2000 PalmScan P2000FP Service life: Not mentioned.	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Application form submitted is unfilled & unsigned. • Justification of applying multiple models in single application, is required. • FSC submitted has expired. • Notarized ISO Certificate of the manufacturer, has not been submitted. • Notarized DOC has not been submitted. • Service life and data has not been submitted.
85.	M/s Jasani Scientifics,	Name of Manufacturer:	Brand name:	Deferred due to

	<p>Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>(ELI-00416)</p> <p>Date of R& I 03-06-2025</p> <p>Fee: PKR 6,000/- Slip # 78303720086</p>	<p>Good-Lite Co., 1155 Jansen Farm Dr. Elgin, IL USA 60123.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 06-03-2026 • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 17-11-2025 	<p>GL Adjustable Trial Frame Grey</p> <p>Generic Name: Adjustable Ophthalmic Trial Frame</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes (as per FSC): 469900</p> <p>Shelf/Service life: 5 Years</p>	<p>following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.
86.	<p>M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>(ELI-00416)</p> <p>Date of R& I 03-06-2025</p> <p>Fee: PKR 6,000/- Slip # 6487673479</p>	<p>Name of Manufacturer: Good-Lite Co., 1155 Jansen Farm Dr. Elgin, IL USA 60123.</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2025 • FSC Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 06-03-2026 • ISO Certificate Type: Copy Notarization: Not Notarized 	<p>Brand name: GL Ophthalmology Full Trial Lense Set (Red & Black Rims)</p> <p>Generic Name: Ophthalmology Trial Lense Set</p> <p>Applied as: Set</p> <p>Class: A</p> <p>Model/Codes/Sizes (as per FSC): 592000</p> <p>Shelf/Service life: 10 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

		Validity: 17-11-2025		
87.	<p>M/s Jasani Scientifics, Office No.1, SC-45, Marium Square, Chandni Chowk, Stadium Road, Karachi.</p> <p>(ELI-00416)</p> <p>Date of R& I 03-06-2025</p> <p>Fee: PKR 6,000/- Slip # 247122682</p>	<p>Name of Manufacturer: Good-Lite Co., 1155 Jansen Farm Dr. Elgin, IL USA 60123.</p> <p>• LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 06-03-2026</p> <p>• ISO Certificate Type: Copy Notarization: Not Notarized Validity: 17-11-2025</p>	<p>Brand name: GL Hess Screen Laser (Complete Kit)</p> <p>Generic Name: Visual alignment & Binocular Vision Diagnostic Device.</p> <p>Applied as: Kit</p> <p>Class: A</p> <p>Model/Codes/Sizes (as per FSC): 671000</p> <p>Shelf/Service life: 5 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.
88.	<p>M/s. Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi.</p> <p>(ELI- 00009)</p> <p>R&I detail 19-06-2025 Fee: 6,000/- Slip: 761959153215</p>	<p>Legal Manufacturer: M/s Roche Molecular Systems Inc., 1080 US Highway 202 South Branchburg, NJ 08876 USA.</p> <p>Manufacturing Site: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany.</p> <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination</p> <p>• FSC (Germany)</p>	<p>Brand name: Cobas® 6800</p> <p>Generic Name: PCR based molecular diagnostic system</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes: 09575154001</p> <p>Shelf life: Not mentioned.</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • Justification of applying system as single, is required. • LOA is copy, not original. • FSC mentions manufacturing site of Germany while Form-6A mentioned manufacturing site of Swotzerland. • Valid notarized ISO certificate of manufacturing site has not been submitted. • Copy of ISO certificate of legal manufacturer is not notarized.

		Type: Original Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 30-06-2027		<ul style="list-style-type: none"> • Service life has not been mentioned.
89.	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 19-06-2025 Fee: PKR 62,000/- Slip # 3594129287	Name of Manufacturer: Ventana Medical Systems Inc. (Tucson) 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 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)	Brand Name: Ventana anti-AREG (SP272) Rabbit Monoclonal Primary Antibody Generic Name: Monoclonal Primary Antibody for qualitative immunohistochemical detection of amphiregulin (AREG) protein. Applied as: Single Class: C Code/sizes: 09858725001 Shelf Life: 24 Months (2-8°C)	The Board approved the case.
90.	M/s Roche Pakistan	Name of Manufacturer:	Brand Name:	The Board approved

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

	19-06-2025 Fee: PKR 62,000/- Slip # 095007001010	Indianapolis, Indiana 46250 USA. <ul style="list-style-type: none"> • 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: 03-02-2025 Validity: Not mentioned (Original in Accu-Chek SmartGuide Predict App File) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 31-10-2027 (Original in AccuChek Active device File) • EU QMS Certificate: Not submitted. 	Code/sizes: 09872272001-Accu-Chek SmartGuide App (iOS) 09873597001- Accu-Chek SmartGuide App (Android) Service Life: Not mentioned	
92.	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 03-06-2025 Fee: PKR 31,000/- Slip # 8326581370	Legal Manufacturer: Roche Diabetes Care GmbH, Sandhofer Strasse 116 68305 Mannheim, Germany. Manufacturing Site: Roche Diabetes Care Spain SL, AV., de la Generalitat 171-173, 08174 Sant Cugat de Valles, Barcelona, Spain.	Brand Name: Accu-Chek SmartGuide Predict App Generic Name: Software for real-time glucose monitoring device. Applied as: Family Class: B Code/sizes:	The Board approved the case subject to submission of separate fee for each type of app and confirmation of class before issuance of registration letter.

		<ul style="list-style-type: none"> • LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File) • FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 03-02-2025 Validity: Not mentioned • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 31-10-2027 (Original in AccuChek Active device File) 	09493620001-Accu-Chek SmartGuide Predict App (iOS) 09873627001- Accu-Chek SmartGuide Predict App (Android) Service Life: Not mentioned	
93.	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 03-06-2025 Fee: PKR 31,000/- Slip # 7701136010	Legal Manufacturer: Roche Diabetes Care GmbH, Sandhofer Strasse 116 68305 Mannheim, Germany. Manufacturing Site: ACQ Science GmbH, Etzwiesenstrabe 37, 72108 Rottenburg-Hailfingen, Deutschland, Germany. <ul style="list-style-type: none"> • LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File) • FSC Type: Copy of legalized 	Brand Name: Serum DAT Control Set Generic Name: Serum DAT Control Set . Applied as: Set Class: B Code/sizes: 09543112190 Shelf Life: 24 Months (2-8oC)	The Board approved the case.

		Issued By: Govt. Body Legalization: Legalized Issue Date: 12-02-2025 Validity: Not mentioned (Original in Cobas ISE Neo 900 file) • ISO – Certificate: Type: Original Notarization: Notarized Validity: 27-02-2028		
94.	M/s Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, P.E.C.H.S., Karachi East 75400. (ELI-00009) Date of R& I 03-06-2025 Fee: PKR 31,000/- Slip # 5978741448	Name of Manufacturer: COPAN ITALIA S.p.A., Via F.Perotti n.10-25125 Bresica, Italy. • LOA Type: Original Notarization: Notarized Validity: 05-09-2029 • FSC Type: Original Issued By: Govt. Body Legalization: MOH Issue Date: 02-01-2024 Validity: Not mentioned • ISO – Certificate: Type: Original Notarization: Notarized Validity: 01-09-2027	Brand Name: FLOQSwab Self-Vaginal Swab, Marked Breakpoint Generic Name: Self-Vaginal Swab, Marked Breakpoint Applied as: Single Class: B Code/sizes: 552C.80 Shelf Life: 36 Months	The Board approved the case.
95.	M/s. Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009) R&I detail	Legal Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany. Manufacturing Site:	Brand name: Cobas Magnesium Gen.2 MG2 Generic Name: In-vitro test kit fot quantitative determination of magnesium in human serum, plasma & urine	The Board approved the case.

	19-06-2025 Fee: 31,000/- Slip: 0097293027	Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China. <ul style="list-style-type: none"> • 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: 12-02-2025 Validity: Not mentioned (Original in Cobas ISR neo 900 File) • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File) 	Applied as: Kit Class: B Model/Codes/Sizes: 08058016214 Shelf life: 24 Months	
96.	M/s. Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009) R&I detail 03-06-2025 Fee: 31,000/- Slip: 642838916	Legal Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany. Manufacturing Site: Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China. <ul style="list-style-type: none"> • LOA 	Brand name: Cluster of Liver Enzymes Generic Name: Cluster of Liver Enzymes Applied as: Cluster Class: B Model/Codes/Sizes (as per SC	The Board approved the case subject to submission of differential fee.

		<p>Type: Copy of Notarized</p> <p>Notarization: Notarized</p> <p>Validity: Till termination</p> <p>Original in Ventana DP 200 Slide Scanner File)</p> <p>• FSC1 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 06-11-2024 Validity: Not mentioned (Original in Elecsys CA 72-4)</p> <p>• FSC2 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 12-02-2025 Validity: Not mentioned (Original in Cobas ISR neo 900 File)</p> <p>• ISO Certificate 1 Type: Copy of notarized Notarization: Notarized Validity: 20-10-2025 (Original in Elecsys Cyfra 21-1 Test Kit)</p> <p>• ISO Certificate 2 Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)</p>	<p>& application):</p> <p>05166888214 (ALP-2)</p> <p>08056757214 (ALP-2)</p> <p>05168775214 (GGT-2)</p> <p>08057796214 (GGT-2)</p> <p>Shelf life: 12 Months (2-8 oC)</p>	
97.	M/s. Roche Pakistan Limited, 1 st Floor, 37-B,	Legal Manufacturer:	Brand name:	The Board approved

	<p>Block-6, PECHS, Karachi.</p> <p>(ELI- 00009)</p> <p>R&I detail 03-06-2025 Fee: 31,000/- Slip: 73479993956</p>	<p>M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany.</p> <p>Manufacturing Site: Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China.</p> <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination Original in Ventana DP 200 Slide Scanner File)</p> <p>• FSC1 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 06-11-2024 Validity: Not mentioned (Original in Elecsys CA 72-4)</p> <p>• FSC2 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 12-02-2025 Validity: Not mentioned (Original in Cobas ISR neo 900 File)</p> <p>• ISO Certificate 1 Type: Copy of notarized Notarization: Notarized</p>	<p>Ureal</p> <p>Generic Name: In vitro diagnostic reagent</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Model/Codes/Sizes (as per SC & application): 08058806214 05171873214</p> <p>Shelf life: 12 Months (2-8 oC)</p>	<p>the case.</p>
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		Validity: 20-10-2025 (Original in Elecsys Cyfra 21-1 Test Kit) • ISO Certificate 2 Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)		
98.	M/s. Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009) R&I detail 03-06-2025 Fee: 31,000/- Slip: 369952667	Legal Manufacturer: M/s. Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany. Manufacturing Site: 1.Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany 2.Roche Diagnostics (Suzhou) Ltd., No. 259 Zhongyuan Road 215028 Suzhou, Jiangsu, China. • LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination Original in Ventana DP 200 Slide Scanner File) • FSC1 Type: Original Issued By: Govt Body Legalization: Legalized Issue Date: 01-04-2025 Validity: Not mentioned	Brand name: Cobas Iron2 Generic Name: in vitro diagnostic reagent Applied as: Kit Class: B Model/Codes/Sizes (as per SC & application): 10059605190 08057931214 05169291214 Shelf life: 15 Months (2-8 oC)	The Board approved the case.

		<ul style="list-style-type: none"> • FSC2 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 12-02-2025 Validity: Not mentioned • FSC3 Type: Copy of legalized Issued By: Govt Body Legalization: Legalized Issue Date: 31-01-2024 Validity: Not mentioned • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File) 		
99.	<p>M/s. Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi.</p> <p>(ELI- 00009)</p> <p>R&I detail 02-07-2025 Fee: 6,000/- Slip: 7765423415</p>	<p>Name of Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany.</p> <ul style="list-style-type: none"> • 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: 01-04-2025 	<p>Brand name: Cobas HypoCleaner</p> <p>Generic Name: ISE Deproteinizer</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Model/Codes/Sizes (as per FSC & Application) : 10166274001 (500ml)</p> <p>Shelf life: 25 Months (2-8°C)</p>	The Board approved the case.

		Validity: Not mentioned (Original in IRON2 File) • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)		
100.	M/s. Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009) R&I detail 02-07-2025 Fee: 62,000/- Slip: 13889480643	Legal Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany. Manufacturing Site: Ventana Medical Systems Inc. (Tucson) 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 Type: Copy of notarized	Brand name: Ventana Eber Probe Generic Name: Epstein-Barr virus-encoded RNA (EBER) Reagent Applied as: Single Class: C Model/Codes/Sizes: 10070323001 Shelf life: 24 Months (2-8oC)	The Board approved the case.

		Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File)		
101.	M/s. Roche Pakistan Limited, 1 st Floor, 37-B, Block-6, PECHS, Karachi. (ELI- 00009) R&I detail 02-07-2025 Fee: 6,000/- Slip: 990836279434	Legal Manufacturer: M/s Roche Diagnostics GmbH, Sandhofer Strasse 116 68305 Mannheim Deutschland/Germany. Manufacturing Site: Ventana Medical Systems Inc. (Tucson) 1910 E. Innovation Park Drive Tucson, AZ 85755, USA. <ul style="list-style-type: none"> • LOA Type: Copy of Notarized Notarization: Notarized Validity: Till termination (Original in Ventana DP 200 Slide Scanner File) • FSC Type: Original Issued By: Govt Body Legalization: Legalized Issue Date: 26-03-2025 Validity: Not mentioned • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 29-06-2027 (Original in Elecsys AFP File) 	Brand name: PAS Stain Core Kit Generic Name: Qualitative Histologic stain Applied as: Single Class: A Model/Codes/Sizes: 09328823001 Shelf life: 12 Months	The Board approved the case.
102.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan.	Legal Manufacturer: Boston Scientific Corporation, 300, Boston Scientific Way,	Brand Name: Easy-Mate SureLink Generic Name:	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Justification of

	<p>(ELI-00120)</p> <p>Date of R& I 16-06-2025</p> <p>Fee: PKR 25,000/- Slip # 99055424</p>	<p>Marlborough, MA 01752 USA.</p> <p>Manufacturing Site: Philips-Medisize Costa Mesa, LLC, 3545 Harbor Blvd, Suite 150 Costa Mesa, CA 92626, USA.</p> <p>Packaged and labelled at: Boston Scientific Corporation, 302 Parkway, Global Park, Heredia Costa Rice</p> <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: 30-06-2025</p> <p>• FSC Type: Original Issued By: US FDA Legalization: Apostilled Validity: 10-06-2026</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 01-09-2026</p>	<p>Sterile Electrode Cables.</p> <p>Applied as: Family</p> <p>Class: A</p> <p>Models/Code/sizes:</p> <ol style="list-style-type: none"> M0042000088P0 Cable, Easy-Mate, 125cm/4ft, 4-Pin M0042000089P0 Cable, Easy-Mate, 125cm/4ft, 6-Pin M004200774P0 Cable, Easy-Mate, 125cm/4ft, 8-Pin M004560001A0 Cable, SureLink, 210cm/7ft, 10-Pin M004560001P0 Cable, SureLink, 210cm/7ft, 10-Pin M004560002A0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002BA0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002BP0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002P0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002RA0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002RP0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002YA0 Cable, SureLink, 125cm/4ft, 4-Pin M004560002YP0 Cable, SureLink, 125cm/4ft, 4-Pin M004560003A0 Cable, SureLink, 210cm/7ft, 4-Pin M004560003P0 Cable, SureLink, 210cm/7ft, 4-Pin 	<p>applying two types of cables as family, is required.</p> <ul style="list-style-type: none"> • Original ISO certificate has not been submitted. • LOA is copy and has expired. Moreover, LOA has been issued by Boston Scientific International B.V. Netherlands.
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			xvi. M004560004A0 Cable, SureLink, 125cm/4ft, 10-Pin xvii. M004560004P0 Cable, SureLink, 125cm/4ft, 10-Pin Service Life: Easy-mate-3 Years SureLink-2 Years	
103.	M/s Ferozsos Laboratories Limited, P.O. Ferozsos, Amangarh, Nowshera-KPK, Pakistan. (ELI-00120) Date of R& I 24-06-2025 Fee: PKR 100,000/- Slip # 508235813420	Legal Manufacturer: 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 Validity: 31-03-2026 • FSC Type: Original Issued By: Ministry of Health Legalization: Apostilled Validity: 10-06-2026 • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 05-04-2027	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; <ul style="list-style-type: none"> • LOA is copy and is not notarized. • Service life has not been mentioned.
104.	M/s Ferozsos Laboratories Limited, P.O. Ferozsos, Amangarh, Nowshera-	Legal Manufacturer: Boston Scientific	Brand Name: INTELLAGEN Cardiac Ablation System &	Deferred due to following deficiencies

	<p>KPK, Pakistan.</p> <p>(ELI-00120)</p> <p>Date of R& I 16-06-2025</p> <p>Fee: PKR 120,000/- Slip # 37227033937</p>	<p>Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA.</p> <p>Manufacturing Sites:</p> <ol style="list-style-type: none"> 1. Stockert GmbH, Boetzingen Strasse 31 Freiburg, Baden-Wurttemberg, Germany 79111. 2. Creation Technologies Ltd., 8977-8999 Fraserton Court Burnaby, British Columbia, Canada V5J 5H8 <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: 30-06-2025</p> <p>• FSC (Verified Online) Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 06-01-2027</p> <p>• ISO – Certificate: Type: Original Notarization: Notarized Validity: 17-07-2027</p>	<p>Accessories</p> <p>Generic Name: Cardiac Ablation System & Accessories.</p> <p>Applied as: System</p> <p>Class: C</p> <p>Models/Code/sizes:</p> <ol style="list-style-type: none"> 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 	<p>in application;</p> <ul style="list-style-type: none"> • 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.
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			<p>Set 1 PK</p> <p>xv. M004GEN100206251- INTELLAGEN Tubing Set 10 PK</p> <p>xvi. M004GEN100206241- INTELLAGEN Tubing Set 40 PK</p> <p>xvii. M004GEN100199510- INTELLAGEN Catheter Adapter Cable, 0.3 Meter</p> <p>xviii. M004GEN100199430- INTELLAGEN Grounding Cable, 3 Meter</p> <p>xix. M004GEN100199470- INTELLAGEN Grounding Cable, 3 Meter</p> <p>xx. M004GEN100200900- INTELLAGEN Foot Pedal Extension Cable, 7 Meter</p> <p>xxi. M004GEN100200810- INTELLAGEN Irrigation Pump Connection Cable, 1 Meter</p> <p>xxii. M004GEN100200840- INTELLAGEN Irrigation Pump Connection Cable, 3 Meter</p> <p>xxiii. M004GEN100199460- INTELLAGEN Irrigation Pump Connection Cable, 5 Meter</p> <p>xxiv. M004GEN100200870- INTELLAGEN Irrigation Pump Connection Cable, 10 Meter</p> <p>xxv. M004GEN100200720- INTELLAGEN Remote Control Connection Cable, 10 Meter</p> <p>xxvi. M004GEN100200750- INTELLAGEN Remote Control Connection Cable, 15 Meter</p>	
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			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 xxxi. 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) Service Life: Not mentioned	
105.	M/s Ferozs Laboratories Limited, P.O. Ferozs, Amangarh, Nowshera- KPK, Pakistan. (ELI-00120) Date of R& I 24-06-2025 Fee: PKR 100,000/- Slip # 76361236	Legal Manufacturer: Boston Scientific Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA. Manufacturing Sites: 1. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. 2. Boston Scientific Corporation, 4100	Brand Name: AngioJet™ Ultra 5000A Console Generic Name: Mechanical Atherectomy/Throbectomy drive. Applied as: System Class: C Models/Code/sizes: 105650-025 (Model No. 5000A)	Deferred due to following deficiencies in application; • LOA is copy and has expired. Moreover, LOA has been issued by Boston Scientific International B.V. Netherlands. • FSC is copy, not legalized, could not be verified online and has expired • ISO certificate is copy.

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

		Not submitted		<ul style="list-style-type: none"> Valid Notarized ISO certificate has not been submitted. Notarized DOC has not been submitted. Service life data has not been submitted.
107.	<p>M/s Biologic Medical Systems, 166E Annex B, Block 3, PECHS, OFF Khalid Bin Waleed Road, Karachi.</p> <p>(ELI-00346)</p> <p>Date of R& I 23-06-2025</p> <p>Fee: PKR 25,000/- Slip # 7958125616</p>	<p>Name of Manufacturer: Ingenious Medical GmbH, Berta-Ottenstein-Strasse 11, 79106 Freiburg im Breisgau, Germany.</p> <ul style="list-style-type: none"> LOA Type: Copy Notarization: Not Notarized Validity: 31-12-2027 FSC (Spain) Type: Copy Issued By: Govt. Body Legalization: Not legalized Issue Date: 22-06-2022 Validity: Not mentioned ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 28-10-2025 	<p>Brand Name: Ingenious laproscopic system</p> <p>Generic Name: Laprosopic system.</p> <p>Applied as: System</p> <p>Class: A</p> <p>Models/Code/sizes: Not mentioned</p> <p>Service Life: 10 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> LOA is copy and not notarized The system applied has not been mentioned in FSC submitted. The codes of the component devices are required to be mentioned. FSC submitted is copy and not legalized. ISO certificate is copy and not notarized. Notarized DOC has not been submitted. Service life data has not been submitted
108.	<p>M/s Biologic Medical Systems, 166E Annex B, Block 3, PECHS, OFF Khalid Bin Waleed Road, Karachi.</p> <p>(ELI-00346)</p> <p>Date of R& I 23-06-2025</p> <p>Fee: PKR 31,000/- Slip # 157404520627</p>	<p>Name of Manufacturer: Walz Elektronik GmbH, Walddorfer Str. 40 72229 Rohrdorf, Germany.</p> <ul style="list-style-type: none"> LOA Type: Copy Notarization: Not Notarized Validity: 01-01-2027 FSC Type: Copy of apostilled 	<p>Brand Name: WALZ Lithotron EL 27 Compact with Probe</p> <p>Generic Name: Laprosopic system.</p> <p>Applied as: System</p> <p>Class: B</p> <p>Models/Code/sizes: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> LOA is copy and not notarized. FSC submitted is copy not original. Three different systems have been mentioned in FSC. The applied one is required to be specified alongwith required probes with their codes. ISO certificate is

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

		<p>3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan.</p> <p>2. Shirakawa Olympus Co., Ltd., 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan.</p> <ul style="list-style-type: none"> • LOA Type: Copy of notarized Notarization: Notarized Validity: 31-03-2026 • FSC Type: Original Issued By: Ministry of Health Legalization: Apostilled Issue Date: 13-09-2024 Validity: Not mentioned. • ISO – Certificate: Not submitted 	<p>application & FSC. Model needs to be specified.</p> <p>Service Life: 6 Years</p>	<p>while LOA has been issued by Olympus, Singapore.</p> <ul style="list-style-type: none"> • The manufacturing site mentioned in Form-7A is different from mentioned in FSC. • Justification of applying multiple models Brochovideoscopes in single application is required. • LOA is copy, not original. • ISO certificate of legal manufacturer & manufacturing sites mentioned on FSC has not been submitted. • Service life data has not been submitted
111.	<p>M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.</p> <p>(ELI-00153)</p> <p>Date of R& I 13-06-2025</p> <p>Fee: PKR 6,000/- Slip # 944244503524</p>	<p>Name of Manufacturer: G-Flex Europe SPRL 20, Rue de l' Industries 1400-Nivelles-Belgium.</p> <p>LOA Type: Copy of notarized Notarization: Notarized Issue Date: 15-10-2018 Validity: Not mentioned</p> <ul style="list-style-type: none"> • FSC Type: Original Issued By: Federal Agency of Medicines 	<p>Brand Name: Performance</p> <p>Generic Name: Biopsy Forceps</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Models/Code/sizes: Models mentioned in application are not for forceps</p> <p>Service Life: Not mentioned</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • The models/codes applied in application are for foreign body retrievers, not for biopsy forceps. The model of forcep required to be enlisted/registered, is needed to be mentioned. • LOA is copy, not original. • ISO certificate is copy and not notarized. • Notarized DOC has not been submitted.

		Legalization: Legalized Issue Date: 30-06-2021 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 03-06-2027		<ul style="list-style-type: none"> • Service life and data has not been submitted.
112.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot. (ELI-00153) Date of R& I 13-06-2025 Fee: PKR 6,000/- Slip # 0322351243	Name of Manufacturer: G-Flex Europe SPRL 20, Rue de l'Industries 1400- Nivelles-Belgium. LOA Type: Copy of notarized Notarization: Notarized Issue Date: 15-10-2018 Validity: Not mentioned • FSC Type: Original Issued By: Federal Agency of Medicines Legalization: Legalized Issue Date: 30-06-2021 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 03-06-2027	Brand Name: Inflation Device Generic Name: Inflation Device Applied as: Single Class: A Models/Code/sizes (as per tech documents and application) INFL20 INFL40 Shelf Life: 3 Years	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Justification of applying multiple models of Inflation device in single application, is required • LOA is copy, not original. • ISO certificate is copy and not notarized.
113.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot. (ELI-00153) Date of R& I	Name of Manufacturer: G-Flex Europe SPRL 20, Rue de l'Industries 1400- Nivelles-Belgium. LOA Type: Copy of notarized	Brand Name: Disposable Endoscopic Forceps Retrievers Generic Name: Disposable Endoscopic Forceps & Retrievers Applied as: Single	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Justification of applying multiple models of Forceps & Retrievers in single application, is required.

	12-06-2025 Fee: PKR 31,000/- Slip # 0413561883	Notarization: Notarized Issue Date: 15-10-2018 Validity: Not mentioned <ul style="list-style-type: none"> • FSC Type: Copy of Legalized Issued By: Federal Agency of Medicines Legalization: Legalized Issue Date: 25-06-2021 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 03-06-2027 	Class: B Models/Code/sizes (as per tech documents and application) i. Sharp Prongs: <ul style="list-style-type: none"> • GF1222 ii. Rotatable Net-system for Polyp retrieval: <ul style="list-style-type: none"> • GF4500 (Oval) • GF4500-120 (Oval) • GF4501 (Oval) • GF4502 (Hexagonal) iii. Forceps <ul style="list-style-type: none"> • U860-230 (Alligator With Rat Tooth) • U870-180 (Pelican Shape) • U870-130 (Pelican Shape) • U622-165 (Alligator) • U822-165 (Rat Toot) Shelf Life: 3 Years	<ul style="list-style-type: none"> • FSC is copy, not original. Moreover, models have not been mentioned in FSC. • LOA is copy, not original. • ISO certificate is copy and not notarized.
114.	M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot. (ELI-00153) Date of R& I 12-06-2025 Fee: PKR 62,000/- Slip # 34770194250	Name of Manufacturer: G-Flex Europe SPRL 20, Rue de l'Industries 1400- Nivelles-Belgium. LOA Type: Copy of notarized Notarization: Notarized Issue Date: 15-10-2018 Validity: Not mentioned <ul style="list-style-type: none"> • FSC Type: Copy of Legalized Issued By: Federal Agency of Medicines Legalization: Legalized Issue Date: 25-06-2021 Validity: Not mentioned. • ISO – Certificate: Type: Copy 	Brand Name: Sensor Generic Name: Disposable Polypectomy Snares Applied as: Single Class: C Models/Code/sizes (as per tech documents and application): i. GF4532R (Asymmetrical, Rotatable, Multibraded with lateral connection) ii. GF4564R (Oval, Rotatable, Multibraided, with lateral connection) iii. GF4580R (Oval, Rotatable, Multibraided, with lateral connection) iv. GF4300 (Hexagonal, Multibraided) v. GF4301 (Hexagonal, Multibraided) vi. GF4406 (Oval,	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> • Justification of applying multiple models of Snares in single application, is required. • FSC is copy, not original. Moreover, models have not been mentioned in FSC. • LOA is copy, not original. • ISO certificate is copy and not notarized.

		Notarization: Not Notarized Validity: 03-06-2027	Multibraided, No HF Connection) vii. GF4410 (Oval, Multibraided, No HF Connection) viii. GF4606R (Oval, Multibraided, Rotatable) ix. GF4610R (Oval, Multibraided, Rotatable) x. GF4615R (Oval, Multibraided, Rotatable) xi. GF4625R (Oval, Multibraided, Rotatable) xii. GF4635R (Oval, Multibraided, Rotatable) xiii. GF4710R (Round, Multibraided, Rotatable) xiv. GF4606 (Oval, Multibraided) xv. GF4610 (Oval, Multibraided) xvi. GF4615 (Oval, Multibraided) xvii. GF4625 (Oval, Multibraided) xviii. GF4635 (Oval, Multibraided) xix. GF4815R (Oval, Monofilament, Rotatable) xx. GF4825R (Oval, Monofilament, Rotatable) xxi. GF481525CR (Oval-Combi, Monofilament, Rotatable) xxii. GF461525CR (Oval-Combi, Multibraided, Rotatable) Shelf Life: 3 Years	
115.	M/s Rehabilitation Centre for Hearing Impaired Pvt. Ltd., Ghafoor Plaza, 289-Ferozpur Road, 12-L, Gulberg, Lahore. (ELI-01209) Date of R& I 12-06-2025	Legal Manufacturer: GN Hearing A/S, Lautrupbjerg 7 DK-2750 Ballerup, Denmark. Manufacturing Sites: 1. GN ReSound (Malaysia) Sdn, Bhd No. 5, Jalan i-Park 1/1 Kawasan Perindustrian i-Park 81000	Brand Name: Beltone Generic Name: Hearing Aid Applied as: Single Class: B Models/Code/sizes (as per FSC and application:	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/- has been deposited. • FSC is apostilled

	<p>Fee: 31,000/- Slip # 24371263844</p>	<p>Bandar Indahpura, Kulai, Johor, Malaysia. 2. GN ReSound China Ltd., No. 15, Chuang Xin Road, CTP Area 361006 Xiamen, China.</p> <p>LOA Type: Original Notarization: Notarized Issue Date: 15-10-2018 Validity: 19-03-2028</p> <p>• FSC Type: Original Issued By: Danish Medicine Agency Legalization: Apostilled Validity: 27-10-2026</p> <p>• ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-12-2026</p>	<p>i. Rely:</p> <ul style="list-style-type: none"> • RLY4CIC-MP • RLY4CIC-LP • RLY4CIC-HP • RLY3CIC-MP • RLY3CIC-LP • RLY3CIC-HP <p>ii. Amaze:</p> <ul style="list-style-type: none"> • AMZ9CIC-MP • AMZ9CIC-LP • AMZ9CIC-HP • AMZ6CIC-MP • AMZ9CIC-LP • AMZ9CIC-HP • AMZ17CIC-MP • AMZ17CIC-LP • AMZ17CIC-HP <p>Service Life: 10 Years</p>	<p>not legalized by embassy</p> <ul style="list-style-type: none"> • Valid notarized ISO certificates of manufacturing sites, have not been submitted. • Service life data is required.
116.	<p>M/s Meditech Supplies & Solutions, Office No. 1, First Floor, AKLASC Commercial Plaza, Sector G-10 Markaz Islamabad.</p> <p>(ELI-00787)</p> <p>Date of R& I 23-06-2025</p> <p>Fee1: 31,000/- Fee2: 6,000/- Slip1 # 049311458113 Slip2 # 233493611871</p>	<p>Name of Manufacturer: Cooper Surgical, Denmark (Complete address and manufacturing sites are not clear)</p> <p>LOA Not submitted</p> <p>• FSC Not Submitted</p> <p>• ISO – Certificate: Not submitted</p>	<p>Brand Name:</p> <ol style="list-style-type: none"> 1. Wallace IUI Catheters 2. Wallace Sure-Pro & Sure-Pro Ultra Catheter 3. Pipettes 4. Origio Equipment 5. Sage Vittrification Solutions 6. Sage 1st Step Medium 7. Sage Quinn's Advantage Medium with HEPES 8. Sage PVP 9. Sage PureCeption 10. Sage Oil for Tissue Culture. 11. Sage Human Serum Albumin 12. Sage Quinn's Advantage Sperm Freezing Medium 13. Sage Quinn's Advantage Fertilization Medium 	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • The applicant has submitted application forms for all devices in single application under one R&I and has deposited one fee challan of Rs. 31,000/- for Class- B and another fee challan of Rs. 6000/- for all Class- A Devices. Separate application for each device with separate fee alongwith required documents is

			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 Shel Life: 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 Issued By: Govt. Body Legalization: legalized Issue Date: 12-07-2023 Validity: Not Mentioned	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.

		<p>• ISO – Certificate: Type: Copy of Notarized Notarization: Notarized Validity: 21-03-2027</p>		
118.	<p>M/s Nassir Trading Company, Suit No. 109, 1st Floor, Al-Rehman Trade Centre, Shahrah-e-Liaquat, Opp. Sindh Madrasa, Karachi.</p> <p>(ELI-00511)</p> <p>Date of R& I 24-06-2025</p> <p>Fee: 62,000/- Slip # 14077184996</p>	<p>Name of Manufacturer: Adria S.R.L., Via Modena, 46-40017 San Giovanni in Persiceto (BO), Italy.</p> <p>LOA Type: Copy Notarization: Not Notarized Validity: 09-03-2027</p> <p>• FSC Type: Copy of Apostilled Issued By: MOA Legalization: Apostilled Issue Date: 28-03-2025 Validity: Not Mentioned</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 06-11-2026</p>	<p>Brand Name: P-Drain</p> <p>Generic Name: Direct Puncture Drainage Set</p> <p>Applied as: Set Class: C</p> <p>Models/Code/sizes (as per FSC and application):</p> <p>i. 14/xxxx</p> <ul style="list-style-type: none"> • 14/0630 • 14/0730 • 14/0830 • 14/0930 • 14/1030 • 14/1230 <p>ii. 15/xxxx</p> <ul style="list-style-type: none"> • 15/0630 • 15/0730 • 15/0830 • 15/0930 • 15/1030 • 15/1230 <p>iii. 24/xxxx</p> <ul style="list-style-type: none"> • 24/0630 • 24/0830 • 24/0930 • 24/1030 • 24/1230 <p>iv. 25/xxxx</p> <ul style="list-style-type: none"> • 25/0630 • 25/0730 • 25/0830 • 25/0930 • 25/1030 • 25/1230 <p>v. 34/xxxx</p> <ul style="list-style-type: none"> • 34/0730 • 34/0830 • 34/0930 	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • Justification of applying three types of sets in single application, is required. • LOA is copy, not original and not notarized. • ISO certificate is copy, not notarized. • FSC is copy not original.

			<ul style="list-style-type: none"> 34/1030 34/1230 	
			Shelf Life: 5 Years	
119.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 03-06-2025</p> <p>Fee: 6,000/- Slip # 948444076</p>	<p>Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original in Exigo C200 File)</p> <p>• FSC Not submitted</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)</p>	<p>Brand name: Exigo System Cleaner</p> <p>Generic Name: Enzyme based cleaner for Veterinary Hematology Analyzer</p> <p>Applied as: Kit Class: A</p> <p>Code/sizes (as per DOC & Application): 1504203 (Exigo System Cleaner 1.9L) 1504503 (Exigo System Cleaner 1.9L RFID)</p> <p>Shelf Life: 36 Months</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> 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.
120.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 03-06-2025</p> <p>Fee: 6,000/- Slip # 6695588130</p>	<p>Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original in Exigo C200 File)</p> <p>• FSC</p>	<p>Brand name: Exigo EOS Reagent</p> <p>Generic Name: Hematology Lytic Reagent for cell Counting</p> <p>Applied as: Kit Class: A</p> <p>Code/sizes (as per DOC & Application): 1504278 (Exigo EOS Reagent 1.9L) 1504502 (Exigo EOS Reagent 1.9L RFID)</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> 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.

		<p>Not submitted</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)</p>	<p>Shelf Life: 24 Months</p>	
121.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 03-06-2025</p> <p>Fee: 6,000/- Slip # 18816254224</p>	<p>Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original in Exigo C200 File)</p> <p>• FSC Not submitted</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)</p>	<p>Brand name: Boule Vet Cal & Cont.</p> <p>Generic Name: Control & Calibration Kit for</p> <p>Applied as: Kit</p> <p>Class: A</p> <p>Code/sizes (as per DOC & Application):</p> <ul style="list-style-type: none"> • 1440184 (Boule Vet-Cal-5Diff 1x3ml) • 1440181 (Boule Vet-Con-5Diff Normal 1x3ml) • 1440182 (Boule Vet-Con-5Diff Normal 6x3ml) <p>Shelf Life: Control 160 Days Calibrator 70 Days (2-10oC)</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.	<p>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.</p>	<p>Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized</p>	<p>Brand name: Exigo H 400</p> <p>Generic Name: Automatic Veterinary Hematology Analyzer</p> <p>Applied as: Set</p> <p>Class: A</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • The FSC has not been submitted rather a statement has been submitted stating that the product is for veterinary use and

	<p>ELI-00160</p> <p>Date of R& I 03-06-2025</p> <p>Fee: 6,000/- Slip # 48066884</p>	<p>Validity: 31-12-2025 (Original in Exigo C200 File)</p> <ul style="list-style-type: none"> • FSC Not submitted • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File) 	<p>Code/sizes (as per DOC & Application):</p> <ul style="list-style-type: none"> • 142000 <p>Service Life: Not mentioned</p>	<p>there is no authority in Sweden to issue FSC to Veterinary Medical devices.</p> <ul style="list-style-type: none"> • Justification of applying as set is required. • Service life and data has not been submitted.
123.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 03-06-2025</p> <p>Fee: 6,000/- Slip # 4798512457</p>	<p>Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163 53 Spanga, Sweden.</p> <ul style="list-style-type: none"> • 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) 	<p>Brand name: Exigo Diluent & Lyse Reagent</p> <p>Generic Name: Automatic Veterinary Hematology Analyzer</p> <p>Applied as: Kit</p> <p>Class: A</p> <p>Code/sizes (as per DOC & Application):</p> <ul style="list-style-type: none"> • 1504201 (Exigo Diluent 1.9L) • 1504328 (Exigo Diluent 10L) • 1504504 (Exigo Diluent 10L RFID) • 1504202 (Exigo Lyse 1.9L) • 1504500 (Exigo Lyse 1.9L RFID) <p>Shelf Life: 36 Months</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building,</p>	<p>Name of Manufacturer: Boule Medical AB, Domnarvsgatan 4, SE-163</p>	<p>Brand name: Exigo C200 & C200 Consumables</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • The FSC has not

	<p>Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 03-06-2025</p> <p>Fee: 6,000/- Slip # 0921621349</p>	<p>53 Spanga, Sweden.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2025 (Original in Exigo C200 File)</p> <p>• FSC Not submitted</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 20-05-2028 (Original in Exigo C200 File)</p>	<p>Generic Name: Automatic Veterinary Biochemistry Analyzer & consumables</p> <p>Applied as: Set</p> <p>Class: A</p> <p>Code/sizes (as per DOC & Application):</p> <ul style="list-style-type: none"> • 1430001 (Analyzer) • 1430002(Comprehensive Panel, 20 Rotors) • 1430003 (Health check Panel, 20 Rotors) • 1430004 (Liver Panel, 20 Rotors) • 1430005 (Kidney Panel, 20 Rotors) • 1430006 (Electrolyte Panel, 20 Rotors) • 1430008 (Preparation Panel, 20 Rotors) • 1430009 (Canine CRP Panel, 20 Rotors) • 1430011 (Feline SAA Panel, 20) <p>Service Life:</p> <ul style="list-style-type: none"> • 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 • 1430005 (Kidney Panel, 20 Rotors)-12 Months • 1430006 (Electrolyte Panel, 20 Rotors)-12 Months • 1430008 (Preparation Panel, 20 Rotors)-12 Months • 1430009 (Canine CRP Panel, 20 Rotors)-12 Months • 1430011 (Feline SAA Panel, 20)-12 Months 	<p>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.</p> <ul style="list-style-type: none"> • Justification of applying as set is required. • Service life of analyzer has not been mentioned.
125.	M/s Martin Dow Specialties (Private)	Name of Manufacturer:	Brand name: Microlab 300	The Board approved

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

		<ul style="list-style-type: none"> • FSC Type: Copy of legalized Issued By: MOH Legalization: Legalized Validity: 08-10-2029 (Original submitted separately vide R&I dated 20-11-2024) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 21-06-2027 (Original submitted separately vide R&I dated 20-11-2024) 		
127.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 6,000/- Slip # 55510400620</p>	<p>Name of Manufacturer: VitalScientific B.V., Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands.</p> <ul style="list-style-type: none"> • LOA: Type: Copy of notarized Notarization: Notarized Validity: 16-10-2027 (Original submitted separately vide R&I dated 20-11-2024) • FSC Type: Copy of Legalized Issued By: MOH Legalization: Legalized Validity: 31-12-2029 (Original submitted separately vide R&I dated 20-11-2024) 	<p>Brand name: Selectra ProS</p> <p>Generic Name: Automated chemistry analyzer</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Code/sizes (as per Free sale certificate & Application): 6003-541 Selectra ProS (O/PSID)</p> <p>Service Life: 7 Years</p>	The Board approved the case.

		<p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 21-06-2027 (Original submitted separately vide R&I dated 20-11-2024)</p>		
128.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 953803674630</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: Bilirubin Direct</p> <p>Generic Name: In-vitro diagnostic reagent kit for direct bilirubin</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): BIDI-0500</p> <p>Shelf Life: 24 Months (2-8oC)</p>	The Board approved the case.
129.	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building,</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees,</p>	<p>Brand name: Microalbumin IP</p> <p>Generic Name:</p>	The Board approved the case.

	<p>Block-6, PECHS, Main Razi East, Shahr-e-Faisal, Road, Karachi Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 47711078871</p>	<p>France.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)</p> <p>• 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)</p> <p>• 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)</p>	<p>In-vitro diagnostic reagent kit for urine albumin</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): IMAL-M230</p> <p>Shelf Life: 60 Months (2-8oC)</p>	
130.	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building, Block-6, PECHS, Main Razi East, Shahr-e-Faisal, Road, Karachi Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 2018332562</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)</p>	<p>Brand Name: Direct TIBC</p> <p>Generic Name: In-vitro diagnostic reagent kit for serum Total Iron Binding Capacity</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): TIBC-0250</p>	The Board approved the case.

		<ul style="list-style-type: none"> • 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: 24 Months (2-8oC)	
131.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 03852829</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.</p> <ul style="list-style-type: none"> • 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 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) 	<p>Brand name: HDL Cholestrol</p> <p>Generic Name: In-vitro diagnostic reagent kit for HDL Cholestrol</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): CHDL-0600</p> <p>Shelf Life: 24 Months (2-8oC)</p>	The Board approved the case.

		<p>• 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)</p>		
132.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 43926521644</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)</p> <p>• 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)</p> <p>• 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)</p>	<p>Brand name: LDL Cholestrol</p> <p>Generic Name: In-vitro diagnostic reagent kit for LDL Cholestrol</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): CLDL-0250</p> <p>Shelf Life: 24 Months (2-8oC)</p>	The Board approved the case.
133.	<p>M/s Martin Dow Specialties (Private) Limited., 7th Floor, Nice Trade Orbit Building,</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees,</p>	<p>Brand name: Magnesium XB</p> <p>Generic Name:</p>	The Board approved the case.

	<p>Block-6, PECHS, Main Shahrah-e-Faisal, Razi Road, Karachi East, Jamshed Town.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 67562479916</p>	<p>France.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)</p> <p>• 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)</p> <p>• 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)</p>	<p>In-vitro diagnostic reagent kit for Magnesium</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): MGXB-0250</p> <p>Shelf Life: 14 Months (2-8oC)</p>	
134.	<p>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.</p> <p>ELI-00160</p> <p>Date of R& I 02-07-2025</p> <p>Fee: 31,000/- Slip # 070618832436</p>	<p>Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 28-07-2027 (Original in another file SMI/mm/RA/331/2024 dated 20-11-2024)</p>	<p>Brand name: HDL LDL Calibrator</p> <p>Generic Name: Calibrator Kit for HDL or LDL IVD Reagent Kits</p> <p>Applied as: Kit</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application): HLCA-0041</p>	The Board approved the case.

		<ul style="list-style-type: none"> • 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: 30 Months (2-8oC)	
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, Jamshed Town. ELI-00160 Date of R & I 02-07-2025 Fee: 31,000/- Slip # 6180527101	Name of Manufacturer: VitalScientific, Zone Industrielle 61500 Sees, France. <ul style="list-style-type: none"> • 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 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) 	Brand name: HbA1c Enzyme Calibrator Set Generic Name: Calibrator Kit for HbA1c IVD Reagent Kits Applied as: Kit Class: B Code/sizes (as per Free sale certificate & Application): HBAE-0043 Shelf Life: 15 Months (2-8oC)	The Board approved the case.

		• 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)		
136.	M/s Deejhons Pharma, 185, F-Block Sabzazaar, Lahore. ELI-00976 Date of R & I 03-07-2025 Fee: 62,000/- Slip # 5931492624	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): <ul style="list-style-type: none"> • HPMC MD GEL MD GEL PLUS • Sodium Hyaluronate MD GEL SH Shelf Life: Not Mentioned	Deferred due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC (Certificate 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.
137.	M/s Deejhons Pharma, 185, F-Block Sabzazaar, Lahore. ELI-00976 Date of R& I	Name of Manufacturer: EyeKon Medical Inc., 2451 Enterprise Rd., Clearwater, FL 33763, USA. • LOA:	Brand name: MDR Hydrophobic Generic Name: Hydrophobic Acrylic IOL Applied as: Single	Deferred due to following deficiencies in the application; <ul style="list-style-type: none"> • FSC (Certificate of Exportability) submitted mentions that the product is

	03-07-2025 Fee: 62,000/- Slip # 6939834385	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: 12-03-2024	Class: C Code/sizes (as per Free sale certificate & Application): <ul style="list-style-type: none"> • MB60B-0UV • MY60B-0UV • MB60-P22 • MB60-P28 • MY60-P22 • MY60-P28 Shelf Life: 5 Years	not approved for 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.
138.	M/s Deejhons Pharma, 185, F-Block Sabzazaar, Lahore. ELI-00976 Date of R & I 03-07-2025 Fee: 62,000/- Slip # 5931492624	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	Brand name: MDR PMMA Generic Name: Posterior Chamber IOLs Applied as: Single Class: C Code/sizes (as per Free sale certificate & Application): <ul style="list-style-type: none"> • PN148-BUV • P165-0UV • P165-2UV • P146-CUV • P260-0UV • P260-2UV • P160-0UV • P160-2UV • TC65C-2UV • PN55-BUV • SJ65D-2UV • P150L-0UV 	Deferred due to following deficiencies in the application; • FSC (Certificate of Exportability) submitted mentions that the product is not approved for 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. • Shelf life & stability studies data has not been submitted.

		Validity: 01-02-2026 • EC FQA – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 05-07-2020	<ul style="list-style-type: none"> • PN50A-0UV • S155-AUV • S155-BUV • S165-BUV • PS55-BUV • SN55-BUV Shelf Life: Not Mentioned	
139.	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 # 060135723	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK. • LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier) • 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)	Brand name: Optilite® IgE Control Generic Name: Immuno-chemistry Control Applied as: Single Class: B Code/sizes (as per Free sale certificate & Application): <ul style="list-style-type: none"> • NQ014.OPT Shelf Life: 24 Months (2-8oC)	The Board approved the case subject to verification/confirmation of availability of storage facility at 2-8°C before issuance of registration letter.
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/confirmation of availability of

	<p>ELI-00105</p> <p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 387270884</p>	<p>West Midlands, B15 1QT, UK.</p> <p>• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)</p> <p>• FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027 (Original in Optilite Freelite Kappa Free Kit Dossier)</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)</p>	<p>Immuno-chemistry test reagent</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application):</p> <ul style="list-style-type: none"> LK014.OPT <p>Shelf Life: 24 Months (2-8oC)</p>	<p>storage facility at 2-8°C before issuance of registration letter.</p>
141.	<p>M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105</p> <p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 0867358976</p>	<p>Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK.</p> <p>• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)</p> <p>• FSC</p>	<p>Brand name: Optilite® IgE Calibrator</p> <p>Generic Name: Immuno-chemistry calibrator</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application):</p> <ul style="list-style-type: none"> NC014.OPT <p>Shelf Life: 24 Months (2-8oC)</p>	<p>The Board approved the case subject to verification/confirmation of availability of storage facility at 2-8°C before issuance of registration letter.</p>

		<p>Type: Copy of apostilled</p> <p>Issued By: MHRA</p> <p>Legalization: Apostilled</p> <p>Validity: 19-08-2027</p> <p>(Original in Optilite Freelite Kappa Free Kit Dossier)</p> <p>• ISO – Certificate:</p> <p>Type: Copy of notarized</p> <p>Notarization: Notarized</p> <p>Validity: 10-04-2027</p> <p>(Original in Optilite IgE Reagent Dossier)</p>		
142.	<p>M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.</p> <p>ELI-00105</p> <p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 216913847</p>	<p>Name of Manufacturer:</p> <p>The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK.</p> <p>• LOA:</p> <p>Type: Original</p> <p>Notarization: Notarized</p> <p>Validity: 31-12-2025</p> <p>(Original in Optilite IgE Reagent Dossier)</p> <p>• FSC</p> <p>Type: Copy of apostilled</p> <p>Issued By: MHRA</p> <p>Legalization: Apostilled</p> <p>Validity: 19-08-2027</p> <p>(Original in Optilite Freelite Kappa Free Kit Dossier)</p> <p>• ISO – Certificate:</p> <p>Type: Copy of notarized</p>	<p>Brand name: Optilite® Low Level IgG Kit</p> <p>Generic Name: Immuno-chemistry test kit</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application):</p> <ul style="list-style-type: none"> NK004.LL.OPT <p>Shelf Life: 24 Months (2-8oC)</p>	<p>The Board approved the case subject to verification/confirmation of availability of storage facility at 2-8°C before issuance of registration letter.</p>

		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. ELI-00105 Date of R & I 04-07-2025 Fee: 31,000/- Slip # 57649836849	Name of Manufacturer: The Binding Site Group Limited, 8 Calthorpe Road, Edgbaston, Birmingham, West Midlands, B15 1QT, UK. • LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier) • 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)	Brand name: Optilite® Low Level Albumin Kit Generic Name: Immuno-chemistry test kit Applied as: Single Class: B Code/sizes (as per Free sale certificate & Application): <ul style="list-style-type: none"> NK032.L.OPT Shelf Life: 18 Months (2-8oC)	The Board approved the case subject to verification/confirmation of availability of storage facility at 2-8°C before issuance of registration letter.
144.	M/s Labserv, House No. B-165/2, Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi. ELI-00105	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/confirmation of availability of storage facility at 2-8°C before issuance of registration letter.

	<p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 1154236080</p>	<p>• LOA: Type: Original Notarization: Notarized Validity: 31-12-2025 (Original in Optilite IgE Reagent Dossier)</p> <p>• FSC Type: Copy of apostilled Issued By: MHRA Legalization: Apostilled Validity: 19-08-2027 (Original in Optilite Freelite Kappa Free Kit Dossier)</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 10-04-2027 (Original in Optilite IgE Reagent Dossier)</p>	<p>Class: B</p> <p>Code/sizes (as per Free sale certificate & Application):</p> <ul style="list-style-type: none"> NK034.OPT <p>Shelf Life: 18 Months (2-8oC)</p>	
145.	<p>M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad.</p> <p>ELI-01125</p> <p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 64967856353</p>	<p>Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier)</p> <p>• FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023</p>	<p>Brand name: Clarinet</p> <p>Generic Name: Middle Ear Analyzer/Tympanometer</p> <p>Applied as: Family</p> <p>Class: B</p> <p>Code/sizes (as per DOC, Application & Lables):</p> <ul style="list-style-type: none"> 10517 (Clarinet Basic) 10542 (Clarinet Plus) <p>Service Life: 10 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> 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.

		Validity: Not mentioned (Original in Audiometer Bell Dossier) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)		
146.	M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad. ELI-01125 Date of R & I 04-07-2025 Fee: 31,000/- Slip # 1847571099	Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy. • LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier) • FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023 Validity: Not mentioned (Original in Audiometer Bell Dossier) • ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)	Brand name: Timpani Generic Name: Audiometer/Middle Ear Analyzer Applied as: Family Class: B Code/sizes (as per DOC, Application & Lables): <ul style="list-style-type: none"> 11440 Service Life: 10 Years	Deferred due to following deficiencies in application; <ul style="list-style-type: none"> 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 Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue,	Name of Manufacturer: INVENTIS SRL, Corso Stati	Brand name: Flute Model	Deferred due to following deficiencies

	<p>Blue Area, Islamabad.</p> <p>ELI-01125</p> <p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 91278885380</p>	<p>Uniti n.1/3-35127 Padova, Italy.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier)</p> <p>• FSC Type: Copy Issued By: MOH Legalization: Not legalized Issue Date: 19-09-2023 Validity: Not mentioned (Original in Audiometer Bell Dossier)</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 03-04-2028 (Original in Audiometer Bell Dossier)</p>	<p>Generic Name: Middle Ear Analyzer/Tympanometer</p> <p>Applied as: Family</p> <p>Class: B</p> <p>Code/sizes (as per DOC, Application & Lables):</p> <ul style="list-style-type: none"> • 10337 (Flute Basic) • 10340 (Flute Plus) • 10409 (Flute HF) <p>Service Life: 10 Years</p>	<p>in application;</p> <ul style="list-style-type: none"> • Justification for applying three 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.
148.	<p>M/s Hearing Care Services, Shop No. 4, Mazzanine Panorama Centre, Avenue, Blue Area, Islamabad.</p> <p>ELI-01125</p> <p>Date of R & I 04-07-2025</p> <p>Fee: 31,000/- Slip # 217120507</p>	<p>Name of Manufacturer: INVENTIS SRL, Corso Stati Uniti n.1/3-35127 Padova, Italy.</p> <p>• LOA: Type: Copy of notarized Notarization: Notarized Validity: 31-12-2026 (Original in Audiometer Bell Dossier)</p> <p>• FSC Type: Copy</p>	<p>Brand name: Harp</p> <p>Generic Name: Audiometer</p> <p>Applied as: Family</p> <p>Class: B</p> <p>Code/sizes (as per DOC, Application & Lables):</p> <ul style="list-style-type: none"> • 10145 (Harp Basic) • 10146 (Harp Plus) <p>Service Life: 10 Years</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • 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.

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

	<p>ELI-00769</p> <p>Date of R & I 27-06-2025</p> <p>Fee: 62,000/- Slip # 870820486784</p>	<p>Manufacturing Sites (FSC):</p> <p>1. IOLs: SIFI S.p.A., Ercol Patti, 36-95025 Aci S. Antonio (CT), Italy</p> <p>2. Injector: Medicel AG-Altenrhein, Switzerland.</p> <p>• LOA: Type: Copy Notarization: Not Notarized Validity: 31-12-2025</p> <p>• FSC Type: Copy of legalized Issued By: MOH Legalization: Legalized Issue Date: 10-02-2021 Validity: Not mentioned</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 12-09-2023</p>	<p>Class: C</p> <p>Code/sizes (as per FSC, Application): 1121CCZ (Mini Well Proxa) X7560CZ (Mini Well Toric)</p> <p>Shelf Life: Not Mentioned</p>	<p>IOLs in single application. Moreover, two models have been mentioned separately in FSC but the applicant has combined them in one brand.</p> <ul style="list-style-type: none"> • The FSC mentions both models as Kit comprising of Injector & IOLs. Clarification is required whether complete Kit has been applied or otherwise. • The ISO certificate of the manufacturer (Switzerland) mentioned in FSC, has not been submitted. • LOA is copy and not notarized. • FSC is copy not original. • ISO certificate has not been notarized and has been expired. • DOC of the product has not been submitted. • Shelf life and studies data has not been submitted.
151.	<p>M/s Hanson International, No. 57-D., Block DHA, EME Multan Road, Lahore.</p> <p>ELI-00773</p> <p>Date of R & I 02-07-2025</p> <p>Fee: 31,000/- Slip # 9709851681</p>	<p>Name of Manufacturer: SIBEL HEALTH INC., 2017 N Mendell Street, Suite 2SE Chicago, IL USA 60614.</p> <p>• LOA: Type: Original Notarization: Notarized Validity: 28-05-2030</p>	<p>Brand name: Anne View Central Hub System</p> <p>Generic Name: Patient Monitor System</p> <p>Applied as: System</p> <p>Class: B</p> <p>Code/sizes (as per FSC & Application):</p>	<p>The Board approved the case subject to submission of differential fee & service/shelf life information.</p>

		<ul style="list-style-type: none"> • FSC Type: Original Issued By: US FDA Legalization: Apostilled Validity: 09-04-2027 • ISO – Certificate: Type: Original Notarization: Notarized Validity: 01-10-2025 	<ul style="list-style-type: none"> • 35-019 (Anne Chest Sensor) • 17-039 (Anne Limb Sensor) • 17-009 (Anne Wireless Charger) • 35-025 (Anne Tablet with Anne View Application) • 12-095 (Anne 24-Hour Chest Adhesive) • 43-048 (Anne 7-Day Chest Adhesive) • 17-041 (Anne Limb Adhesive) • 17-024 (Wireless Charger Wall Adapter) • 17-011 (Charger for Anne Tablet) <p>Service/Shelf Life: Not provided (Only adhesive's shelf life mentioned)</p>	
152.	<p>M/s Cor-Med, 2nd Floor, 38/62, Rehman Plaza, Bank Road, Saddar, Rawalpindi.</p> <p>ELI-00226</p> <p>Date of R & I 03-07-2025</p> <p>Fee: 25,000/- Slip # 2896981017</p>	<p>Name of Manufacturer: Iberhopsitex S.A., Avda Cataluna, 4, 08185-LLICA DE VALL (BARCELONA), Spain.</p> <ul style="list-style-type: none"> • 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: 	<p>Brand name: Oper Cat Classic</p> <p>Generic Name: Self-adhesive dressing Pouch for catheters</p> <p>Applied as: Family</p> <p>Class: A</p> <p>Code/sizes (as per FSC & Application):</p> <ul style="list-style-type: none"> • 0037438 (8x7.5cm) • 0037448 (16x5cm) <p>Shelf Life: Not provided</p>	<p>Deferred due to following deficiencies in application;</p> <ul style="list-style-type: none"> • LOA is copy and validity has not been mentioned. • FSC is copy not original. • ISO Certificate is copy not original. • Shelf life and data has not been submitted.

		Type: Copy of Notarized Notarization: Notarized Validity: 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 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	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.
154.	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 # 52651769901	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	Brand name: Xpert Lense PMMA Generic Name: PMMA IOL Applied as: Single Class: C Code/sizes Application): PJ313565CRO 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.

		Issue Date: 13-12-2023 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027		
155.	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 # 52651769901	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 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027	Brand name: Mesto Hydrophobic Preloaded Lense Generic Name: Hydrophobic Preloaded IOL Applied as: Single Class: C Code/sizes (as per DOC & Application): FCL113060-CRA-PL Shelf Life: 5 Years	Deferred due to following deficiencies in application; • Justification for application as single, is required • LOA is copy not original. • FSC is copy and not legalized. • ISO certificate is copy and not notarized. • Model applied has not been mentioned in DOC & FSC.
156.	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 # 3205927362	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	Brand name: I-Xpert IOL Generic Name: Hydrophilic Clear Foldable IOL Applied as: Single Class: C Code/sizes (as per FSC & Application): HFL1125606CRA	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.

		<ul style="list-style-type: none"> • FSC Type: Copy Issued By: MHRA Legalization: Not Legalized Issue Date: 13-12-2023 Validity: Not mentioned. • ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027 	Shelf Life: 5 Years	
157.	M/s Medco, 19-Khyber Bazar, Peshawar. ELI-00686 Date of R & I 19-06-2025 Fee: 31,000/- Slip # 5474828092 Fee: 31,000/- Slip # 08896687824	Name of Manufacturer: Ecotron Co., Ltd., 501, 502, 504, 505, 506 Ho, Hanshin IT Tower, 47 Digital-ro 9-gil, Geumcheon-gu Seoul, Korea South 08511. <ul style="list-style-type: none"> • LOA: Type: Original Notarization: Notarized Validity: 14-05-2029 • FSC (Korea) Type: Original Issued By: National Ins. Of Medical Device Safety Info. Legalization: Apostilled Issue Date: 22-05--2025 Validity: Not mentioned. • FSC (US)(Verified Online) Type: Copy Issued By: USFDA Legalization: Not Legalized Validity: 26-01-2027. 	Brand name: Ecotron Mobile/Portable X-Ray System Generic Name: Portable X-Ray System Applied as: System Class: C Code/sizes (as per FSC & Application): EPX-F5000 Service Life: 10 Years	The Board approved the case subject to submission of differential fee before issuance of registration letter.

		<p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 17-11-2027</p> <p>• CE – Certificate: Type: Copy Notarization: Not Notarized Validity: 26-05-2024</p>		
158.	<p>M/s MAZ International Office No. 42,43,44, Ibrahim Block, Al-Hafeez Garden Phase-I, Manawan, G.T. Road, Lahore.</p> <p>(ELI-00862)</p> <p>Date of R& I 16-04-2022</p> <p>Fee: 5,000/- Slip # 14077184996</p>	<p>Name of Manufacturer: A1 Globe SDN. BHD. A1-2, Block A, Jalan Haruan 5/9, Pusat Komercial Oakland II, 70300, Seremban, Negeri Sembilan, Malaysia.</p> <p>LOA Type: Copy of Notarized Notarization: Notarized Validity: 24-10-2027</p> <p>• FSC Type: Copy of Legalized Issued By: MOH Legalization: Legalized Issue Date: 19-06-2027</p> <p>• ISO – Certificate: Type: Copy of Notarized Notarization: Notarized Validity: 26-09-2027</p>	<p>Brand Name: Handex Glove</p> <p>Generic Name: Powdered Latex Examination Gloves Powder Free Latex Examination Gloves</p> <p>Applied as: Single</p> <p>Class: A</p> <p>Models/Code/sizes Small Medium Large Extra Large</p> <p>Shelf Life: 5 Years</p>	<p>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;</p> <p>i.Valid, notarized Letter of Authorization issued by the legal manufacturer abroad.</p> <p>ii.Copy of Receiving (R&I) of application(s) under discussion.</p> <p>The Board further directed the Division of MD&MC to convey following deficiencies to the instant applicant;</p> <ul style="list-style-type: none"> • Justification of applying two types of examination gloves (Powdered & Powder Free) in single application, is required. • Evidence of available sizes is required. • Stability studies data confirms shelf

				life of 3 Years, while, the applicant has claimed 5 years in Form.
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Abdul Qadir
Assistant Director-I (MIS)
(O/B Web Publisher)
Wednesday, 17 September, 2025, 9:55:17 AM

Abdul Qadir
Assistant Director-I (MIS)
(O/B Web Publisher)
Wednesday, 17 September, 2025, 9:55:17 AM

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

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

	<p>Paid Fee: 62,000/-</p> <p>Fee Challan No: 6371025106</p>	<p>2027(Copy)</p> <p>ISO Validity: 28-11-2027 (Copy)</p> <p>EU QA/ EC Certificate</p>		<p>already. Also submit ed Notasreid and valid LOA , Desigh nexamination and ISO 13485 certificaite.</p>
161.	<p>Applicant Name:</p> <p>Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi</p> <p>ELI-01304</p> <p>Date of R&I 26-06-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Fee Challan No: 24443048499</p>	<p>Name of Manufacturer:</p> <p>M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD 20878, USA</p> <p>LOA Validity: 30-04-2027 (Copy)</p> <p>FSC: USA</p> <p>Validity: 18-03-2027(Copy)</p> <p>ISO Validity: 28-11-2027 (Copy)</p> <p>EU QA/ EC Certificate</p>	<p>Brand name:</p> <p>Collatek Collagen Gel</p> <p>Generic Name: Collagen Wound Dressing</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification</p>	<p>Deferred for submission of the clarificaion of the brand name since the applied name is Collatek Collagen Gel Hoever the name in the FSC is Collatek gel Collagen based Wound Care Dressing</p> <p>Also submit valid and Apostilled FSC of USFDA if not submitted already. Also submit ed Notasreid and valid LOA , Desigh nexamination and ISO 13485 certificaite.</p> <p>Clarify the stability studies for 03 years</p>
162.	<p>Applicant Name:</p> <p>Global Marketing Services, 111, Hali Road, Westridge 1, Rawalpindi</p>	<p>Name of Manufacturer:</p> <p>M/s GreatBatch Medical, 2300 Berkshire Lane North, Minneapolis, MN</p>	<p>Brand name:</p> <p>Myopore</p> <p>Generic Name: Sutureless Pacing Lead</p>	<p>Deferred for submission of the clarificaion of the brand name since the applied name is Myopore and</p>

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

	67967691851	<p>FSC:Italy</p> <p>Issue date: 28-03-2025(Copy)</p> <p>ISO Validity: 03.12.2024</p> <p>EU QA/ EC Certificate 01-11-2028 (Copy)</p>		<p>ISO 13485 certificaite.</p> <p>Clarify the stability studies for 03 years</p> <p>Calrify the address of the manufactuere the addres and name mentioned in the FSC shall be applied.</p>
164.	<p>Applicant Name:</p> <p>Global Marketing Services, 111, Hali Road, Westridge 1, Rawalpindi</p> <p>ELI-00109</p> <p>Date of R&I 10-06-2025</p> <p>Fee Details:</p> <p>Paid Fee: 62,000/-</p> <p>Fee Challan No: 401504968</p>	<p>Name of Manufacturer:</p> <p>Abbott Medical 15900 Valley View Court, Sylmar, California-91342, USA</p> <p>Manufacturing site: Abbott Medical (Also Known as ST, Jude Medical) 15900 Valley View Court, Sylmar, California, USA</p> <p>Abbott Medical (Also Known as ST, Jude Medical) Plot No. 102, Lebuhraya Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia, Country, Malaysia</p> <p>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</p>	<p>Brand name:</p> <p>Allure RF</p> <p>Generic Name: Cardiac Resynchronization Therapy Pacemaker</p> <p>Class-D</p> <p>Shelf life: 18 months</p> <p>Models/ Specification PM 3222</p>	<p>Deferred for submission of Original Legalized Valid FSC , Nortized LOA, 13485</p>

		LOA Validity: 31-12-2026 (Copy) FSC: USA Validity: 31-03-2027 (Copy) ISO Validity: 31-03-2028 (Copy) EU QA/ EC Certificate Validity: 14-08-2027		
165.	Applicant Name: Global Marketing Services, 111, Hali Road, Westridge 1, Rawalpindi ELI-00109 Date of R&I 10-06-2025 Fee Details: Paid Fee: 100000/- Fee Challan No: 15622816060	Name of Manufacturer: Abbott Medical 15900 Valley View Court, Sylmar, California-91342, USA Manufacturing site: Abbott Medical (Also Known as ST, Jude Medical) 15900 Valley View Court, Sylmar, California, USA 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 67.5 Santana Industrial	Brand name: Optisure Generic Name: Defibrillation Leads Class-D Shelf life: 3 Years Models/ Specification	Deferred for submission of the clarificaion of the brand name since the applied name is Optisure Generic Name: Defibrillation Leads and name in the FSc is Implantable Cardioverter/Defibr illator Leads. Also submit valid and Apostilled FSC of USFDA if not submitted already. Also submit ed Notasreid and valid LOA , Design nexamination and ISO 13485 certificaite.

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

		14-07-2026 (Copy) EU QMS / EC Certificate Validity: 05-08-2026 notarized copy		
167.	<p>Applicant Name:</p> <p>Cardiac Care, 848-C, Shadman-1 Lahore-54610</p> <p>ELI-00070</p> <p>Date of R&I 02-06-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 346047687</p>	<p>Name of Manufacturer:</p> <p>On-X Life Technologies, Inc. 1300 East Anderson Lane building B Austin, TX USA</p> <p>LOA Validity: 31-12-2025 (Copy)</p> <p>FSC: USA Issue Date: 28-01-2027 (Copy)</p> <p>ISO Validity: 29-03-2026 (Copy)</p> <p>EU QA/ EC Certificate Validity: 26-05-2024</p> <p>Design examination certificate Valid till 26.05.2024 extension letter given</p>	<p>Brand name:</p> <p>ON-X conform –X Aortic Prosthetic Heart Valve On-X Confrom-X Mitral Prosthetic Heart Valve</p> <p>Generic Name: Heart Valve Aortic/Mitral</p> <p>Class-D</p> <p>Shelf life: 6 years</p> <p>Models/ Specification: ONXACE-19 ONXACE-21 ONXACE-23 ONXACE-25 ONXACE-27/29 ONXMC-25/33</p>	<p>Deferred for submission of the submit valid and Apostilled FSC of USFDA if not submitted already. Also submit ed Notasreid and valid LOA , Desigh nexamination certifcaite</p>
168.	<p>Applicant Name:</p> <p>Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p>	<p>Brand name:</p> <p>Inno-Ce Mesha Intense</p> <p>Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p>	<p>Deferred for submission of the clarificaion of the formulation in the FSC is not identical with the one mentioned Also submit valid</p>

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

	Plaza, 6-CL-10, Beaumont Road, Karachi ELI-00412 Date of R&I 30-05-2025 Fee Details: Paid Fee: 62,000/- 040092056372	Spain LOA Validity: 30-11-2026 (Copy) FSC: Spain Issue date: 14-05-2024(Copy) ISO Validity: 15-03-2027 (Copy) EU QA/ EC Certificate Validity:	Generic Name: 1 x 3ml/0.07 fl oz. Sodium Hyaluronate 2.5% Route of administration: Intradermal injections Class-D Shelf life: 3 years Models/ Specification	the applied name is Inno-Ce Bi-Dens 2.5 and name in the FSC is BI-DENS 2.5 fuethermore the formulation in the FSC is not identical with the applied one need clarification Also submit valid and Apostilled FSC of spain if not submitted already. Also submit ed Notasreid and valid LOA , Desigh nexamination certificaite
171.	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 Fee Details: Paid Fee: 62,000/- 42247277229	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) ISO Validity: 15-03-2027 (Copy) EU QA/ EC Certificate Validity:	Brand name: Brand name: Inno-Ce Mesha Smile 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 Models/ Specification	Deferred for submission of the clarificaion of the brand name since the applied name is Inno-Ce Mesha Smile and name in the FSC is MESHA® SMILE fuethermore the formulation in the FSC is not identical with the applied one need clarification Also submit valid and Apostilled FSC of spain if not submitted already. Also submit ed Notasreid and

				valid LOA , Desigh nexamination certificaite
172.	<p>Applicant Name:</p> <p>Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I 30-05-2025</p> <p>Fee Details: Paid Fee: 62,000/- 8174193787</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain Issue date: 14-05-2024(Copy)</p> <p>ISO Validity: 15-03-2027 (Copy)</p> <p>EU QA/ EC Certificate Validity:</p>	<p>Brand name:</p> <p>Brand name: Inno-Ce Mesha Scars</p> <p>Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p> <p>Route of administration: Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification</p>	<p>Deferred for submission of the clarificaion of the brand name since the applied name is Inno-Ce Mesha Scars and name in the FSC is MESHA® SCARS fuethermore the formulation in the FSC is not identical with the applied one need clarification</p> <p>Also submit valid and Apostilled FSC of spain if not submitted already. Also submit ed Notasreid and valid LOA , Desigh nexamination certificaite</p>
173.	<p>Applicant Name:</p> <p>Zam Zam Corporation, Suit No. 205, 206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi</p> <p>ELI-00412</p> <p>Date of R&I 30-05-2025</p>	<p>Laboratorio Innoaesthetics SL C/ Pont Reixat 3, 08960, Sant Just Desvern, Barcelona, Spain</p> <p>LOA Validity: 30-11-2026 (Copy)</p> <p>FSC: Spain Issue date: 14-05-2024(Copy)</p>	<p>Brand name:</p> <p>Inno-Ce Moist 1.5</p> <p>Generic Name: 1 x 1.2ml/0.04 fl oz. Crosslinked Hyaluronic Acid 20mg/ml</p> <p>Route of administration: Intradermal injections</p> <p>Class-D</p> <p>Shelf life: 3 years</p>	<p>Deferred for submission of the clarificaion of the brand name since the applied name is Inno-Ce Moist 1.5 and name in the FSC is MOIST 1.5 fuethermore the formulation in the FSC is not identical with the applied one need clarification</p>

	Fee Details: Paid Fee: 62,000/- 5143040484	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 submitted Notarized and valid LOA, ISO 13485.
174.	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 Fee Details: Paid Fee: 62,000/- 4082100844	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) ISO Validity: 15-03-2027 (Copy) EU QA/ EC Certificate Validity:	Brand name: Inno-Ce Mesha Deep 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 Models/ Specification	Deferred for submission of the clarification of the brand name since the applied name is Inno-Ce Mesha Deep and name in the FSC is MESHA® DEEP furthermore the formulation in the FSC is not identical with the applied one need clarification Also submit valid and Apostilled FSC of Spain if not submitted already. Also submit Notarized and valid LOA, and ISO 13485.
175.	M/s ACP Systems Pakistan, 13 & 23 Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi – 75530, Pakistan Tel: +92 21 32783726 License No: ELI-00001 DRAP receiving date 29.05.2025 Fee Rs. 62000 Slip No.8792893931 dt.	M/s Japan Lifeline Co., Ltd. Address: 2-2-20, Higashishinagawa Shinagawa-ku, Tokyo 140-0002, Japan Manufacturing site Japan Lifeline Co., Ltd. Toda Factory Medical Technology Park, 5-22 Minami-cho, Toda-shi, Saitama, 335-0025 Japan	Device name: JLL EP Diagnostic Catheter Product Class: class D as per DOC Shelf Life : 3 years Models as per FSC	Approved subject to submission of the fee for family as per SRO.

	<p>27.05.2025</p>	<p>Manufacturing site</p> <p>Japan Lifeline Co., Ltd. Oyama Factory 2399-12 Oaza Nobushima, Oyama-shi, Tochigi, 323-0152 Japan</p> <p>FSC: Issue Date: 03/04/2025 Expiry Date: will remain valid until drawn by the manufacturer (APOSTILLE ATTACHED) (NOTARIZED (original))</p> <p>LOA: Validity Date: 28/02/2025 – 27/02/2028 (APOSTILLE ATTACHED) NOTARIZED (original)</p> <p>ISO Validity Date: 20/04/2023 to 20/04/2026 NOTARIZED (original)</p> <p>EC-FQAS: Validity Date: 25/05/2023 to 20/04/2026 (notarized)(original)</p> <p>DOC: Issue date: 01/04/2025 Expiry Date: N/A (Original)</p>	<p>4552M, 4552L, 5555HIS-120R, 5555M-120R, 10255M-L100, 10255M-L100R, 10245M-L100R, 13445HV-R, 10256CS-80, F5554J-120R, F5555J-120R, F5555RV-120R, F10556CSL-65HT, F10444HV-120, F13445HV-120R, F8552, F105527AVL, F11556CSL-95HT, 10556BI-100, 10556BITS, 10556BITS-3D, 11555BITS-R, 11556BITS-3DR, 20156BI, 201106BI, 20226BI, 202586BITS, 20226BITS, PVI1015-110, PVI1017.5-110, PVI1020-110, PV2012.5-110, PV2015-110, PV2017.5-110, PV2020-110</p>	
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176.	<p>M/s FT Surgical, 916, Sagar Road, Saddar Bazar, Near Post Office Lahore</p> <p>ELI- 01015</p> <p>R& I dated 27-05-2025</p> <p>Fee details: Amount paid: PKR 62,000 /-</p> <p>Paid Slip/ challan No. 66300736506</p>	<p>M/S Aditus Medical GmbH, Kurfurstendamm 224 10719 Berlin /Germany</p> <p>LOA Validity: 31-12-2026 (embassy attested)</p> <p>FSC: Germany</p> <p>Issue date: 13-06-2023(Copy) (Embassy attested)</p> <p>Expiry NA</p> <p>ISO Validity: 21-03-2027(Copy) (embassy attested)</p> <p>EU QA/ EC/ DE Certificate</p> <p>Validity: 24-05-2024 (copy) (embassy attested)</p>	<p>Brand name: Cemad G40</p> <p>Generic Name: Standard Viscosity Bone Cement with Gentamicin</p> <p>Class-D</p> <p>Shelf life: 3 years</p> <p>Models/ Specification S</p>	Approved
177.	<p>M/s Varitron,, First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan.</p> <p>ELI-00510</p> <p>R& I dated 26-05-2025</p> <p>Fee details: Amount paid: PKR 100,000 /-</p> <p>Paid Slip/ challan No. 705171599440</p>	<p>Smith & Nephew INC, Endoscopy Division 150 Minuteman Rd, Andover, MA, USA as per fsc</p> <p>Legal Manufacturer: Smith & Nephew INC, Endoscopy Division 150 Minuteman Rd, Andover, MA, USA</p> <p>Manufacturer: Smith & Nephew INC Endoscopy 120 Forbes BLVD / 130 Forbes BLVD Mansfield, MA USA</p> <p>Arthrocare Corporation, B32.1, St2, Zona Franca</p>	<p>Brand name: Biosure HA Screw</p> <p>Generic Name: Interference screws</p> <p>Class-D</p> <p>Shelf life: 03 Years</p> <p>Models/ Specification 72201771 72201772 72201773 72201774</p>	<p>Dferred for submission of the notasried and valid LOA and submit stability studies. Also submit the Catalogue for justfciaion of the product in family under the MDR 2017.</p>

		<p>Coyol, Coyol ALajuela Costa Rica</p> <p>Contract Manufacturer: Henke-Sass Wolf, GmbH Keltenstrasse 1 Tuttlingen, Baden- Wurttemberg Germany</p> <p>Manufacturer: Smith & Nephew INC, Endoscopy 76-S Meridian Ave Oklahoma City, Ok USA</p> <p>LOA Issue date: 02-06-2022 (Copy) Notarized Expiry NA</p> <p>FSC: USA</p> <p>Validity: 14-05-2026 (Copy) apostille attached</p> <p>ISO Validity: 06-03-2028 (Copy) apostille attached</p> <p>EU QA/ EC Certificate Validity: 02-03-2027 (Copy) Notarized</p>	<p>72201775</p> <p>72201776</p> <p>72201777</p> <p>72201778</p> <p>72201779</p> <p>72201780</p> <p>72201781</p> <p>72201782</p> <p>72201783</p> <p>72201784</p> <p>72201785</p> <p>72201786</p> <p>72201787</p> <p>72201788</p> <p>72201789</p> <p>72201790</p>	
178.	<p>M/s Varitron,, First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan.</p> <p>ELI-00510</p> <p>R& I dated 26-05-2025</p> <p>Fee details: Amount paid: PKR 100,000</p>	<p>Legal Manufacturer: Smith & Nephew INC, Endoscopy 150 Minuteman Rd, Andover, MA, USA</p> <p>Manufacturer: Smith & Nephew INC Endoscopy 120 Forbes BLVD / 130 Forbes BLVD Mansfield, MA USA As per fsc</p> <p>Arthrocare Corporation,</p>	<p>Brand name: Biosure Regenesorb Interference Screw</p> <p>Generic Name: Interference screws</p> <p>72204391</p> <p>72204392</p> <p>72204394</p> <p>72204395</p> <p>72204397</p> <p>72204398</p>	<p>Dferred for submission of the notasried and valid LOA and submit stability studies. Also submit the Catalogue for justficiaion of the product in family under the MDR 2017</p>

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

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

	<p>ELI-00189</p> <p>R& I dated 29-05-2025</p> <p>Fee details: Amount paid: PKR 100,000 /-</p> <p>Paid Slip/ challan No. 8505649726</p>	<p>LOA Validity: 31-12-2026(Copy) Apostille Attached</p> <p>FSC: Spain</p> <p>Issue date: 18-11-2024 (Copy) Notarized</p> <p>ISO Validity: 08-10-2025(Copy) Apostille Attached</p> <p>EU QA/ EC Certificate Validity: 27-5-2024 (Copy) Apostille Attached</p>	<p>Shelf life: 3 Years</p> <p>Models/ Specification Dredger Revascularization Device</p> <p>RD-3-20 RD-3-30 RD-4-20 RD-4-30 RD-4-40 RD-5-20 RD-5-30 RD-5-40 RD-6-24 RD-6-30 RD-6-42 RD-7-30 RD-7-42</p>	
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Item No. IV: DEFERRED APPLICATIONS FOR REGISTRATION/ENLISTMENT OF MEDICAL DEVICE 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™ 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 Private Limited	Manufacturer: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325 USA	Carelink™ System (Software) MMT- 7333 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-7333 will be used. 3.Submit product broucher/catalogue.

3.	M/s Medtronic Pakistan Private Limited	<p>Legal Manufacturer: MEDTRONIC INC 710 Medtronic Pkwy Minneapolis MN USA 55432</p> <p>Manufacturing facilities: MEDTRONIC PERFUSIONS SYSTEMS 7611 Northland Dr Minneapolis MN USA 55428</p>	<p>HMS Plus Instrument 30514, 30515, 30517, 30518, 30522, 30524, 30526, 30527, 30528</p> <p>Shelf life: 3 years Class: B</p>	<p>Approved subject to submission of</p> <ol style="list-style-type: none"> 1. Prescribed Form 7A. 2. Fee for family of class B medical Devices as per revised SRO.
4.	M/s Medtronic Pakistan Private Limited	<p>Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com +1 763 514 4000 Manufacturing site: Contract Manufacturer</p> <p>DONATELLE, 501 Country Rd, E-2 Extension, New Brighton, MN USA 55112</p>	<p>Medtronic Slitter</p> <p>Adjustable Slitter 6232ADJ Universal Slitter II 6230UNI</p> <p>Shelf life: 2 years Class: D</p>	<p>Deferred for submission of (last opportunity);</p> <ol style="list-style-type: none"> 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.	<p>Ali Gohar & Company (Pvt) Ltd., State Life Building 1-B, I.I. Chundrigar Road, Karachi.</p> <p>(ELI-00004)</p> <p>4638</p> <p>30-06-2022</p>	<p><u>Legal Manufacturer:</u> Zimmer Trabecular Metal Technology inc. 10 Pomeroy Road, Parsippany, New Jersey 07054 USA.</p> <p>FSC US FDA validity 04-03-2022</p>	<p>Trabecular Metal Acetabular Revision System (Hip implants, Trabecular Metal Acetabular Augment)</p> <p>Class-C</p> <p>Shelf life: 5 years</p>	<p>Deferred the case for (as last opportunity for);</p> <ol style="list-style-type: none"> 1. Legalized valid FSC. 2. Correction of the applied name of the medical device. 3. submission of the Form 7A as per corrected name.

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

8.	<p>Ali Gohar & Company (Pvt) Ltd</p> <p>State Life Building 1-B, I.I Chundrigarh Road, Karachi</p> <p>Eli-00004</p> <p>1558-C</p> <p>13-03-2023</p>	<p><u>Legal Manufacturer:</u></p> <p>Zimmer Surgical Inc. 200 West Ohio Ave, Dover Oh 444622 USA 330-343-8801.</p> <p>FSC USFDA Valid till 14-04-2023</p>	<p>Zimmer Mesh Graft II Expansion System</p> <p>(Mesh Graft II Expansion System)</p> <p>Class-C</p> <p>Shelf life: 5 years</p> <p>Codes as per FSC:</p> <p>Meshgraft II Tissue Expansion System Complete (00219500000)</p> <p>Meshgraft II Dermatome with Ratchet (00219500100)</p> <p>Graft II Autoclave Case (00219500600)</p>	<p>Deffered the case for submission of (last opportunity);</p> <ol style="list-style-type: none"> 1. legalized valid FSC. 2. product name and compnents as per submitted brochure. 3. Form 7A as per correct name. 4. Product label. 5. copy of fee challan (for verification as fee for system).
9.	<p>Hakimsons (PVt) Ltd, Hakimsons House, A-58/B S.i.t.E,Manghopir Road, Karachi</p> <p>(ELI-00396</p>	<p>Atrasorb IndustriA De Products Hospitalares Ltda,</p> <p>Avenida Piracicaba, 351, Vila Nova Sao Roque/SP-Brazil</p>	<p>Atrasorb Soda Lime</p> <p>Soda Lime</p>	<p>Deferred for clarification that;</p> <ol style="list-style-type: none"> 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. 3. Name of product not as per FSC. 4. /Submission of valid legalized FSC,

				and Notrized ISO13485, DoC, LOA etc.
10.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 01-04-2024</p> <p>Fee Challan No.: 3208379373</p> <p>PKR: 25000/-</p> <p>Dated: 23-02-2024</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Neural & Neuroendocrine Markers (Immunohistochemistry)</p> <p>MD group: Cluster</p> <p>Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Calcitonin Rabbit Polyclonal Antibody 229A-14, 229A-15, 229A-16, 229A-18</p> <p>Calcitonin (SP17) Rabbit Monoclonal Antibody 229R-14, 229R-15, 229R-16, 229R-18</p> <p>CD56 (123C3.D5) Mouse Monoclonal Antibody 156M-84, 156M-85, 156M-86, 156M-88</p> <p>CD56 (MRQ-42) Rabbit Monoclonal Antibody 156R-94, 156R-95, 156R-96, 156R-98</p> <p>Chromogranin A (LK2H10) Mouse Monoclonal Antibody 238M-94, 238M-95, 238M-96, 238M-98</p> <p>Gastrin Rabbit Polyclonal Antibody 256A-14, 256A-15, 256A-16, 256A-18</p> <p>Glial Fibrillary Acidic Protein (EP672Y) Rabbit Monoclonal Primary</p>	Approved subject to submission of fee as cluster.

			<p>Antibod 258R-14, 258R-15, 258R-16, 258R-18</p> <p>Glial Fibrillary Acidic Protein (GFAP) (SP78) Rabbit Monoclonal Antibody 258R-24, 258R-25, 258R-26, 258R-28</p> <p>Glucagon (EP74) Rabbit Monoclonal Primary Antibody 259R-14, 259R-15, 259R-16, 259R-18</p> <p>Glucagon Rabbit Polyclonal Antibod 259A-14, 259A-15, 259A-16, 259A-18</p> <p>IDH-1 R132H (MRQ-67) Rabbit Monoclonal Antibody 456R-34, 456R-35, 456R-36, 456R-38</p> <p>INSM1 (MRQ-70) Rabbit Monoclonal Antibody 475R-94, 475R-95, 475R-96, 475R-98</p> <p>Islet-1 (EP283) Rabbit Monoclonal Primary Antibody 431R-14, 431R-15, 431R-16, 431R-18</p> <p>Neurofilament (2F11) Mouse Monoclonal Antibody 302M-14, 302M-15, 302M-16, 302M-18</p> <p>Neurofilament (EP79) Rabbit Monoclonal Primary Antibody 302R-14, 302R-15, 302R-16, 302R-18</p>	
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			<p>NSE (MRQ-55) Mouse Monoclonal Antibody 306M-24, 306M-25, 306M-26, 306M-28</p> <p>Olig2 (211F1.1) Mouse Monoclonal Antibody 387M-14, 387M-15, 387M-16, 387M-18</p> <p>Olig2 (EP112) Rabbit Monoclonal Primary Antibody 387R-14, 387R-15, 387R-16, 387R-18</p> <p>Parathyroid Hormone (PTH) (MRQ-31) Mouse Monoclonal Antibody 310M-24, 310M-25, 310M-26, 310M-28</p> <p>PGP 9.5 Rabbit Polyclonal Antibody 318A-14, 318A-15, 318A-16, 318A-18</p> <p>PHOX2B (EP312) Rabbit Monoclonal Primary Antibody 422R-14, 422R-15, 422R-16, 422R-18</p> <p>SF-1 (EP434) Rabbit Monoclonal Primary Antibody 462R-14, 462R-15, 462R-16, 462R-18</p> <p>Somatostatin (EP130) Rabbit Monoclonal Primary Antibody 332R-14, 332R-15, 332R-16, 332R-18</p> <p>Somatostatin Receptor 2a (EP149) Rabbit Monoclonal Primary Antibody 486R-14, 486R-15, 486R-</p>	
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			<p>16, 486R-18</p> <p>STAT6 (EP325) Rabbit Monoclonal Primary Antibody 426R-14, 426R-15, 426R-16, 426R-18</p> <p>Synaptophysin (EP158) Rabbit Monoclonal Primary Antibody 336R-14, 336R-15, 336R-16, 336R-18</p> <p>Synaptophysin (MRQ-40) Rabbit Monoclonal Antibody 336R-94, 336R-95, 336R-96, 336R-98</p> <p>Synaptophysin Rabbit Polyclonal Antibody 336A-74, 336A-75, 336A-76, 336A-78</p> <p>Tyrosine Hydroxylase (LNC1) Mouse Monoclonal Antibody 490M-14, 490M-15, 490M-16, 490M-18</p>	
11.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahr-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 08-08-2024</p> <p>Fee Challan No.: 77727461</p> <p>PKR: 25000/-</p> <p>Dated: 12-07-2024</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Viral Infection Markers (Immunohistochemistry)</p> <p>MD group: Cluster Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes: Adeno virus (20/11 & 2/6) Mouse Monoclonal Antibody 212M-14, 212M-15, 212M-16, 212M-18</p> <p>Epstein-Barr Virus (CS1-4)</p>	Approved subject to submission of fee as cluster.

			<p>Mouse Monoclonal Antibody 245M-14, 245M-15, 245M-16, 245M-18</p> <p>Epstein-Barr Virus (MRQ-47) Rabbit Monoclonal Antibody 245R-14, 245R-15, 245R-16, 245R-18</p> <p>Herpes Simplex Virus I (10A3) Mouse Monoclonal Antibody 361M-14, 361M-15, 361M-16, 361M-18</p> <p>Herpes Simplex Virus I Rabbit Polyclonal Antibody 361A-14, 361A-15, 361A-16, 361A-18</p> <p>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</p> <p>Parvovirus B19 (R92F6) Mouse Monoclonal Antibody 218M-14, 218M-15, 218M-16, 218M-18</p> <p>Varicella Zoster Virus (SG-1, SG1-SG4, NCP-1 & IE-62) Mouse Monoclonal Antibody 364M-14, 364M-15, 364M-16, 364M-18</p>	
12.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal,</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA</p>	<p>Mesothelioma Markers (Immunohistochemistry)</p> <p>MD group: Cluster</p>	<p>Approved subject to submission of fee as cluster</p>

	<p>Karachi (ELI-00323)</p> <p>Date of R&I: 01-04-2024</p> <p>Fee Challan No.: 3860649777</p> <p>PKR: 25000/-</p> <p>Dated: 23-02-2024</p>	<p>95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes:</p> <p>Calretinin (SP13) Rabbit Monoclonal Antibody 232R-14, 232R-15, 232R- 16, 232R18</p> <p>Cytokeratin 5 & 6 (D5 & 16B4) Mouse Monoclonal Antibody 356M-14, 356M- 15, 356M-16, 356M-18</p> <p>Cytokeratin 5 & 6 (EP24 & EP67) Rabbit Monoclonal Primary Antibody 356R-14, 356R-15, 356R-16, 356R18</p> <p>Cytokeratin 5 (EP1601Y) + Cytokeratin 14 (LL002) Mouse & Rabbit Monoclonal Antibody 905H-08</p> <p>HBME-1 (HBME-1) Mouse Monoclonal Antibody 283M-14, 283M-15, 283M- 16, 283M-18</p> <p>HBME-1 (HBME-1) Mouse Monoclonal Antibody 283M-14, 283M-15, 283M- 16, 283M-18</p> <p>Thrombomodulin (1009) Mouse Monoclonal Antibody 339M-14, 339M- 15, 339M-16, 339M-18</p>	
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13.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahr-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 08-08-2024</p> <p>Fee Challan No.: 3860649777</p> <p>PKR: 25000/-</p> <p>Dated: 12-07-2024</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Cancer Markers (Immunohistochemistry)</p> <p>MD group: Cluster Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes:</p> <p>Androgen Receptors (EP120) Rabbit Monoclonal Antibody 200R-24, 200R-25, 200R-26, 200R-28</p> <p>Androgen Receptors (SP107) Rabbit Monoclonal Antibody 200R-14, 200R-15, 200R-16, 200R-18</p> <p>Beta-Catenin (14) Mouse Monoclonal Antibody 224M-14, 224M-15, 224M-15, 224M-18</p> <p>Hepatocyte Specific Antigen (Hep-Par1) (EP265) Rabbit Monoclonal Antibody 264R-14, 264R-15, 264R-16, 264R-18</p> <p>Hepatocyte Specific Antigen (Hep-Par1) (OCH1E5) Rabbit Monoclonal Antibody 264M-94, 264M-95, 264M-96, 264M-98</p> <p>p27 kip1 (SX53G8) Mouse Monoclonal Brief Description The cancer</p>	<p>Approved subject to submission of fee as cluster.</p>
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			market encompasses the global industry focused on the diagnosis, treatment, and management of cancer Remarks Antibody 427M-98, 427M-96, 427M-95, 427M-94	
14.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahr-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 08-08-2024</p> <p>Fee Challan No.: 248268717588</p> <p>PKR: 25000/-</p> <p>Dated: 12-07-2024</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Undifferentiated Tumor Marker (Immunohistochemistry)</p> <p>MD group: Cluster</p> <p>Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes:</p> <p>CD99 (EPR3097Y) Rabbit Monoclonal Antibody 199R-14, 199R-15, 199R-16, 199R-18</p> <p>Cytokeratin Cocktail (AE1 & AE3) Mouse Monoclonal Antibody 313M-14, 313M-15, 313M-16, 313M-18</p> <p>Galectin-3 (9C4) Mouse Monoclonal Antibody 255M-14, 255M-15, 255M-16, 255M-18</p> <p>Vimentin (EP21) Rabbit Monoclonal Antibody 347R-24, 347R-25, 347R-26, 347R-28</p> <p>Vimentin (V9) Mouse Monoclonal Antibody</p>	Approved subject to submission of fee as cluster.

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

	<p>Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 01-04-2024</p> <p>Fee Challan No.: 62799881</p> <p>PKR: 25000/-</p> <p>Dated: 23-02-2024</p>	<p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>(Immunohistochemistry)</p> <p>MD group: Cluster</p> <p>Class B</p> <p><u>LOA validity:</u></p> <p>31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes:</p> <p>A-1 Antitrypsin Rabbit Polyclonal Antibody 223A-14, 223A-15, 223A-16, 223A18</p> <p>ALK Protein (ALK-1) Mouse Monoclonal Antibody 204M-14, 204M-15, 204M-16, 204M-18</p> <p>Annexin A1 (MRQ-3) Mouse Monoclonal Antibody 221M-14, 221M-15, 221M-16, 221M-18</p> <p>BCL2 (124) Mouse Monoclonal Antibody 226M-94, 226M-95, 226M-96, 226M-98</p> <p>BCL2 (E17) Rabbit Monoclonal Primary Antibody 226R-14, 226R-15, 226R-16, 226R18</p> <p>BCL2 (SP66) Rabbit Monoclonal Antibody 226R-24, 226R-25, 226R-26, 226R28</p> <p>BCL6 (EP278) Rabbit</p>	<p>submission of fee as cluster.</p>
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			<p>Monoclonal Primary Antibody 227R-24, 227R-25, 227R-26, 227R28</p> <p>BCL6 (GI191E/A8) Mouse Monoclonal Antibody 227M-94, 227M-95, 227M-96, 227M-98</p> <p>BOB.1 (SP92) Rabbit Monoclonal Antibody 294R-14, 294R-15, 294R-16, 294-18</p> <p>CD10 (56C6) Mouse Monoclonal Antibody 110M-14, 110M-15, 110M-16, 110M-18</p> <p>CD103 (EP206) Rabbit Monoclonal Primary Antibody 437R-14, 437R-15, 437R-16, 437R- 18</p> <p>CD11c (5D11) Mouse Monoclonal Antibody 111M-14, 111M-15, 111M-16, 111M-18</p> <p>CD123 (6H6) Mouse Monoclonal Antibody 198M-14, 198M-15, 198M-16, 198M-18</p> <p>CD13 (EP117) Rabbit Monoclonal Primary Antibody 113R-24, 113R-25, 113R-26, 113R28</p> <p>CD13 (SP187) Rabbit Monoclonal Antibody 113R-14, 113R-15, 113R-</p>	
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			<p>16, 113R18</p> <p>CD138 (EP201) Rabbit Monoclonal Primary Antibody 138R-24, 138R-25, 138R-26, 138R28</p> <p>CD138/syndecan-1 (B-A38) Mouse Monoclonal Antibody 138M-14, 138M-15, 138M-16, 138M-18</p> <p>CD14 (EPR3653) Rabbit Monoclonal Primary Antibody 114R-14, 114R-15, 114R-16, 114R18</p> <p>CD15 (MMA) Mouse Monoclonal Antibody 115M-14, 115M-15, 115M-16, 115M-18</p> <p>CD16 (SP175) Rabbit Monoclonal Antibody 116R-14, 116R-15, 116R-16, 116R18</p> <p>CD163 (MRQ-26) Mouse Monoclonal Antibody 163M-14, 163M-15, 163M-16, 163M-18</p> <p>CD19 (EP169) Rabbit Monoclonal Primary Antibody 119R-14, 119R-15, 119R-16, 119R18</p> <p>CD19 (MRQ-36) Mouse Monoclonal Antibody 119M-14, 119M-15, 119M-16, 119M-18</p>	
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			<p>CD1a (EP3622) Rabbit Monoclonal Primary Antibody 101R-14, 101R-15, 101R-16, 101R18</p> <p>CD2 (EP222) Rabbit Monoclonal Primary Antibody 102R-14, 102R-15, 102R-16, 102R18</p> <p>CD2 (MRQ-11) Mouse Monoclonal Antibody 102M-14, 102M-15, 102M-16, 102M-18</p> <p>CD20 (L26) Mouse Monoclonal Antibody 120M-84, 120M-85, 120M-86, 120M-88</p> <p>CD20 (SP32) Rabbit Monoclonal Antibody 120R-14, 120R-15, 120R-16, 120R18</p> <p>CD21 (2G9) Mouse Monoclonal Antibody 121M-14, 121M-15, 121M-16, 121M-18</p> <p>CD21 (EP3093) Rabbit Monoclonal Primary Antibody 121R-14, 121R-15, 121R-16, 121R18</p> <p>CD23 (1B12) Mouse Monoclonal Antibody 123M-14, 123M-15, 123M-16, 123M-18</p> <p>CD23 (MRQ-57) Mouse Monoclonal Antibody 123M-24, 123M-25, 123M-</p>	
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			<p>26, 123M-28</p> <p>CD23 (SP23) Rabbit Monoclonal Antibody 123R-14, 123R-15, 123R-16, 123R18</p> <p>CD25 (4C9) Mouse Monoclonal Antibody 125M-14, 125M-15, 125M-16, 125M-18</p> <p>CD3 (MRQ-39) Rabbit Monoclonal Antibody 103R-94, 103R-95, 103R-96, 103R98</p> <p>CD3 Rabbit Polyclonal Antibody 103A-74, 103A-75, 103A-76, 103A78</p> <p>CD30 (Ber-H2) Mouse Monoclonal Antibody 130M-94, 130M-95, 130M-96, 130M-98</p> <p>CD31 (EP78) Rabbit Monoclonal Primary Antibody 131R-24, 131R-25, 131R-26, 131R28</p> <p>CD31 (JC70) Mouse Monoclonal Antibody 131M-94, 131M-95, 131M-96, 131M-98</p> <p>CD33 (PWS44) Mouse Monoclonal Antibody 133M-14, 133M-15, 133M-16, 133M-18</p> <p>CD35 (EP197) Rabbit</p>	
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			<p>Monoclonal Primary Antibody 135R-14, 135R-15, 135R-16, 135R18</p> <p>CD38 (SP149) Rabbit Monoclonal Antibody 118R-14, 118R-15, 118R-16, 118R- 18</p> <p>CD4 (EP204) Rabbit Monoclonal Primary Antibody 104R-24, 104R-25, 104R-26, 104R28</p> <p>CD4 (SP35) Rabbit Monoclonal Antibody 104R-14, 104R-15, 104R-16, 104R18</p> <p>CD43 (MT1) Mouse Monoclonal Antibody 143M-14, 143M-15, 143M-16, 143M-18</p> <p>CD45 (LCA) (2B11 & PD7/26 Mouse Monoclonal Antibody 145M-94, 145M-95, 145M-96, 145M-98</p> <p>CD45RO (UCHL-1) Mouse Monoclonal Antibody 147M-94, 147M-95, 147M-96, 147M-98</p> <p>CD5 (4C7) Mouse Monoclonal Antibody 205M-14, 205M-15, 205M-16, 205M-18</p> <p>CD5 (EP77) Rabbit Monoclonal Primary Antibody 205R-24, 205R-</p>	
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			<p>25, 205R-26, 205R28</p> <p>CD5 (SP19) Rabbit Monoclonal Antibody 205R-14, 205R-15, 205R-16, 205R18</p> <p>CD57 (NK-1) Mouse Monoclonal Antibody 157M-94, 157M-95, 157M-96, 157M-98</p> <p>CD61 (2f2) Mouse Monoclonal Antibody 161M-14, 161M-15, 161M-16, 161M-18</p> <p>CD68 9Kp-1) Mouse Monoclonal Antibody 168M-94, 168M-95, 168M-96, 168M-98</p> <p>CD7 (EP132) Rabbit Monoclonal Primary Antibody 107R-14, 107R-15, 107R-16, 107R18</p> <p>CD7 (MRQ-56) Mouse Monoclonal Antibody 107M-24, 107M-25, 107M-26, 107M-28</p> <p>CD71 (EP232) Rabbit Monoclonal Primary Antibody 171R-14, 171R-15, 171R-16, 171R18</p> <p>CD71 (MRQ-48) Mouse Monoclonal Antibody 171M-94, 171M-95, 171M-96, 171M-98</p>	
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			<p>CD79a (JCB117) Mouse Monoclonal Antibody 179M-94, 179M-95, 179M-96, 179M-98</p> <p>CD79a (SP18) Rabbit Monoclonal Antibody 179R-14, 179R-15, 179R-16, 179R18</p> <p>CD8 (C8/144B) Mouse Monoclonal Antibody 108M-94, 108M-95, 108M-96, 108M-98</p> <p>CD8 (SP16) Rabbit Monoclonal Antibody 108R-14, 108R-15, 108R-16, 108R18</p> <p>c-Myc (EP121) Rabbit Monoclonal Primary Antibody 395R-14, 395R-15, 395R-16, 395R18</p> <p>Cyclin D1 (EP12) Rabbit Monoclonal Primary Antibody 241R-44, 241R-45, 241R-46, 241R48</p> <p>Cyclin D1 (SP4) Rabbit Monoclonal Antibody 241R-14, 241R-15, 241R-16, 241R18</p> <p>Factor XIIIa (AC-1A1) Mouse Monoclonal Antibody 251M-14, 251M-15, 251M-16, 251M-18</p> <p>Factor XIIIa (EP3372) Rabbit Monoclonal Primary Antibody 251R-14, 251R-</p>	
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			<p>15, 251R-16, 251R18</p> <p>Fascin (55-k2) Mouse Monoclonal Antibody 252M-14, 252M-15, 252M-16, 252M-18</p> <p>FoxP1 (EP137) Rabbit Monoclonal Primary Antibody 350R-24, 350R-25, 350R-26, 350R28</p> <p>FoxP1 (SP133) Rabbit Monoclonal Antibody 350R-14, 350R-15, 350R-16, 350R18</p> <p>Glycophorin A (GA-R2) Mouse Monoclonal Antibody 260M-14, 260M-15, 260M-16, 260M-18</p> <p>Granzyme B Rabbit (EP230) Monoclonal Primary Antibody 262R-14, 262R-15, 262R-16, 262R18</p> <p>Granzyme B Rabbit Polyclonal Antibody 262A-14, 262A-15, 262A-16, 262A18</p> <p>Hemoglobin A (EPR3608) Rabbit Monoclonal Primary Antibody 360R-14, 360R-15, 360R-16, 360R18</p> <p>HGAL (MRQ-49) Mouse Monoclonal Antibody 375M-94, 375M-95, 375M-96, 375M-98</p>	
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			<p>IgA (EP170) Rabbit Monoclonal Primary Antibody 267R-14, 267R-15, 267R-16, 267R18</p> <p>IgA Rabbit Polyclonal Antibody 267A-14, 267A-15, 267A-16, 267A18</p> <p>IgD (EP173) Rabbit Monoclonal Primary Antibody 268R-14, 268R-15, 268R-16, 268R18</p> <p>IgD Rabbit Polyclonal Antibody 268A-14, 268A-15, 268A-16, 268A18</p> <p>IgG Rabbit Polyclonal Antibody 269A-14, 269A-15, 269A-16, 269A18</p> <p>IgG4 (EP138) Rabbit Monoclonal Primary Antibody 367R-14, 367R-15, 367R-16, 367R18</p> <p>IgG4 (MRQ-44) Mouse Monoclonal Antibody 367M-14, 367M-15, 367M-16, 367M-18</p> <p>IgM Rabbit Polyclonal Antibody 270A-14, 270A-15, 270A-16, 270A18</p> <p>Kappa (EP171) Rabbit Monoclonal Primary Antibody 274R-14, 274R-15, 274R-16, 274R18</p> <p>Kappa (L1C1) Mouse</p>	
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			<p>Monoclonal Antibody 274M-94, 274M-95, 274M-96, 274M-98</p> <p>Lambda (EP172) Rabbit Monoclonal Primary Antibody 277R-14, 277R-15, 277R-16, 277R18</p> <p>Lambda (Lamb 14) Mouse Monoclonal Antibody 277M-94, 277M-95, 277M-96, 277M-98</p> <p>Langerin (12D6) Mouse Monoclonal Antibody 392M-14, 392M-15, 392M-16, 392M-18</p> <p>LEF1 (EP310) Rabbit Monoclonal Primary Antibody 442R-14, 442R-15, 442R-16, 442R-18</p> <p>LMO2 (SP51) Rabbit Monoclonal Antibody 370R-14, 370R-15, 370R-16, 370R18</p> <p>Lysozyme Rabbit Polyclonal Antibody 278A-14, 278A-15, 278A-16, 278A18</p> <p>MUM1 (EP190) Rabbit Monoclonal Primary Antibody 358R-14, 358R-15, 358R-16, 358R18</p> <p>MUM1 (MRQ-43) Rabbit Monoclonal Antibody 358R-74, 358R-75, 358R-</p>	
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			<p>76, 358R78</p> <p>MUM1 (MRQ-8) Mouse Monoclonal Antibody 358M-14, 358M-15, 358M-16, 358M-18</p> <p>Myeloperoxidase (EP151) Rabbit Monoclonal Primary Antibody 289R-24, 289R-25, 289R-26, 289R28</p> <p>Myeloperoxidase Rabbit Polyclonal Antibody 289A-74, 289A-75, 289A-76, 289A78</p> <p>Myeloperoxidase (SP72) Rabbit Monoclonal Antibody 289R-14, 289R-15, 289R-16, 289R18</p> <p>Oct-2 (MRQ-2) Mouse Monoclonal Antibody 308M-14, 308M-15, 308M-16, 308M-18</p> <p>PAX-5 (24) Mouse Monoclonal Antibody 312M-14, 312M-15, 312M-16, 312M-18</p> <p>Pax-5 (EP156) Rabbit Monoclonal Primary Antibody 312R-24, 312R-25, 312R-26, 312R28</p> <p>PAX-5 (SP34) Rabbit Monoclonal Antibody 312R-14, 312R-15, 312R-16, 312R18</p>	
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			<p>PD-1 (EP239) Rabbit Monoclonal Primary Antibody 315R-14, 315R-15, 315R-16, 315R18</p> <p>PD-1 (NAT105) Mouse Monoclonal Antibody 315M-94, 315M-95, 315M-9, 315M98</p> <p>Perforin (MRQ-23) Mouse Monoclonal Antibody 316M-14, 316M-15, 316M-16, 316M-18</p> <p>PU.1 (EPR3158Y) Rabbit Monoclonal Primary Antibody 328R-14, 328R-15, 328R-16, 328R18</p> <p>SOX-11 (MRQ-58) Mouse Monoclonal Antibody 382M-14, 382M-15, 382M-16, 382M-18</p> <p>Spectrin (RBC2/3D5) Mouse Monoclonal Antibody 333M-14, 333M-15, 333M-16, 333M-18</p> <p>T-bet (MRQ-46) Rabbit Monoclonal Antibody 368R-74, 368R-75, 368R-7, 368R-78</p> <p>TCL1 (MRQ-7) Mouse Monoclonal Antibody 357M-14, 357M-15, 357M-16, 357M-18</p> <p>TdT (EP266) Rabbit Monoclonal Primary Antibody 338R-24, 338R-</p>	
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			<p>25, 338R-2, 338R-28</p> <p>TdT Rabbit Polyclonal Antibody 338A-74, 338A-75, 338A, 76338A-78</p> <p>Tryptase (G3) Mouse Monoclonal Antibody 342M-14, 342M-15, 342M-16, 342M-18</p>	
17.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 01-04-2024</p> <p>Fee Challan No.: 65926424918</p> <p>PKR: 25000/-</p> <p>Dated: 23-02-2024</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Melanoma Markers (Immunohistochemistry)</p> <p>MD group: Cluster</p> <p>Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes:</p> <p>Cathepsin K (3F9) Mouse Monoclonal Antibody 402M-14, 402M-15, 402M-16, 402M-18</p> <p>CD63 (NKI/C3) Mouse Monoclonal Antibody 263M-14, 263M-15, 263M-16, 263M-18</p> <p>CDK4 (DCS-31) Mouse Monoclonal Antibody 478M-94, 478M-95, 478M-96, 478M-98</p> <p>HMB-45 (HMB-45) Mouse Monoclonal Antibody 282M-94, 282M-95, 282M-96, 282M-98</p>	<p>Approved subject to submission of fee as cluster.</p>

			<p>KBA.62 (KBA.62) Mouse Monoclonal Antibody 366M-94, 366M-95, 366M-96, 366M-98</p> <p>MART-1 (Melan A) (A103) Mouse Monoclonal Antibody 281M-84, 281M-85, 281M-86, 281M-88</p> <p>MART-1 (Melan A) (M2-7C10) Mouse Monoclonal Antibody 281M-94, 281M-95, 281M-96, 281M-98</p> <p>MART-1 (M2-7C10) + Tyrosinase (T311) Mouse Monoclonal Antibody 903H-08</p> <p>Microphthalmia Transcription Factor (MiTF) (C5/D5) Mouse Monoclonal Antibody 284M-94, 284M-95, 284M-96, 284M-98</p> <p>Nestin (10C2) Mouse Monoclonal Antibody 388M-14, 388M-15, 388M-16, 388M-18</p> <p>PNL2 (PNL2) Mouse Monoclonal Antibody 365M-98</p> <p>PRAME (EP461) Rabbit Monoclonal Primary Antibody 484R-14, 484R-15, 484R-16, 484R-18</p> <p>S100 beta (EP32) Rabbit</p>	
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			<p>Monoclonal Primary Antibody 449R-14, 449R-15, 449R-16, 449R18</p> <p>SOX-10 (EP268) Rabbit Monoclonal Primary Antibody 383R-14, 383R-15, 383R-16, 383R18</p> <p>SOX-10 Rabbit Polyclonal Antibody 383A-74, 383A-75, 383A-76, 383A78</p> <p>Tyrosinase (T311) Mouse Monoclonal Antibody 344M-94, 344M-95, 344M-96, 344M-98</p>	
18.	<p>M/s F Y Diagnostics & Surgicals</p> <p>Anum Blessing, Suite# 203, Near Duty Free Shop, BL7/8, K.C.H.S.U, Shahrach-e-Faisal, Karachi</p> <p>(ELI-00323)</p> <p>Date of R&I: 01-04-2024</p> <p>Fee Challan No.: 3310203182</p> <p>PKR: 25000/-</p> <p>Dated: 12-07-2024</p>	<p><u>Manufacturing site:</u></p> <p>M/s CELL MARQUE CORP 6600 SIERRA COLLEGE BLVD ROCKLIN, CA USA 95677.</p> <p>ISO 13485 certificate validity: 25-03-2024</p>	<p>Endothelial Markers (Immunohistochemistry)</p> <p>MD group: Cluster</p> <p>Class B</p> <p><u>LOA validity:</u> 31-12-2025</p> <p>Shelf Life: 03 years</p> <p>Codes:</p> <p>CD34 (EP88) Rabbit Antibody 134R-18, 134R-16, 134R-15, 134R-14</p> <p>CD34 (QBEnd/10) Mouse Monoclonal Antibody 134M-18, 134M-16, 134M-15, 134M-14</p> <p>Claudin-4 (EP417) Rabbit Monoclonal Antibody 468R-18, 468R-16, 468R-</p>	<p>Approved subject to submission of fee as cluster</p>

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

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

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

	(ELI-00029) Date of submission: 02.06.2022	Jiangbei new area, Nanjing city, Jiangsu, China Copy of FSC: China, Valid Till: 20-04-2024	Class C Shelf Life: 2 years Article no. 1. Electrosurgical Generator (SL100) 2. Sterile Vessel Sealer / divider (SL1120A) 3. Sterile Vessel Sealer / divider (SL1137A) 4. Sterile Vessel Sealer / divider (SL1120S) 5. Sterile Vessel Sealer / divider (SL1137S) 6. Sterile Vessel Sealer / divider (SL5137S) 7. Sterile Vessel Sealer / divider (SL5137A) 8. Sterile Vessel Sealer / divider (SL5120S) 9. Sterile Vessel Sealer / divider (SL5300S) 10. Sterile Vessel Sealer / divider (SL0837) 11. Sterile Vessel Sealer / divider (SL0823)	single pack as system or separately. Further firm has not provided the labeling, instructions-for-use, brochures or catalogues for each constituent-component state that the constituent-component is intended for use with the system.
24.	M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details	<u>Legal Manufacturer:</u> KARL STORZ SE & CO. KG Germany Address: Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany FSC: Germany	KARL STORZ Imaging Systems (Camera Heads, CCU's, Monitors, Imaging Accessories) Class A Shelf Life: N/A	The case was deferred as firm has failed 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

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

			Irrigation rod for Unidrive ENT	
26.	<p>Applicant Name:</p> <p>M/s. Allmed Solutions</p> <p>Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi</p> <p>ELI:00029</p> <p>R&I details Date: 18/01/2023 Slip no. 47935234289 Rs. 5000. Dated: 12-01-2023</p> <p>Tracking ID. NDH-Y7N-3VAP</p>	<p>Name of Manufacturer:</p> <p>KARL STORZ SE & CO. KG Germany</p> <p>Address: Dr. Karl-Storz- StraBe 34 78532 Tuttlingen, Germany</p> <p>FSC: Germany Validity: Not mentioned, issued in Oct. 2022</p> <p>LOA Validity: 31/12/2025</p>	<p>Brand Name:</p> <p>KARL STORZ Fiberscopes and Semiflexible Endoscopes (Fiberscopes with and without channel, Semiflexible endoscopes with and without channel)</p> <p>Class A</p> <p>Shelf Life: N/A</p> <p>Codes / Sizes:</p> <p>S # Article No. Description 1 27033A A Miniature Telescope 0°, 1.2 mm, 20 cm 2 10331B2 Retromolar Intubation Endoscope 5,0x40 3 11014Y Fiber Fixation 4 11301CA Leaflet Valve, for single use, 20x 5 11301CF LIPP Tube</p>	<p>The case was deffered as firm has failed 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 devices fall in family as per MDR 2017 along with supporting documents e.g. brochure, catalogue etc.</p>

			Holder 6 27001G Instrument Port, 1 channel 7 27001GF Instrument Port, 2 channels 8 27001G H Instrument Port, 2 channels 9 27014Y LUER-Adaptor, with seal 10 2763013 6 Adaptor for Uretero Renoscopes	
27.	Applicant Name: M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi ELI:00029 R&I details Date: 03/01/2023	Name of Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr. Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not mentioned, issued in Oct. 2022 LOA Validity: 31/12/2025	Brand Name: KARL STORZ OR1 (Data Storage, Data Management and Routing Systems, Active controlling systems, components of software) Class A Shelf Life: N/A Codes / Sizes S # Article	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 of the permissible variants. MDB decided to give last opportunity to justify that collection of applied medical devices fall in family as per MDR 2017 along with supporting documents e.g. brochure, catalogue

	<p>Slip no. 59976410</p> <p>Rs. 5000.</p> <p>Dated: 28-12-2022</p> <p>Tracking ID.</p> <p>17D-6YJ-RRM6</p>		<p>No.</p> <p>Description</p> <p>1 WD300</p> <p>KARL STORZ</p> <p>AIDA</p> <p>2 WD310 AIDA C</p> <p>3 WM200 OR1</p> <p>SmartScreen</p> <p>4</p> <p>WO1026</p> <p>5</p> <p>OR1 NEO IP</p> <p>HDMI Encoder,</p> <p>single channel</p> <p>5</p> <p>WO1026</p> <p>6</p> <p>OR1 NEO IP</p> <p>HDMI Decoder,</p> <p>single channel</p> <p>6</p> <p>WO1026</p> <p>7</p> <p>OR1 NEO IP DP</p> <p>Encoder, single</p> <p>channel</p> <p>7</p> <p>WO1026</p> <p>8</p> <p>OR1 NEO IP VGA</p> <p>Encoder, single</p> <p>channel</p> <p>8</p> <p>WO1026</p>	<p>etc.</p>
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			<p>9</p> <p>OR1 NEO IP</p> <p>Analog</p> <p>Encoder,single</p> <p>channel</p> <p>9</p> <p>WO1027</p> <p>0</p> <p>OR1 NEO IP SDI</p> <p>Encoder, single</p> <p>channel</p> <p>10 WO300</p> <p>KARL STORZ</p> <p>OR1 FUSION</p> <p>CONTROL</p> <p>11 WO301 OR1 .avm</p> <p>System</p> <p>12</p> <p>2009047</p> <p>0</p> <p>SCB Connecting</p> <p>Cord, length 7.5 m</p> <p>13</p> <p>2009057</p> <p>0</p> <p>SCB Connecting</p> <p>Cord, length 15 m</p> <p>14</p> <p>2009077</p> <p>0</p> <p>SCB Connecting</p> <p>Cord, length 30 m</p> <p>15</p> <p>2009087</p>	
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			0	
			SCB Connecting Cable, 37 m	
			16	
			2009172	
			2	
			SCB/Universal OR-Light Module	
			17	
			2009232	
			2	
			SCB/KLS Martin marLED module	
			18	
			2009262	
			2	
			SCB/Dräger Polaris OR Light module	
			19	
			2009272	
			2	
			SCB Maquet Power LED OR Light Module	
			20	
			2009292	
			2	
			SCB Dräger Polaris 600 OR Light Module	
			21	
			2009312	
			2	

			SCB TRUMPF iLED 7 OR Light Module 22 2009322 2 SCB Maquet VOLISTA OR Light Module 23 2009332 2 SCB Maquet PowerLED II OR Light Module 24 W22168 S OR1 Panel PC 21.5", Stand-Alone 25 WU1000 0 OR1 Table Interface Unit	
28.	Applicant Name: M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi	Name of Manufacturer: KARL STORZ SE & CO. KG Germany Address: Dr. Karl-Storz- StraBe 34 78532 Tuttlingen, Germany FSC: Germany Validity: Not	Brand Name: KARL STORZ Equipment Carts (Equipment Carts and accessories) Class A Shelf Life: N/A	The case was deffered as firm has failed 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

	<p>ELI:00029</p> <p>R&I details</p> <p>Date: 03/01/2023</p> <p>Slip no. 5136248360</p> <p>Rs. 5000.</p> <p>Dated: 28-12-2022</p> <p>Tracking ID.</p> <p>X9N-XZV-GZS6</p>	<p>mentioned, issued in Oct. 2022</p> <p>LOA</p> <p>Validity: 31/12/2025</p>	<p>Codes / Sizes</p> <p>S # Article</p> <p>No. Description</p> <p>1 UG041 Beam package, equipment cart low</p> <p>2 UG051 Beam package, equipment cart high</p> <p>3 UG052 Beam package, equipment cart LC</p> <p>4 UG055 Beam Package high,</p> <p>CH version</p> <p>5 UG310</p> <p>Isolation</p> <p>Transformer 200V</p> <p>240V, 2000VA</p> <p>6 UG410</p> <p>Earth leakage monitor 200V - 240V</p> <p>7 UG500 Monitor Holder</p> <p>8 UG510 Monitor Holding Arm</p> <p>9 UG520 Monitor Holding Arm, long</p> <p>10 UG530 Swivel Arm for Navigation Camera</p> <p>11 UG540 Monitor Swivel Arm</p>	<p>that collection of applied medical devices fall in family as per MDR 2017 along with supporting documents e.g. brochure, catalogue etc.</p>
29.	<p>M/s Johnson & Johnson Pakistan (Pvt) Ltd,</p> <p>Office No. 506, 5th Floor, Horizon Tower, Block 3, Scheme No 5, Clifton, Karachi.</p>	<p>Legal Manufacturer:</p> <p>Medos International SARL</p> <p>Chemin Blanc 38, Le Locle CH-2400,</p>	<p>CEREBASE DA Guide Sheath_</p> <p>MDIR-0005568</p>	<p>Approved.</p>

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

	(ELI 00154 (Post-registration variation for PM change))	Switzerland"	Date of Reg.: 12-Jan-23 Date of Registration Dossier Submission: 28-Jun-21										
33.	M/s Johnson & Johnson Pakistan (Pvt) Ltd, Office No. 506, 5 th Floor, Horizon Tower, Block 3, Scheme No5, Clifton, Karachi. (ELI 00154 (Post-registration variation for PM change))	Legal Manufacturer: "Medos International SARL Chemin Blanc 38, Le Locle CH-2400, Switzerland"	PROWLER PLUS Infusion Catheter MDIR-0004564 Class D Date of Reg.: 12-Jan-23 Date of Registration Dossier Submission: 28-Jun-21	Approved.									
34.	Johnson & Johnson Pakistan (Pvt) Ltd., Office No.506, 5th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) [2966] 25-08-2020	Legal Manufacturer: Synthes GmbH 3 Eimattstrasse, 4436 Oberdorf, CH FSC # 00015771 valid until 29-Sep-2025 FSC # 00015773 valid until 24-Oct-2025 (submitted in Response to 48 th MDB Decision Letter) FSC # 00015778 valid until 24-Oct-2025	Cable Implants Class C <table><tr><th></th><th>Descriptions</th><th>Shelf-life (years)</th></tr><tr><td>281001</td><td>Cercla geFix Insert</td><td>N/A</td></tr><tr><td>2</td><td>Cercla</td><td>N/</td></tr></table>		Descriptions	Shelf-life (years)	281001	Cercla geFix Insert	N/A	2	Cercla	N/	Deffered the case (last oppotunity) for: 1. justification of the grouping of applied devices according to MDR 2017 and RRA with supporting documents. 2. Submission of copy of fee challan.
	Descriptions	Shelf-life (years)											
281001	Cercla geFix Insert	N/A											
2	Cercla	N/											

			8 1 . 0 0 2	geFix f/LCP 4.5/5. 0	A		
			2 9 1 . 0 4 4	Coil w/Cer clage Wire Ø 0.4m m, L 8 m	N/ A		
			2 9 1 . 0 5 0	Coil w/Cer clage Wire Ø 1.0m m, L 10 m	N/ A		
			2 9 1 . 0 6 0	Coil w/Cer clage Wire Ø 1.25m m, L 10 m	N/ A		
			2 9 1 . 0 7 0	Coil w/Cer clage Wire Ø 0.6m m, L 8 m	N/ A		
			2 9 1 . 0 9 0	Coil w/Cer clage Wire Ø 0.8m m, L 10 m	N/ A		
			2	Coil	N/		

			91130	w/Cerclage Wire Ø 1.5m, L 10 m	A		
			29837	Cerclage Positioning Pin f/LCP 3.5 + LC-DCP® 3.5	N/A		
			29839	Cerclage Positioning Pin f/LCP 4.5 + LC-DCP® 4.5	N/A		
			481002	CerclageFix f/LCP 4.5/5.0	N/A		
			49806	TRD - Trochanter Reattachment Device, small	N/A		
			49808	TRD - Trochanter Reattachment	N/A		

			07	t Devic e, large			
			498 Pin f/LCP 3.5 + LC- DCP® 3.5	Cercla ge Positi oning	N/ A		
			498 Pin f/LCP 4.5 + LC- DCP® 4.5	Cercla ge Positi oning	N/ A		
			02 Cercla ge Eye f/Scre ws Ø 3.5m m		N/ A		
			02 Cercla ge Eye f/Scre ws Ø 3.5m m		10		
			02 S				

			02.2.2025	Cerclage Eye f/Screens Ø 4.5m	N/A		
			02.2.2025	Cerclage Eye f/Screens Ø 4.5m	10		
			02.2.2025	Cerclage Eye f/Hexagonal Socket, Ø 4.0m	N/A		
			02.2.2025	Cerclage Eye f/Hexagonal Socket, Ø 4.0m	10		

			02310222	Positioning Pin f/VA 5.0, cruciform	N/A		
			02310222S	Positioning Pin f/VA 5.0, cruciform	10		
			02401000S	Wire-Cable Ø 1.0mm, w/Crimp	10		
			0422100205	Cerclage Eye f/Screws Ø 3.5mm	N/A		
			04	Cerclage Eye	10		

			221002S	f/Screens Ø 3.5m			
			042210035	Cerclage Eye f/Screens Ø 4.5m	N/A		
			042210035	Cerclage Eye f/Screens Ø 4.5m	10		
			042210045	Cerclage Eye f/Hexagonal Socket, Ø 4.0m	N/A		
			042210045	Cerclage Eye	10		

			221004S	f/Hexagonal Socket, Ø 4.0mm			
			042310222	Positioning Pin f/VA 5.0, cruciform	N/A		
			042310222S	Positioning Pin f/VA 5.0, cruciform	10		
			281001S	CerclageFix Insert	10		
			281002S	CerclageFix f/LCP 4.5/5.0	10		
			291	Cerclage Wire	N/A		

			91030010	ge Wire Ø 1.0m m w/Eye , L 600m m	A		
			29104001	Cercla ge Wire Ø 1.25m m w/Eye , L 600m m	N/A		
			29104001	Cercla ge Wire Ø 1.25m m w/Eye , L 600m m	N/A		
			29108001	Cercla ge Wire Ø 0.8m m w/Eye , L 280m m	N/A		
			29108001	Cercla ge Wire Ø 0.8m m w/Eye , L 280m m	N/A		

			0	m			
			291	Cercla ge Wire Ø 1.5m m w/Eye , L 280m m	N/ A		
			291	Cercla ge Wire Ø 1.5m m w/Eye , L 280m m	N/ A		
			291	Cercla ge Wire Ø 1.5m 2m w/Eye , L 600m m	N/ A		
			291	Cercla ge Wire Ø 1.5m 2m w/Eye , L 600m m	N/ A		
			292	Cercla ge Wire Ø 0.4m m, L 150m	N/ A		

			01	m			
			29122010	Cercla ge Wire Ø 0.4m m, L 150m	N/ A		
			29124001	Cercla ge Wire Ø 0.6m m, L 175m m	N/ A		
			29124001	Cercla ge Wire Ø 0.6m m, L 175m m	N/ A		
			29126001	Cercla ge Wire Ø 0.8m m, L 200m m	N/ A		
			2912	Cercla ge Wire Ø 0.8m	N/ A		

			6010	m, L 200m m			
			29127001	Cercla ge Wire Ø 1.0m m, L 250m m	N/ A		
			29127001	Cercla ge Wire Ø 1.0m m, L 250m m	N/ A		
			29128001	Cercla ge Wire Ø 1.25m m, L 300m m	N/ A		
			29128001	Cercla ge Wire Ø 1.25m m, L 300m m	N/ A		
			298	Cercla ge Cable	N/ A		

			8001	w/Cri mp Ø 1.0m m		
			2988001S	Cercla ge Cable w/Cri mp Ø 1.0m m	10	
			2988001	Cercla ge Cable w/Cri mp Ø 1.7m m	N/ A	
			2988001S	Cercla ge Cable w/Cri mp Ø 1.7m m	10	
			29880030	Positi oning Pin 4.5 w/thre ad	N/ A	

			1				
			298 . 8 0 3 . 0 1 S	Positi oning Pin 4.5 w/thre ad, f/LCP	10		
			298 . 8 3 7 S	Cercla ge Positi oning Pin f/LCP +LC-DCP® 3.5	10		
			298 . 8 3 8 . 0 1 S	Positi oning Pin 3.5 w/thre ad	N/ A		
			298 . 8 3 8 . 0 1 S	Positi oning Pin 3.5 w/thre ad, f/LCP	10		
			298 . 8 3	Cercla ge Positi oning Pin f/LCP	10		

			9 S	+LC- DCP® 4.5			
			4 9 8 . 8 0 0 . 0 1	Cercla ge Cable w/Cri mp Ø 1.0m m	N/ A		
			4 9 8 . 8 0 0 . 0 1 S	Cable w/Cri mp Ø 1.0m m	10		
			4 9 8 . 8 0 3 . 0 1	Positi oning Pin 4.5 w/thre ad, f/LCP	N/ A		
			4 9 8 . 8 0 3 . 0 1 S	Positi oning Pin 4.5 w/thre ad, f/LCP	10		
			4 9 8	TRD- Troch. Reatta	10		

			806S	chm. Devic e, small, f/Cabl e Syst.			
			49807S	TRD- Troch. Reatta chm. Devic e, large, f/Cabl e Syst.	10		
			498037S	Cercla ge Positi oning Pin f/LCP +LC- DCP® 3.5	10		
			49803801S	Positi oning Pin 3.5 w/thre ad, f/LCP	N/ A		
			49803801S	Positi oning Pin 3.5 w/thre ad, f/LCP	10		
			49803801S	Cercla ge Positi	10		

			<table><tr><td>839S</td><td>oning Pin f/LCP +LC- DCP® 4.5</td><td></td></tr><tr><td>61110501</td><td>Cercla ge Cable w/Cri mp Ø 1.7m m</td><td>N/ A</td></tr><tr><td>61110501S</td><td>Cercla ge Cable w/Cri mp Ø 1.7m m</td><td>10</td></tr><tr><td>9014650</td><td>Tuber cable Ø 1.0m m, w/Cri mp</td><td>10</td></tr></table> <p>Fee Deposited: PKR 50,000/-</p> <p>Submission Date: 25-Aug- 20</p>	839S	oning Pin f/LCP +LC- DCP® 4.5		61110501	Cercla ge Cable w/Cri mp Ø 1.7m m	N/ A	61110501S	Cercla ge Cable w/Cri mp Ø 1.7m m	10	9014650	Tuber cable Ø 1.0m m, w/Cri mp	10	
839S	oning Pin f/LCP +LC- DCP® 4.5															
61110501	Cercla ge Cable w/Cri mp Ø 1.7m m	N/ A														
61110501S	Cercla ge Cable w/Cri mp Ø 1.7m m	10														
9014650	Tuber cable Ø 1.0m m, w/Cri mp	10														
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)		<p>Shelf life 24 Months Storage Condition 2°C-8°C</p> <p>Alinity m CMV WB CTRL Kit (09N46-082) Shelf life 12 Months Storage Condition -25°C- -15°C</p> <p>Alinity M CMV WB CAL Kit (09N46-072) Shelf life 12 Months Storage Condition -25°C- -15°C</p> <p>CWV WB</p> <p>Class C</p>	<p>2. Undertaking on stapm paper.</p> <p>3. calrification of grouping of the applied kits as these have different storage conditions and shelf life.</p> <p>4. Verification of storage facilities 2°C-8°C and -25°C- -15°C.</p>
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	<p>Alinity m EBV WB AMP Kit, (09N43-092) Shelf life 12 Months Storage Condition 2°C-8°C</p> <p>Alinity m EBV WB CTRL Kit, (09N43-082) Shelf life 24 Months Storage Condition -25°C- -15°C</p> <p>Alinity m EBV WB CAL Kit (09N43-072) Shelf life 12 Months Storage Condition -25°C- -15°C</p>	<p>Deffered the case for submission of;</p> <p>1. Form 7A with annexures.</p> <p>2. Undertaking on stapm paper.</p> <p>3. calrification of grouping of the applied kits as these have different storage conditions and shelf life.</p> <p>4. Verification of storage facilities 2°C-8°C and -25°C- -15°C.</p>

			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) R& I Date: (08-01-2025) Fee details: Amount paid: PKR 62,000/- Paid Slip / challan No.: 64760315 Dated: (03-12-2024)	Hangzhou, 310018. China Free Sale Certificate Date of Issue: (31-10-2024) Letter of authorization: Date of Issue: (19-11-2024)	Virus Rapid Test Device (Whole Blood/Serum/Plasma) Codes: 38221990, 30829 Class-D Shelf life: 24 Months	
41.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTURER 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 original documents.
42.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTURER 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 original documents
43.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTURER 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 original documents.
44.	Name Health Care Products 237/A, Block-2 P.E.C.H.S., Shahrah-e- Quaideen, Karachi, Pakistan	LEGAL MANUFACTURER 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 original 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	MANUFACTUREUR 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 original 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

				stamp paer not submitted.
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 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 Blood Transfusion Set Blood Transfusion Set 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.
51.	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 Burette 100ml with Infusion Set (Burette Infusion Set 100ml)	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.
52.	BAIN Medical SMC- Pvt) Ltd Shop No. 2, Ground	Legal Manufacturer: Bain Medical Equipment (Guangzhou) Co., Ltd.	BAIN Hollow Fiber Dialyzer	Approved subject to submission of original FSC of

	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 Development 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	<u>Legal Manufacturer:</u> Terumo BCT, Ltd., Old Belfast Road, Millbrook, Larne BT40 2SH, United Kingdom. <u>Manufacturing site:</u> 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 68 th meeting:
55.	Glo-Med Technologies, A-21/2B-1, KDA	<u>Legal Manufacturer:</u> Urotronic, Inc. 2495	Optilume Urethral Drug Coated Balloon catheter	Deferred for provision of

	<p>Scheme 1 (Ext.) National Stadium Road Karachi.</p> <p>(ELI-00712)</p> <p>4486</p> <p>02-06-2022</p>	<p>Xenium Lane N Minneapolis, MN 55441 USA</p> <p>FSC: USA</p> <p>Valid Till: 14-12-2023</p>	<p>(Urethral Drug Coated Balloon Catheter)</p> <p>Class-D</p> <p>Shelf life: 12 Months</p> <p>Codes are not provided. per FSC</p>	<p>documents/ information as mentioned in 62nd meeting.</p>
56.	<p>Biomedical Star Enterprises, Plot E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road SITE Karachi (ELI-01186)</p>	<p>Tianchang City Anrui Medical Equipment Co., Ltd Renhe Industrial District 239331 Tianchang city Anhui Province, China</p>	<p>Biofit Powder Free Latex Surgical Gloves</p> <p>Powder Free Latex Surgical Gloves</p> <p>Class B</p>	<p>Deferred for;</p> <ol style="list-style-type: none"> 1. Submission of Form 7A with annexures. 2. Clarification that FSC spain bears name latex surgical glove (powdered free not mentioned). <p>FSC china have product name sterile surgical gloves for single use.</p>
57.	<p>Biomedical Star Enterprises, Plot E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road SITE Karachi (ELI-01186)</p>	<p>Tianchang City Annrui Medical Equipment Co., Ltd Renhe Industrial District 239331 Tianchang city Anhui Province, China</p>	<p>Biofit Powdered Latex Surgical Gloves</p> <p>Powdered Latex Surgical Gloves</p> <p>Class B</p>	<p>Deferred for;</p> <ol style="list-style-type: none"> 1. submission of Form 7A with annexures. 2. clarification that FSC spain bears name latex surgical glove (powdered not mentioned). <p>FSC china have product name sterile surgical gloves for single use.</p>
58.	<p>Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800, Pakistan. (ELI-000416)</p> <p>Date of issuance:23rd</p>	<p>Legal Manufacturer.</p> <p>PhysIOL</p> <p>Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium</p>	<p>PODEYE</p> <p>Hydrophobic Acrylic lens</p> <p>Class: C</p> <p>Shelf life: 5 years (shelf life or validation study for claimed duration is attached at Annexed at.05)</p>	<p>Approved subject to submission of fee.</p>

	<p>May 2019</p> <p>Validity:22nd May 2024 Annexed at.01</p>	<p>Mfg Site:</p> <p>PhysIOL</p> <p>Address:Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium</p> <p>Embassy attested FSC: Belgium</p> <p>Issuance date: 17-11-2023</p>		
59.	<p>Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800, Pakistan. (ELI-000416)</p> <p>Date of issuance:23rd May 2019</p> <p>Validity:22nd May 2024 Annexed at.01</p>	<p>Legal Manufacturer.</p> <p>PhysIOL</p> <p>Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium</p> <p>Mfg Site:</p> <p>PhysIOL</p> <p>Address:Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium</p> <p>Embassy attested FSC: Belgium</p> <p>Issuance date: 17-11-2023</p>	<p>POD F</p> <p>Hydrophilic Acrylic lens</p> <p>Class: C</p> <p>Shelf life: 5 years</p> <p>Date of submission: 14-11-2023</p> <p>Fee Submission: 22-12-2020</p> <p>Fee Slip no. 2048520</p> <p>Annexed at.06</p>	<p>Approved subject to submission of fee.</p>
60.	<p>Ms. Jasani Scientifics SC-45, Marium Square, chandni Chowk, Stadium road, Karachi, 74800, Pakistan. (ELI-000416)</p> <p>Date of issuance:23rd May 2019</p> <p>Validity:22nd May 2024 Annexed at.01</p>	<p>Legal Manufacturer.</p> <p>PhysIOL</p> <p>Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium</p> <p>Mfg Site:</p> <p>PhysIOL</p> <p>Address:Liege Science Park,Allee des Noisetiers 4,B-4031 Liege,Belgium</p>	<p>POD FT</p> <p>Fine vision toric lense</p> <p>Class: C</p> <p>Shelf life: 5 years</p>	<p>Approved subject to submission of fee.</p>

		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	
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. <u>East Health Care</u> A-17/1 ground floor Gulshan e Iqbal Block 6 Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	<u>Legal Manufacturer:</u> 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	Brand Name; KAYO Red Cap (Clot Activator) Vacuum Blood Collection Tubes Generic Name; Blood collecting vacuum Tube(vecutanier) Class A Shelf Life: 2 Years Sizes 0.5ml, 2ml,3ml,4ml, 5ml, 6ml, 8ml, 10ml	Deferred for submission of copy of complete application.
63.	M/s. <u>East Health Care</u>	<u>Legal Manufacturer:</u> M/s	Brand Name; KAYO Purple Cap (ETDA K3) Vacuum Blood Collection	Deferred for submission of copy of complete

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

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

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

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

	Karachi. ELI-01115 Mfg 09/08/2023 Exp 8/08/2028	West Road, Hangzhou, Zhejiang Province, P. R China. FSC: China Validity: Valid 19 sep 2026 LOA Validity: 31/12/2028	Shelf Life: 5 Years Sizes 21G , 22G, 23G , 24G, 26G, 27G	
73.	JF International 4th Floor, 10-C, 6th sunset commercial Lane Phase 2 EXT DHA Karachi Pakistan (ELI-00246) Evaluator: AD-VI	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	CONTEC Electrocardiograph ECG 1200G. Class: C Shelf Life: Codes & Sizes as per FSC	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	<u>Legal Manufacturer:</u> 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	<u>Legal Manufacturer:</u> 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 11-04-2023	Guangzhou. P.R. China FSC China valid till 21-1-24 FSC Belgium issuance 23-09-2022	Shelf life: 2 years Code: W109-C	FSC of China, FSC of any RRA country, ISO 13485, FQA and DE certificates. 2. Labels of applied codes. 3. Copy of fee challan.
76.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi. ELI-00066 1457-C 04-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd 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	Safety Combined Diagnostic kit Dengue NSI Antigen and IgG/IgM Antibody test (Colloidal Gold) Class-C Shelf life: 2 years Code: W111-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.
77.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi. ELI-00066 1456-C 04-04-2023	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd 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	Safety One Step One Step Malaria HRP2/pLDH (P.f/P.v) test Class-C Shelf life: 2 years Code: W056-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.
78.	A. Feroz & Co Medicine street No. 1, Marriot Road Karachi.	<u>Legal Manufacturer:</u> Guangdong Wondfo Biotech Co., Ltd	Safety One Step Dengue NSI Antigen Whole Blood/Serum/Plasma Test	Deferred (last opportunity) for submission of; 1. Original

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

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

	[758-6L]	Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0585046989		for family.
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) [758-6L]	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	Bonree Reinforced Endotracheal Tubes Class-B Shelf Life: 5 Years Type Size: 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,	Approved subject to submission of fee for family valid original FSC.

		CE certificate with extension notification letter.	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,	
89.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> 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 CE certificate with extension notification letter.	Bonree Feeding Tubes Class-B Shelf Life: 5 Years <u>Type or Size:</u> Fr4, Fr5, Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20,	Approved subject to submission of fee for family valid original FSC.
90.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 31,000/-	<u>Legal Manufacturer:</u> 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 CE certificate with extension notification letter.	Bonree Ureteral Catheters Class-B Shelf Life: 5 Years <u>Type</u> Straight Tip Closed Straight Tip Open <u>Size</u> Straight Tip Closed:4.0FR, 5.0FR, 6.0FR, 7.0FR Straight Tip Open:4.0FR, 5.0FR, 6.0FR, 7.0FR	Approved Bonree Ureteral Catheters Straight Tip Closed, subject to submission of fee for family and valid original FSC. . Firm will apply separately for Bonree Ureteral Catheters Straight Tip Open.

		letter.		
91.	Cabbot Surgicals, 09 Rose Lane 1 Gulberg Avenue New Lalazar Rawalpindi 46000. ELI-00415 6040-P 62,000/-	<u>Legal Manufacturer:</u> 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 Skin Stapler Class-C Shelf Life: 5 Years Product Codes: HPF-15A, HPF-15B, HPF- 25A, HPF-25B, HPF-35A, HPF-35B, HPF-45A, HPF- 45B; Stapler Remover: HPF-C	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/-	<u>Legal Manufacturer:</u> 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, HQ-100L/M/H; HQZ-60L/M/H, HQZ-80L/M/H, HQZ-100L/M/H, HDQ- 60L, HDQ-60M, HDQ-60H, HDQ-80L,	Approved

			HDQ-/80M, HDQ-80H, HDQ-100L, HDQ-100M, HDQ-100H, HDQZ-60L, HDQZ-60M, HDQZ-60H, HDQZ-80L, HDQZ-80M, HDQZ-80H, HDQZ-100L, HDQZ-100M, HDQZ-100H.	
93.	M/s Haji S. Ameer Din & Sons 305-A Upper Mall Lahore. (ELI-00059) Fee-5,000/- April 2024 submission	<u>Legal Manufacturer:</u> Good-Lite Company, 1155 Jansen Farm Drive Elgin, IL 60123, USA. FSC: USA. Validity: 09-01-2025.	Good-Lite Eye Examination Tools Class-A Shelf Life: N/A Models: Handheld Bagolini striated Lens Set Loose individual prism set 22pcs GL Horizontal & Vertical Prism Bar Set Worth 4 – dot attachment for muscle light with adult red/green glasses GL Retinoscopy Paddles w/Axis Compass Heavy duty Hertel Exophthalmometer	Deferred for; 1. Submission of separate application for each medical device. 2. Justification of grouping. 3. Submission of brochure and product catalogue.

			GL OKN Drum 10 GL expanded Amsler Grid book GL Tangent screen 22.5-degree one meter roll-up	
94.	M/s Haji S. Ameer Din & Sons 305-A Upper Mall Lahore. (ELI-00059) Fee-5,000/- 2021 submission	Legal Manufacturer: HEINE Optotechnik GmbH & Co. KG. (Dornierstr 6, 82205 Gilching, Germany) FSC: Germany 22-06-2020	HEINE LARYNGOSCOPES Class-A Service Life: 7 years Models: Classic+ macintosh Flex tip+ macintosh	Approved HEINE LARYNGOSCOPE S Classic+ macintosh subject to valid original FSC. Firm will submit separate application for HEINE LARYNGOSCOPE S 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 Switzerland FSC: Switzerland Valid till: 14.06.2022	HAAG-STREIT Diagnostic (Biometer Lenstar LS 900) Class B Shelf life: not mentioned Models: LENSTAR LS 900 Pro (7220096/1009000) LENSTAR LS 900 Pro T-Cone (7220400/1009000)	Approved Biometer Lenstar LS 900 Pro subject to valid original FSC. Firm will submit separate application for LENSTAR LS 900 Pro T-Cone.
96.	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 –	WAXBIO-CERA PARA OSSO Bone Wax-Wax Bio Sterile Surgical Hemostates Sticks or Tablets containing 2.5g, 3.0g and 5.0g	Deferred for submission of FSC of RRA/CE marking certificate/WHO pre-qualification.

		GO Brazil	Class C Shelf life: 05 Years	
97.	Name Cardio Life Address of Importer House No. 534, Ground Floor Lane 1, Main Khayaban e Tanveer, Scheme 3 Rawalpindi (ELI-00984)	<u>Legal Manufacturer</u> 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 between 1MM and 5 MM in width and 40cm to 120cm in length	Deferred for submission of FSC of RRA/CE marking certificate/WHO pre-qualification.
98.	M/s. F.W DISTRIBUTOR S, F.w building, opposite Poonch house, Adamjee road, saddar, Rawalpindi. <u>ELI:00221.</u>	<u>Legal Manufacturer:</u> CERACARTA SPA located at VIA SECONDO CASADEI N*14, Z.I. VILLA SELVA, 47122 FORLI (FC), ITALY CERACARTA S.p.A. Sede Legale e Operativa Via Secondo Casadei 47122 Forlì Italy FSC: ITALY Validity: Indefinite period LOA Validity: indefinite period	TOP TRACE® ECG ELECTRODE Class A Claimed Shelf Life: 03 years <u>Codes / Sizes:</u> ST 50 RFI ST 50 RLI RT 50 RFI NP 30 RFI	Rejected the case because firm has; Submitted Free Sale Declaration issued by the manufacturer himself. 2. not submitted prescribed fee for the family.
99.	AA Traders, P-871-B Basement Chen One	<u>Legal Manufacturer:</u> Sejoy Biomedical Co.,	Sejoy Easy Check	Deffered for;

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

		Validity 30-12-2028 ISO 13485: Validity 28-05-2025		applications.
102.	Opti Med, 2nd Floor Hassan Plaza 6A Jail Road lahore 54000 Pakistan. ELI-00501	<u>Legal Manufacturer:</u> 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) Silicon sleeve (12355, 12356)	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.
103.	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.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 0568076152 Dated: 24-03-2025</p>	<p>Name of Manufacturer:</p> <p>medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site:</p> <p>Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity:</p> <p>31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity:</p> <p>08-10-2024</p>	<p>Brand name:</p> <p>Y Connector Set</p> <p>Generic Name: Hemostatic Valve and Accessories</p> <p>Class-A</p> <p>Shelf life: 03 years</p> <p>Models/ Specification</p> <p>9822900120 9822905120 9822910110 9822910120 9822915110 9822915120 9822915150 9822903120 9822908120 9822913120 9822904120 9822909120 9822914120 9822900100 9822900150 9822916110 9822916150 9822900112 9822900116 9822900122 9822900126 9822900156 9822901122 9822901152</p>	<p>Deferred the case for clarification that;</p> <p>1. manufacturing site not mentioned on ISO and FSC.</p> <p>2. justification for applying all codes as single.</p> <p>3. As per all submitted documents manufacturer is "medK GmbH, Borkstrasse 10, 48163 Muenster, Germany"</p>
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105.	Applicant Name: 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: 6,000/- Fee Challan No: 9757711310 Dated: 25-03-2025	Name of Manufacturer: 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:	Brand name: Y-PTCA Connector Generic Name: Hemostatic Valve Class-A Shelf life: 03 years Models/ Specification: Tuohy Borst Y PTCA Connector, sterile Push Rotate Y PTCA Connector, sterile Push Click Y PTCA Connector, sterile Push Pull Y PTCA Connector, sterile Tuohy Borst Y PTCA Connector, with 25 cm Extension line and STP 45 psi, sterile Push Click Y PTCA Connector, with 25 cm Extension line and STP 45	Deferred the case 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

		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 Push Pull Y PTCA Connector, with 50 cm Extension line and STP 45 psi, sterile Tuohy Borst Y PTCA Connector, with 50cm Extension line and STP 45 psi, Sterile Push Rotate Y Connector with 50 cm Extension line and STP 45 psi, sterile Push Click Y PTCA Connector, with 50 cm Extension line and STP 45 psi, sterile Tuohy Borst Y PTCA Connector, with 50 cm Extension line and MP STP 500 psi, sterile Push Rotate Y connector with 50 cm Extension line and MP STP 500 psi, sterile Push Click Y PTCA Connector, with 50 cm Extension line and MP STP 500 psi, sterile	
106.	Applicant Name: 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	Legal Manufacturer: 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	Introducer set Vascular catheter Introduction Set Class-B Shelf life: 3 Years Models/ Specification: Introducer Set, 5 Fr, 90 cm Sheath / 970 mm Dilator / 18 g x 7 cm Needle, sterile Introducer Set, 5 Fr, 11 cm Sheath / 169 mm Dilator /	Deferred the case 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,

	Fee Details: Paid Fee: 31,000/- Fee Challan No: 0882246092 Dated: 25-03-2025	LOA Validity: 31-12-2025 FSC: Germany Issue date: 27-06-2024 ISO Validity: 08-10-2024 EC Certificate Validity: 08-10-2023	0.038" x 45 cm Guide Wire / 18g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 6 Fr, 11 cm Sheath / 169 mm Dilator / 0.038" x 45 cm Guide Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 7 Fr, 11 cm Sheath / 169 mm Dilator / 0.038" x 45 cm Guide Wire / 18 g x 7 cm Clear Arterial Needle without Wings, sterile Introducer Set, 6 Fr, 11 cm Sheath / 169 mm Dilator/ 0.035 ^ prime prime *45 cm Gulde Wire / 18 g x 7 cm Dear Arterial Needle 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 prime *45 cm Guide Wire/21 g 1x4 cm Arterial Needle, sterile Radial Introducer Set, 6 Fr, 11 cm Sheath/169 mm Dilator/ 0.021^ prime prime * 45c Guide Wire/21 g 1x4 cm Arterial Needle, sterile	Borkstrasse 10, 48163 Muenster, Germany". 4. Brand name
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			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	
107.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details:</p> <p>Paid Fee: 31,000/-</p> <p>Fee Challan No: 20130269101 Dated: 25-03-2025</p>	<p>Legal Manufacturer:</p> <p>medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site:</p> <p>Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity:</p> <p>31-12-2025</p> <p>FSC: Germany</p> <p>Issue date: 27-06-2024</p> <p>ISO Validity:</p> <p>08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>Manifold Sets Manifold Sets (Fluid Transfer set general purpose)</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: Manifold Set, 3 Port, Right, ON, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, OFF, 500 psi / Control Syringe 12 ml RA / 180cm Vented Spike Line/180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>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</p> <p>Manifold Set, 3 Port, Right, ON, 500 psi / Control Syringe 12 ml LL / 180cm Vented Spike Line/180cm Vented Drip Chamber Line / 120cm Pressure</p>	<p>Deferred the case for clarification that;</p> <ol style="list-style-type: none"> 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

			<p>Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, ON, 500 psl / 180cm Vented Spike Line / 180cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>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</p> <p>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</p> <p>Manifold Set, 3 Port, Right, ON, 500 psi / 275cm Vented Spike Line/275cm Vented Drip Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, OFF, 500 psi / 275cm Vented Spike Line/275cm Vented Drip</p> <p>Chamber Line/120cm Pressure Monitoring Line 500 psi, sterile</p> <p>Manifold Set, 3 Port, Right, OFF, Green - Soft, 500 psi / Control Syringe 10 ml, Palm Pad/Finger Plate,</p>	
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			LL/180cm Vented Spike Line/180cm Vented Drip Chamber Line /120cm Pressure Monitoring Line 500 psi, sterile	
108.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details:</p> <p>Paid Fee: 31,000/-</p> <p>Fee Challan No: 808860841718 Dated: 25-03-2025</p>	<p>Legal Manufacturer:</p> <p>medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site:</p> <p>Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity:</p> <p>31-12-2025</p> <p>FSC: Germany</p> <p>Issue date: 27-06-2024</p> <p>ISO Validity:</p> <p>08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>Manifold (Non-active devices for anesthesia, emergency and intensive care)</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: HP Manifold, 3 Port, Right, OFF, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, ON, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, OFF, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, ON, Blue - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, OFF, Green - Soft, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, OFF, White, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Right, ON, Blue, with Extension Line, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Left,</p>	<p>Deferred the case for clarification that;</p> <p>1. manufacturing site not mentioned on ISO and FSC.</p> <p>2. justification for applying various types in single.</p> <p>3. As per all submitted documents manufacturer is "medK GmbH, Borkstrasse 10, 48163 Muenster, Germany".</p> <p>4. Brand name</p>

			<p>ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 3 Port, Left, OFF, White, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 2 Port, Right, OFF, White, RA, 500 psi, sterile</p> <p>HP Manifold, 4 Port, Right, ON, Blue, RA, 500 psi, sterile</p> <p>HP Manifold, 4 Port, Right, OFF, White, RA, 500 psi, sterile</p>	
109.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details:</p> <p>Paid Fee: 31,000/-</p> <p>Fee Challan No: 5822621260 Dated: 25-03-2025</p>	<p>Legal Manufacturer:</p> <p>medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site:</p> <p>Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity:</p> <p>31-12-2025</p> <p>FSC: Germany</p> <p>Issue date: 27-06-2024</p> <p>ISO Validity:</p> <p>08-10-2024</p>	<p>Pressure Monitoring Line Pressure Monitoring Line</p> <p>Class-B</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification: Pressure Monitoring Line, 30 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 60 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 90 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p> <p>Pressure Monitoring Line, 120 cm, DEHP free PVC, 500 psi, Male/Female LL, sterile</p>	<p>Deferred the case for clarification that;</p> <ol style="list-style-type: none"> 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

		EC Certificate Validity: 08-10-2023	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	
110.	<p>Applicant Name:</p> <p>Global Biotech Medical Devices (Private) Limited, First Floor, Plot No. 34-N/3, PECHS Block-6, Near Rohail Khund Society, Karachi</p> <p>ELI-01292</p> <p>Date of R&I 07-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 16400565854 Dated: 25-03-2025</p>	<p>Legal Manufacturer: medK GmbH, Borkstrasse 10, 48163 Muenster, Germany</p> <p>Manufacturing Site: Shanghai Kindly Medical Instruments Co., Ltd., No. 925, Jin Yuan Yi Road, Jiading District, 201803, Shanghai, China</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Germany Issue date: 27-06-2024</p> <p>ISO Validity: 08-10-2024</p> <p>EC Certificate Validity: 08-10-2023</p>	<p>High Pressure Extension lines Class-B Shelf life: 3 Years</p> <p>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, 30 cm, PUR braided, 1200 psi, RA, sterile High Pressure Extension Line, 60 cm, PUR braided, 1200 psi, RA, sterile High Pressure Extension Line, 90 cm, PUR braided, 1200 psi, RA, sterile</p>	<p>Deferred the case for clarification that;</p> <ol style="list-style-type: none"> 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

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

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

	(ELI-01292) R&I date: 18-03-2025 Fee Rs 62000/- vide Challan no. 71044293	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 ISO Certificate)	Shelf life: 6 Years Codes/Sizes as per FSC	
115.	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. 667274866	<u>Legal Manufacturer:</u> 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 ISO Certificate)	Optimus CoCr Stent Class: D Shelf life: 6 Years Codes/Sizes as per FSC	Deffered for issuance of show cause notice/personal hearing to M/s SES Associates
116.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND	<u>Legal Manufacturer:</u> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany	Optimus-CVS PTFE- Covered Stent Class: D	Deffered for issuance of show cause notice/personal hearing to M/s SES Associates

	<p>SOCIETY KARACHI (ELI-01292)</p> <p>R&I date: 18-03-2025</p> <p>Fee Rs 62000/- vide Challan no. 276311473</p>	<p>LOA/sole agency :09-06-2025 (copy of LOA)</p> <p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Shelf life: 6 Years</p> <p>Codes/Sizes as per FSC</p>	
117.	<p>Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.</p> <p>ELI-00673 62,000/-</p>	<p><u>Legal Manufacturer:</u> 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.</p> <p>Original FSC: Korea Date of Issuance: 30-08-2024.</p> <p>LOA validity 18-12-2029 ISO 13485 validity 29-03-2026</p>	<p>EXTRA I</p> <p>Sterile Absorbable Hyaluronic Acid Dermal Filler</p> <p>Class-D</p> <p>Shelf Life: 30 Months</p> <p>Model/ codes as per FSC.</p>	Approved.
118.	<p>Amson Vaccines & Pharma (Pvt) Ltd, 115 Industrial Triangle Kahuta Road Islamabad.</p> <p>ELI-00673 62,000/-</p>	<p><u>Legal Manufacturer:</u> 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.</p> <p>Original FSC: Korea Date of Issuance: 30-08-2024.</p> <p>LOA validity 18-12-2029</p>	<p>EXTRA II</p> <p>Sterile Absorbable Hyaluronic Acid Dermal Filler</p> <p>Class-D</p> <p>Shelf Life: 30 Months</p> <p>Model/ codes as per FSC.</p>	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	EXTRA III Sterile Absorbable Hyaluronic Acid Dermal Filler Class-D Shelf Life: 30 Months Model/ codes as per FSC.	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 Bazar Peshawar ELI-00686 Date of R& I 19-05-2025 Fee: Rs.31000/ through slip no. 09271620709 and Rs. 31000 70206399529	<u>Legal Manufacturer:</u> M/s Gemss Healthcare Co., Ltd., 822 Bogwang-Ro, Gwangtan-myeon, Paju-Si Gyeonggi-Do, 10952 Korea LOA: Valid till: 31-12-2030 FSC: Validity: ISO - Validity Date: 22-01-2026 EC Certificate Valid till: 05-06-2024	GEMSS Stationary X-Ray System XVision-525 Digital X-Ray Machine Applied as: Single Class-C Shelf Life: Model: XVision-525	Approved subject to FSC
123.	M/s Medco, 19-Khyber Bazar Peshawar ELI-00686 Date of R& I 19-05-2025 Fee: Rs.50000/ through slip no. 20521777101 and Rs. 62000 7607854166	<u>Legal Manufacturer:</u> M/s Gemss Healthcare Co., Ltd., 822 Bogwang-Ro, Gwangtan-myeon, Paju-Si Gyeonggi-Do, 10952 Korea LOA: Valid till: 31-12-2030 FSC: Validity: Not provided ISO - Validity Date: 22-01-2026 EC Certificate Valid till: 05-06-2024	GEMSS Image Intensified Fluoroscopic X-Ray System (Mobile C-Arm) Class-C Shelf Life: Code/sizes: XPLUS 35 XPLUS 35FD	Approved Subject To FSC

124.	Applicant Name: M/s Medco, 19-Kyber Bazar, Peshawar ELI-00686 Date of R&I 19-05-2025 Fee Details: Paid Fee: 50,000/- Fee Challan No: 7170434627	Legal Manufacturer: M/s Ecotron Co. Ltd., 505Ho, Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-gu, Seoul, 08511, Korea. LOA Validity: 14-05-2029 ISO Validity: 18-02-2028 EC Certificate Validity: N/A	Ecotron Image Intensified Fluoroscopic X-Ray System (Mobile C-Arm) Anyview Series Anyview 500DR, Anyview 500R, Anyview 240DR & Anyview 320DR Mobile C-Arm Class-B Shelf life: 10 Years Models/specifications: Anyview 500DR, Anyview 500R, Anyview 240DR Anyview 320DR	Approved with following codes 500DR & 500R
125.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 09549959	Name of Manufacturer: 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	Brand name: EDTA K3 Blood Collection Tube Glass Generic Name: EDTA K3 Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	Approved.

		Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025		
126.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 8114812075	Name of Manufacturer: 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	Brand name: Clot Activator/Separate Gel Blood Collection Tube Glass Generic Name: Gel + Clot Activator Vaccum Blood Collection Tube Class: A Codes/Sizes: 3ml, 4ml, 5ml, 6ml, 7ml, 8ml Applied as: Family Shelf life: Not mentioned	Approved.
127.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225)	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co., Ltd., No. 39, Anye Road Gaoqiao Street Huangyan Taizhou Zhejiang, China. • LOA	Brand name: Sodium Citrate Collection Tube PET Generic Name: Sodium Citrate Collection	Approved.

	R&I detail 15-05-2025 Fee: 25,000/- Slip: 3201664	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	Tube Class: A Codes/Sizes: 1.28ml, 4.5ml, 1.6ml, 2.4ml, 2.7ml, 3.6ml, 1.8ml, 3.2ml Applied as: Family Shelf life: Not mentioned	
128.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 307968530145	Name of Manufacturer: 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	Brand name: Clot Activator/Separate Gel Blood Collection Tube PET Generic Name: Gel + Clot Activator Vaccum Blood Collection Tube Class: A Codes/Sizes: 3ml, 4ml, 5ml, 6ml, 7ml, 8ml Applied as: Family Shelf life: Not mentioned	Approved.

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

	Fee: 25,000/- Slip: 6492402841	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	Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	
131.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 473945571799	Name of Manufacturer: 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	Brand name: EDTA K2 Blood Collection Tube Glass Generic Name: EDTA K2 Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml, Applied as: Family Shelf life: Not mentioned	Approved.

		Validity: 26-10-2025		
132.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 52154302796	Name of Manufacturer: 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	Brand name: Clot Activator Blood Collection Tube PET Generic Name: Clot Activator Vaccum Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml Applied as: Family Shelf life: Not mentioned	Approved.
133.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 33112274401	Name of Manufacturer: 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	Brand name: Heparin/Sodium Fluoride Blood Collection Tube PET Generic Name: Heparin/Sodium Fluoride Blood Collection Tube Class: A Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml	Approved.

		Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025 • ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025	Applied as: Family Shelf life: Not mentioned	
134.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III, Lahore. (ELI- 01225) R&I detail 15-05-2025 Fee: 25,000/- Slip: 59504524272	Name of Manufacturer: 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	Brand name: 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	Approved.
135.	M/s. Biocept Intl., Co., Office No. 28-29, /E1, Old FCC Guberg III,	Name of Manufacturer: M/s. Zhejiang SKG Medical Technology Co.,	Brand name: Clot Activator Blood	Approved.

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

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

	<p>(ELI- 01225)</p> <p>R&I detail 15-05-2025 Fee: 25,000/- Slip: 397625294105</p>	<p>• LOA Type: Copy Notarization: Not notarized. Validity: 22-03-2027</p> <p>• FSC Type: Copy Issued By: Govt. Body Legalization: Not legalized Validity: 28-12-2025</p> <p>• ISO Certificate Type: Original Notarization: Not notarized Validity: 26-10-2025</p>	<p>EDTA K3 Vaccum Blood Collection Tube</p> <p>Class: A</p> <p>Codes/Sizes: 2ml, 3ml, 4ml, 5ml, 6ml, 7ml, 8ml, 9ml, 10ml,</p> <p>Applied as: Family</p> <p>Shelf life: Not mentioned</p>	
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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.	<p>NISA.SF Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura ELM-0001</p>	<p>BM Disposable Heparin Cap (Heparin Cap) Class: B Shelf-life: 5 Years Sizes: Connector: Male Luer Lock Connector Color: Yellow and transparent Length: 18mm 19.32mm 22mm Fee of 20,000 vide Challan No. 07486207625</p>	<p>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.</p>
2.	<p>NISA.SF Private Limited.</p>	<p>Dosiflow Plus</p>	<p>The Board decided to</p>

	10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura 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) Fee of 20,000 vide Challan No. 48643085	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. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura ELM-0001	HP Disposable Stopcock 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	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.
4.	NISA.SF Private Limited. 10-Km, Muridke, Sheikhpura Road, Muridke, Distt. Sheikhpura 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 No. 11296827	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	BM Disposable Breathing	The Board decided to

	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

	Phase II, G.T Road, Islamabad (ELM-0001) [712-7L] Feb-2025	Shelf Life: 5 Year Fee: 25000 Fee Slip No. 89224587	manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
10.	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) [713-7L] Feb-2025	BM Disposable Breathing Circuit Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 933019586	The Board decided to inspect by the panel of manufacturing and testing facilities for the applied product under aseptic conditions to maintain the sterility of the product in the packing area.
11.	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) [714-7L] Feb-2025	BM Disposable Enteral Feeding Class: B Shelf Life: 5 Year Fee: 25000 Fee Slip No. 65267853330	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.

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 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 (Heparin Cap) Class: B Shelf-life: 5 Years Sizes: Connector: Male Luer Lock Connector Color: Yellow and transparent Length: 18mm, 19.32mm, 22mm Fee of 20,000 vide Challan No. 07486207625	Rejected the case as panel informed that firm don't have the facility for assembly & packing.
2	Dosiflow Plus Disposable flow regulator Extension Line Class: B Shelf-life: 3 Years 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) Fee of 20,000 vide Challan No. 48643085	Approved Dosiflow Plus Disposable flow regulator Extension Line as per recommendations of the panel.
3	HP Disposable Stopcock with Extension Tube Stopcock Extension Tube (1 Way, 2 Way, 3 Way & 4 Way) Class: B Shelf-life: 5 Years Length: 10cm, 15cm, 20cm, 25cm, 50cm, 100cm Fee of 20,000 vide Challan No. 51757256	Approved as per panel recommendation subject to fee verification for family.
4	Super Stopper Disposable Stopcock with Extension Tube Stopcock Extension Tube Class: B	Approved Super Stopper Disposable Stopcock with Extension Tube Stopcock Extension Tube as per panel recommendations subject to fee

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

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

1.	Hospital Solutions 174-E, Block-2, PECHS Karachi (ELI-00250)	<p>Surgaid Medical (Xiamen) Co., Ltd.</p> <p>Building 5, No. 18, Shan Bia Nhong east Road, haicang District, 36 1026, Xiamen Fujian PR China.</p> <p>Sites Address as per FSC: Room No. 5602, Building 5, No. 18, Shan Bia Nhong East Road, Haicang District, Xiamen city, Fujian province, PR China.</p> <p>1F Room No. 5101,5102, and 5104), 2F,3F,5F (Room 5502),: Room 102, No. 18, Housxiang Road, Xiamen city, Fujian province 361026, PR China. Zone A, 3rd Floor, No.17-2, Hutou Road, Haicang District, Xiamen city, Fujian province, PR China.</p>	<p>Disposable Laparoscopic Trocar</p> <p>Class-B</p> <p>Sizes/codes: NPVS-100-1-5, NPVS-100-1-10, NPVS-100-1-12, NPCS-100-1-5, NPCS-100-1-10, NPCS-100-1-12, NPCS-100-1-15, NPCS-100-2-A, NPCS-100-2-B, NTCS-100-1-5, NTCS-100-1-10, NTCS-100-1-12.</p>	<p>The product was deferred in 86th meeting for provision of Valid FSC, LoA, copy of Application form & fee slip.</p> <p>Now the firm has submitted the following documents.</p> <ol style="list-style-type: none"> 1. Copy of Letter of Authorization. 2. valid Free Sale Certificate. 3. Copy of CE Certificate with extension letter 4. Copy of Challan Fee Slip vide No. 1011760802 dated 31-10-2024 (Fee: Rs. 31000/-) 5. Clinical Evaluation Report 6. Scan copy of Form-7A 	<p>Decision:</p> <p>Approved with the site as mentioned in the FSC.</p>
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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 77th 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.	<p>M/s Global Biotech 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: 02386055134 PKR 62000/- Dated: 26-11-2024</p>	<p>Legal 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: 03-07-2026 CFG USA Dated 14-12-2018.</p>	<p>Brand: Xcess Guiding Catheter Generic: Guiding 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 validity: 31-07-2026</p>	Approved
2.	<p>M/s Global Biotech 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/- Dated: 26-11-2024</p>	<p>Legal 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: 03-07-2026 CFG USA</p>	<p>Brand: 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 validity: 31-07-2026</p>	Approved

		Dated 14-12-2018.		
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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 House No. CB-708, Lane No 5, 1st Floor, Peshawar Road Rawalpindi	M/s. Curatia Medical Limited 198 Xiangjiang Road, New District, Suzhou 215011, China	URSA Angiographic Catheter	MDIR-0000443
M/s Al Waali Care Concepts 86-Allama Iqbal Road, Chah Baba Shadiwal Street, Garhi Shahu, District Lahore	M/s Curatia Medical Limited 198 Xiangjiang Road New District, Suzhou, Jiangsu, China, 215011	Xcess Guiding Catheter	MDIR-0001719
M/s Al Waali Care Concepts 86-Allama Iqbal Road, Chah Baba Shadiwal Street, Garhi Shahu, District Lahore	M/s Curatia Medical Limited 198 Xiangjiang Road New District, Suzhou, Jiangsu, China, 215011	Vela RX PTA Balloon Dilatation Catheter	MDIR-0003128

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

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
SBK International, 23, Valley Road, Street 3, Westridge 1, Rawalpindi. ELI-00100	<p><u>Legal Manufacturer:</u></p> <p>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</p> <p><u>Manufacturing Site:</u></p> <p>SITE 1: 138, GUANPU ROAD, FUZHOU, FUJIAN, CHINA SITE 2: S2# & S3# BUILDING, MEDICAL DEVICE INDUSTRIAL PARK, INDUSTRIAL NEW ZONE, NO 66 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN PROVINCE, CHINA</p> <p>LOA Validity: 31-12-2028 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</p>	<p>Medibell IV Cannula with Wings (Straight Type) IV Cannula with Wings (Straight Type) Class B Shelf Life: 05 Years Codes / Sizes:</p> <ol style="list-style-type: none"> 1. 10Gx48mm 2. 12Gx48mm 3. 14Gx140mm 4. 14Gx52mm 5. 14Gx50mm 6. 14Gx48mm 7. 14Gx45mm 8. 14Gx32mm 9. 16Gx140mm 10. 16Gx52mm 11. 16Gx50mm 12. 16Gx48mm 13. 16Gx45mm 14. 16Gx32mm 15. 18Gx52mm 16. 18Gx50mm 17. 18Gx48mm 18. 18Gx45mm 19. 18Gx33mm 20. 18Gx32mm 21. 18Gx30mm 	Approved subject to submission of requisite Fee as per SRO 1324(I)/2024 dated 30 th August, 2024.

		22. 18Gx25mm 23. 20Gx52mm 24. 20Gx50mm 25. 20Gx48mm 26. 20Gx45mm 27. 20Gx33mm 28. 20Gx32mm 29. 20Gx30mm 30. 20Gx25mm 31. 22Gx32mm 32. 22Gx25mm 33. 22Gx19mm 34. 24Gx19mm 35. 26Gx19mm 36. 26Gx12.7mm	
SBK International, 23, Valley Road, Street 3, Westridge 1, Rawalpindi. ELI-00100	<p><u>Legal Manufacturer:</u></p> <p>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</p> <p><u>Manufacturing Site:</u></p> <p>SITE 1: 138, GUANPU ROAD, FUZHOU, FUJIAN, CHINA SITE 2: S2# & S3# BUILDING, MEDICAL DEVICE INDUSTRIAL PARK, INDUSTRIAL NEW ZONE, NO 66 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN PROVINCE, CHINA</p> <p>LOA Validity: 31-12-2028 FSC: Country of Origin Validity: 29-12-2025 EC Certificate Validity: 26-10-</p>	Medibell IV Cannula Pen Type IV Cannula Pen 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 11. 16Gx50mm	Approved subject to submission of requisite Fee as per SRO 1324(I)/2024 dated 30 th August, 2024.

	2023 Extended till 31-12-2028 (letter attached) ISO 13485 Validity: 26-10-2027	12. 16Gx48mm 13. 16Gx45mm 14. 16Gx32mm 15. 18Gx52mm 16. 18Gx50mm 17. 18Gx48mm 18. 18Gx45mm 19. 18Gx33mm 20. 18Gx32mm 21. 18Gx30mm 22. 18Gx25mm 23. 20Gx52mm 24. 20Gx50mm 25. 20Gx48mm 26. 20Gx45mm 27. 20Gx33mm 28. 20Gx32mm 29. 20Gx30mm 30. 20Gx25mm 31. 22Gx32mm 32. 22Gx25mm 33. 22Gx19mm 34. 24Gx19mm 35. 26Gx19mm 36. 26Gx12.7mm	
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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 77th meeting of MDB as per following details:

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

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
1	<p>Brand name:Carbosol-PLUS Haemodialysis Concentrate Generic: Bicarbonate Haemodialysis Concentrate Composition: <u>Part A (as per B.P/E.P)</u> 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 <u>Part B (as per B.P/E.P)</u> Sodium: NMT45m.mol Bicarbonate: NMT45m.mol</p> <p>Sizes: Part A and Part B</p> <ul style="list-style-type: none"> • For one dialysis session. • For two dialysis sessions. • For seven dialysis sessions.
2	<p>Brand name: Citrosol Hemodialysis Concentrate Generic: Bicarbonate Haemodialysis Concentrate Composition: <u>Part A</u> 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</p>

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 <ul style="list-style-type: none"> • 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 to 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	Product Details	Remarks	Decision
1.	Shanghai Shape Memory Alloy Co., Ltd Located at 1F and 5F, Tower 41, No. 258, Xinzhuang Road, Songjiang High Tech Park, Caohejing Development District, Shanghai 201612, China	MemoPart™ Ventricular Septal Defect (VSD) Occluder MemoPart™ Occluder System	<i>It is submitted that the subject device is registered for Intek Corporation, #517, Kohistan Tower, Mehfooz Road, opposite AFIC Saddar Rawalpindi. Now, the product has been transferred by the Legal manufacturer from Intek Corporation, #517, Kohistan Tower, Mehfooz Road, opposite</i>	<i>The board decided to give personal hearing to both the firms. (M-72)</i>

			AFIC Saddar Rawalpindi to Intek Corporation Pvt, Ltd. Office # 501-502, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000 with new agreement. M/s Intek Corporation, #517, Kohistan Tower, Mehfooz Road, opposite AFIC Saddar Rawalpindi also applied for deregistration of the subject device.	
2.	Shanghai Shape Memory Alloy Co., Ltd Located at 1F and 5F, Tower 41, No. 258, Xinzhuang Road, Songjiang High Tech Park, Caohejing Development District, Shanghai 201612, China	MemoPart™ Occluder Delivery System MemoPart™ Delivery System	-do-	The board decided to give personal hearing to both the firms. (M-72)
3.	Shanghai Shape Memory Alloy Co., Ltd Located at 1F and 5F, Tower 41, No. 258, Xinzhuang Road, Songjiang High Tech Park, Caohejing Development District, Shanghai 201612, China	MemoPart™ Ventricular Septal Defect (VSD) Occluder MemoPart™ Occluder System	-do-	The board decided to give personal hearing to both the firms. (M-72)
4.	Shanghai Shape Memory Alloy Co., Ltd Located at: 1F and 5F, Tower 41, No. 258, Xinzhuang Road, Songjiang High Tech Park, Caohejing Development District, Shanghai 201612, China.	MemoPart™ ASD Occluder is a percutaneous, transcatheter device applied to the closure of atrial septal defects (ASD). It is also available for the patient who require a closure of fenestrated Fontan.	-do-	The board decided to give personal hearing to both the firms. (M-72)
5.	Occlutech GmbH Located at Winzerlaer Straße 2, 07745 Jena, Germany	Figulla Flex II ASD Arterial Septal Defect Closure device	-do-	The board decided to give personal hearing to both the firms. (M-72)
6.	Legal Manufacturer: OrbusNeich Medical B.V., Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands. Manufacturing sites: OrbusNeich Medical B.V., Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands. and OrbusNeich Medical Co.,	Teleport (Micro Catheter)	It is submitted that the subject device is registered for Intek Corporation, #517, Kohistan Towers, Mehfooz Road, opposite AFIC Saddar Rawalpindi. Now, the product has been transferred by the Legal manufacturer from Intek Corporation, #517, Kohistan Towers, Mehfooz Road, opposite AFIC Saddar	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

	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)	-do-	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.	<u>Legal Manufacturer:</u> 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)

			agreement. M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi also applied for deregistration of the subject device.	
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	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, <u>(Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall,</u> 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, Edificio 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, <u>(Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall,</u> Rawalpindi. <u>ELI-00794</u>	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, Edificio B33, Zona Franca Coyol, Alajuela, Costa Rica.	Headway 27 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, <u>(Pvt) Ltd., Office No. 501, Kohistan tower, Opp AFIC, The Mall,</u> Rawalpindi. <u>ELI-00794</u>	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)
12.	Manufacturer:	Headway Duo	Approved.	The board decided to call

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

	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 Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi ELI-00203 Renewal application: MDIR-0000504 R & I dated: 29-07-2024 Fee submitted 25,000/- 33135598297 Differential fee 32,400/- 772190565964	<u>Legal Manufacturer:</u> 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 31-01-2028.	Cocoon PFO Occluder Accessory Set (PFO Occluder Delivery System) Class D Shelf Life: 3 years Codes: CPF8F CPF9F	Deferred for submission of; 1. Original documents. 2. Differential fee. 3. valid Design Examination
2.	M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi ELI-00203 Renewal application	<u>Legal Manufacturer:</u> M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand. Attested copy of FSC of	Cocoon VSD Occluder Accessory Set II (VSD Occluder Delivery System) Class D Shelf Life: 3 years	Deferred for submission of; 1. Original documents. 2. Differential fee. 3. valid Design Examination

	MDIR-0000505 R&I date: 29-07-2024 Fee Submitted 25,00/- 3683101218 Differential fee 32,4000/- 531162153878	Thailand valid till 04-07-2026. FSC of MHRA without legalization valid till 31-01-2028.	Codes: COV116F COV117F	
3.	M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi ELI-00203 Renewal application MDIR-0000506 R&I date: 29-07-2024 Fee Submitted 25,00/- 320968988 Differential fee 32,4000/- 07414530375	<u>Legal Manufacturer:</u> 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 31-01-2028.	Cocoon Duct Occluder Accessory Set (PDA Occluder Delivery System) Class D Shelf Life: 3 years Codes: COP6F COP7F COP8F COP9F	Deferred for submission of; 1. Original documents. 2. Differential fee. 3. valid Design Examination
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	<u>Legal Manufacturer:</u> 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 Differential fee 32,4000/- 72535025	01-2028.	COA12F COA14F	
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The meeting ended with vote of thanks from and to the Chair.

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