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

<u>DECISIONS OF 101ST MEETING OF THE MEDICAL DEVICE BOARD (MDB)</u> HELD ON 25-09-2025 (MANUAL APPLICATIONS AGENDA PART-II)

101ST 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 25th September, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

	Name and Designation/Department	Position in the MDB
S.No.	, G	(*O) U.S.
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Prof Dr Saqib Shafi Sheikh, Interventional	Member
	Cardiologist, 98 Babar block, New Garden Town, Lahore	(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	Member
	Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	(attended meeting through videolink)
5.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member
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.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)
9.	Ms. Tazeen Saeed Bukhari, Biomedical	Co-Opted Expert
10	Engineer	(attended meeting through videolink)
10.	Mr. Ayyaz Ahmad, 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. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX
9.	Mr. Ammar Ashraf Awan	Deputy Director-X

AGENDA FOR DEFERRED CASES OF IMPORT

Evaluator: Ahsan-ul-Haq Athar, Deputy Director-VIII

S#	Importer Name	Manufacturer Details	Name of MD / Class /	Decision
		, our	Codes / Shelf life /	
1	M 1: 0 : .:C	M/ TD:1	etc.	D: (11 :
1.	Muslim Scientific	M/s Taidoc	Clever Chek	Rejected due to following reasons:
	Corporation	Technology	Glucometer TD-4255	1. Brand Name of product applied is
	Address:- 3,Syed	Corporation, B1-7F,	Glucometer	different in application form, free
	Moj Darya Road	No. 127, Wugong 2 nd	A	sale certificate of Germany and in
	Lahore	Road Wugu District,	Applied as: Single	authorization letter and the firm has
		New Taipei City,	Class-C	also not provided any clarification/
	(ELI-00431)	Taiwan 248.	Class-C	justification in this regard.
			Shelf life: 7 years	
	Date of R& I	LOA :-	Shell life. / years	2. Clarification/ justification not
	11-04-2025	validity:09/03/2026	Models: -TD-4255	provided as the product is applied as
	Fee: PKR 62,000/-	(copy)	Wiodels1D-4255	single while in free sale certificate,
	Slip# 0583362272		111 1111	product is mentioned as system.
		FSC (Germany) issued	00,, 17,	3. differential fee for the system. Not
		on 04-03-2024 wherein	000	submitted.
		the product (TD-	C. C.	
		4255) is mentioned as	1.480, 120	
		Blood Glucose		
		Monitoring System.	A 100.	
		(Copy)	*Ob	
		1610	C	
		ISO Certificate: 01-03-	7	
		2026 (Copy)		
		EC Certificate (FQA):		
		26-05-2025 (Copy)		
2.	Muslim Scientific	M/s Taidoc	Clever Chek	Rejected due to following reasons:
	Corporation	Technology	Glucometer Strips	1. Brand Name of product applied is
	Address:- 3,Syed	Corporation, B1-7F,	TD-4255	different in application form, free
	Moj Darya Road	No. 127, Wugong 2 nd		sale certificate of Germany and in
	Lahore	Road Wugu District,	Glucometer Strips	authorization letter and the firm has

	(ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#30741466086	New Taipei City, Taiwan 248. LOA:- validity:09/03/2026 (copy) FSC (Germany) issued on 04-03-2024 wherein the product (TD-	Applied as: Single Class-C Shelf life: Strips:- 25.6 Months Codes/Sizes: Models: -TD-4255	also not provided any clarification/justification in this regard. 2. Clarification/ justification not provided as the product is applied as single while in free sale certificate, product is mentioned as system. 3. differential fee for the system. Not submitted.
2	Muslim Caise C.	4255) is mentioned as Blood Glucose Monitoring System. (Copy) ISO Certificate: 01-03- 2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy)	Osigner, 1055	Deignated due to full production
3.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#6188377559	M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248. LOA: - validity:09/03/2026 (copy) FSC (Germany) issued on 20-01-2025 wherein the product (TD- 4279) is mentioned as Blood Glucose Monitoring System. (Copy) ISO Certificate: 01-03- 2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy)	CC Super Glucometer TD-4279 Glucometer Applied as: Single Class-C Shelf life: Strips: - 7 Years Codes/Sizes: Models:-TD-4279	Rejected due to following reasons: 1. Brand Name of product applied is different in application form and in authorization letter and the firm has also not provided any clarification/justification in this regard. 2. Clarification/ justification not provided as the product is applied as single while in free sale certificate, product is mentioned as system. 3. differential fee for the system. Not submitted.

4.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#69023028107 8	M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248. LOA:- validity:09/03/2026 (copy) FSC (Germany) issued on 20-01-2025 wherein the product (TD- 4279) is mentioned as Blood Glucose Monitoring System. (Copy) ISO Certificate: 01-03- 2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy)	Glucometer Strips Models: -TD-4279 Glucometer Strips Applied as; Single Class-C Shelf life: Strips: - 25.6 Months Models:-TD-4279	Rejected due to following reasons: 1. Brand Name of product applied is different in application form and in authorization letter and the firm has also not provided any clarification/justification in this regard. 2. Clarification/ justification not provided as the product is applied as single while in free sale certificate, product is mentioned as system. 3. differential fee for the system. Not submitted.
5.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#6957780596	M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248. LOA: validity:09/03/2026 (copy) FSC (Germany) issued on 20-01-2025 wherein the product (TD- 4267) is mentioned as Blood Glucose Monitoring System. (Copy) ISO Certificate: 01-03- 2026 (Copy)	CC Fast Glucometer TD-4267 Glucometer Applied as: Single Class-C Shelf life: :- 7 Years Models: -TD-4267	Rejected due to following reasons: 1. Brand Name of product applied is different in application form and in authorization letter and the firm has also not provided any clarification/justification in this regard. 2. Clarification/ justification not provided as the product is applied as single while in free sale certificate, product is mentioned as system. 3. differential fee for the system. Not submitted.

EC Certificate (FQA) 26-05-2025 (Copy)	:	
entific M/s Taidoc Technology ,Syed Corporation, B1-7F, No. 127, Wugong 2 nd Road Wugu District, New Taipei City, Taiwan 248. LOA:- validity:09/03/2026 (copy) FSC (Germany) issued on 20-01-2025 wherei the product (TD-	Class-C	Rejected due to following reasons: 1. Brand Name of product applied is different in application form and in authorization letter and the firm has also not provided any clarification/justification in this regard. 2. Clarification/ justification not provided as the product is applied as single while in free sale certificate, product is mentioned as system. 3. differential fee for the system. Not submitted.
2026 (Copy) EC Certificate (FQA):		, PM
entific M/s Taidoc Technology ,Syed Corporation, B1-7F, Road No. 127, Wugong 2 nd Road Wugu District, New Taipei City, Taiwan 248. I LOA:- validity:09/03/2026	CC Glucometer Strips TD-4225 Glucometer Strips Applied as: Single Class-C Shelf life: Strips: - 25.6 Months Models: -TD-4225	Rejected due to following reasons: 1. Brand Name of product applied is different in application form and in authorization letter and the firm has also not provided any clarification/justification in this regard. 2. Clarification/ justification not provided as the product is applied as single while in free sale certificate, product is mentioned as system. 3. differential fee for the system. Not submitted.
	entific M/s Taidoc Technology ,Syed Corporation, B1-7F, Road No. 127, Wugong 2 nd Road Wugu District, New Taipei City, Taiwan 248. LOA:- validity:09/03/2026 (copy) FSC (Germany) issued on 20-01-2025 wherein the product (TD-4267) is mentioned as Blood Glucose Monitoring System. (Copy) EC Certificate: 01-03 2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy) entific M/s Taidoc Technology ,Syed Corporation, B1-7F, No. 127, Wugong 2 nd Road Wugu District, New Taipei City, Taiwan 248. LOA:- validity:09/03/2026 (copy)	entific M/s Taidoc Technology ,Syed Corporation, B1-7F, Road No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248. I LOA: validity:09/03/2026 (copy) EC Certificate: 01-03- 2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy) EC Certificate (FQA): 26-05-2025 (Copy) EC Certificate (FQA): 26-05-2025 (Copy) Entific M/s Taidoc Technology ,Syed Corporation, B1-7F, Road No. 127, Wugong 2nd Road Wugu District, New Taipei City, Taiwan 248. CC Super Glucometer Strips TD-4267 (as per covering letter & fee slip etc.) Glucometer Applied as: Single Class-C Shelf life: :- 25.6 months Models: -TD-4267 CC Glucometer Applied as: Single Class-C Shelf life: :- 25.6 months CC Glucometer Applied as: Single Class-C Shelf life: :- 25.6 months CC Glucometer Applied as: Single Class-C Shelf life: Strips Applied as: Single Class-C Shelf life: Strips: - 25.6 Months Applied as: Single Class-C Shelf life: Strips: - 25.6 Months Applied as: Single CC Glucometer Strips Applied as: Single CC Glucometer Strips Applied as: Single Class-C Shelf life: Strips: - 25.6 Months

		EC Certificate (FQA): validity 26-05-2025 (Copy)		
8.	Pakistan Hearing Aid Center, 4-5 Fatima Center, 14-A, Queens Road, Lahore. ELI-01271 5685-P	Legal Manufacturer: Sivantos Pte Ltd 18 Tai Seng Street #08- 08 Singapore 539775 FSC: Detmold, Berlin Date of Issuance: 05- 06-2023.	Audio Service Hearing Aids Class-B Shelf Life: N/A	Approved subject to submission of Original valid FSC with new manufacturer name and model/Codes of BTE as per FSC.
9.	Applicant Name: Muslim Medical Services, 1st Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore ELI-00373 Date of R&I 13-02-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 603857485 Dated:	Lgal Manufacturer: Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany LOA Validity: 31-12-2025 FSC: Germany Issue date: 23-01-2025 ISO Validity: 29-11-2026 EC Certificate Validity: 26-05-2024	Beurer Blood Pressure Monitor Class-B Shelf life: Models/specifications: BM 23 BM 27	Approved Beurer Blood Pressure Monitor (BM 23) subject to submission of valid, notarized ISO 13485 certificate.
10.	Applicant Name: Muslim Medical Services, 1st Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore ELI-00373 Date of R&I 13-02-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 603857485 Dated:	Legal Manufacturer: Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany LOA Validity: 31-12-2025 FSC: Germany Issue date: 23-01-2025 ISO Validity: 29-11-2026 EC Certificate Validity: 26-05-2024	Beurer Nebulizer Class-B Shelf life: 7 years Models/specifications: IH 16 IH 51	Approved Beurer Nebulizer (IH 16) subject to submission of valid, notarized ISO 13485 certificate

11.	M/s Elite Traders Office 342-B 1st Floor,B-Block Satellite Town Rawalpindi. ELI-00193	Legal manufacturer: Beijing Chunlizhengda Medical Instruments Co., Ltd No.10 Xinmi West 2nd Road, South Area of Tongzhou Economic Development Zone, Beijing China. Legalized FSC issued by China validity dated 20-03-2024.	Hip Prosthesis System (Acetabular cup) (Liner-58) Class-D Shelf life: 5years Sizes: 35, 37, 39, 41, 44, 48, 52	Rejected due to following reasons; 1. Firm has not submitted DE certificate. 2. Firm has not submitted FSC of the any Reference regulatory authority. 3. Firm has not clarified the brand name of the medical device. 4. The sizes 35, 37, 39 and 41 not mentioned in FQA.
12.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal- e-Haq Road, Blue Area, Islamabad. ELI-00183 1508-Ibd 6,000/-	Legal Manufacturer: Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Humeca Mesher Skin Graft Mesher Class-A Shelf Life: 4 Years Code: 6.HM01	The case was deferred and Medical Device Board decided to give personal hearing to both importers M/s Biowel Sciences and M/s Medic Ally. M/s Biowel Sciences will submit original, notarized LOA and Cancellation letter issued by the manufacturer before personal hearing.
13.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal- e-Haq Road, Blue Area, Islamabad. ELI-00183 1509-Ibd 6,000/-	Legal Manufacturer: Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Meek Micrograft Skin Graft Mesher Class-A Shelf Life: 10 Years Codes: 3.MD 3.HD	The case was deferred and Medical Device Board decided to give personal hearing to both importers M/s Biowel Sciences and M/s Medic Ally. M/s Biowel Sciences will submit original, notarized LOA and Cancellation letter issued by the manufacturer before personal hearing.
14.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal- e-Haq Road, Blue Area, Islamabad. ELI-00183 1510-Ibd 6,000/-	Legal Manufacturer: Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Humeca V-carrier Skin graft carrier Class-A Shelf Life: 4 Years Codes as per FSC	The case was deferred and Medical Device Board decided to give personal hearing to both importers M/s Biowel Sciences and M/s Medic Ally. M/s Biowel Sciences will submit original, notarized LOA and Cancellation letter issued by the manufacturer before personal hearing.

1.7	D: 1 C:	T 137 6 4	MEETZ A 11 '	1
15.	Biowel Sciences,	Legal Manufacturer:	MEEK Adhesive	approved
	Office No. B-9,	Humeca BV	Adhesive for skin	
	Basement, Gulistan	Oostermaat 5, 7623 CS	grafting	
	Khan Plaza, Fazal-	Borne, The		
	e-Haq Road, Blue	Netherlands.	Class-A	
	Area, Islamabad.			
		FSC: Netherlands.	Shelf Life: 4 Years	
	ELI-00183	Validity: 31-12-2028.		
	1511-Ibd	LOA validity 31-12-	Codes:	
	6,000/-	2027	2.9190	5) AB
		ISO 13485 validity 01-		6.6
		07-2026		
16.	Biowel Sciences,	Legal Manufacturer:	Meek Microgratf	approved
	Office No. B-9,	Humeca BV	gauze	1 2
	Basement, Gulistan	Oostermaat 5, 7623 CS	Sterile woven Guaze	
	Khan Plaza, Fazal-	Borne, The	Pad	
	e-Haq Road, Blue	Netherlands.	D. 61,	
	Area, Islamabad.		Class-A	
		FSC: Netherlands.		
	ELI-00183	Validity: 31-12-2028.	Shelf life: 4 years	
	1507-Ibd	LOA validity 31-12-	·	
	6,000/-	2027	Codes:	
	,	ISO 13485 validity 01-	2.2/10, 2.3/10, 2.3/40,	
		07-2026	2.4/10, 2.4/40, 2.6/10,	
		15	2.6/40, 2.9/10, 2.9/40	
17.	Medequips SMC	Legal Manufacturer:		Rejected due to reason that firm has
1,,	Pvt Ltd,	MEDISONO LLC.	Doppler Ultrasound	•
	30-Shahrah E	3016 NW 82nd	System and P11 Plus	
	Quaid E Azam,	Avenue, Doral, FL	Digital Color Doppler	
	Lahore, 54000,	33122, USA.		3. Justification for applying two
	Pakistan.	55122,	(Digital Color	
	T distant	FSC: USA.	Doppler Ultrasound	
	ELI-00362	Date of Validity: 23-		Digital Color Doppler Ultrasound
	7023-P	10-2026.	System)	System in single application.
	7023 1	LOA issuance 05-12-	Class-B	System in single application.
		2024	Class D	
		ISO 13485 missing.	Service life: 7 years	
		510k No. K231659 for	Service IIIc. / years	
		P11 Plus	Model as per FSC	
18.	Roche Pakistan	Legal Manufacturer:	Cobas MPXV	Deferred for personal hearing. Firm
10.	Limited.	Roche Molecular	Couas IVIFA V	has to submit the FSC of country of
		Systems Inc.	Class: D	•
	1 st Floor, 37-B,	1080 US Highway 202	Fees: 50,000/-	origin and Design Examination certificate.
	Block 6,		1.668. 30,000/-	Cerunicaie.
	P.E.C.H.S,	South Branchburg, NJ	Shalf lifa	
	Karachi.	08876 USA	Shelf life:	
	(ELI-00009)	Manufacturina Cita	1. 11 months at 2 - 8°C	
		Manufacturing Site:	0 C	
	Date of R&I			

	00th g = 2024	D - 1 - M 1 1	2 12 1 : 2	
	09 th Sep 2024	Roche Molecular	2. 12 months at 2 -	
		Systems Inc.	8°C	
		1080 US Highway 202		
		South Branchburg, NJ	1. Cobas MPXV	
		08876 USA	CAT #: 09863338190	
			Pack size: 192 Tests	
		FSC:	Shelf life: 11 months	
		FSC of Germany	at 2 - 8°C	
		Validity		
		EUA Letter	2. Cobas MPXV	
			Control Kit	
		LOA:	CAT #: 09863320190	0.10
		Validity	Pack size: 16 x 1.0 ml	, O,
		17-01-2026	Shelf life: 12 months	13
		17-01-2020		
		OF G . C	at 2 - 8°C	
		CE Certificate:		
		Validity	V 700,	
		N/A	*0	
			C	
		ISO Certificate:		
		Validity		
		29-06-2027		
		30-06-2027		
19.	TRI-TECH	Foras Bilg. Elekt.	Binefes	Approved subject to submission of
	INTERNATIONA	Medikal san ve Tic ltd.	Ventilator	copy of Form 7A
	L	Sti	(ICU Ventilator SV	
	10-C, 6TH Sunset	Ostim OSB Mahallesi	100)	
	Commercial Lane,	1269. adde, No:35	Class C	Ola
	Phase 2 EXT,	06374 Ankara/ Turkey		
	DHA, KARACHI,			51\
	PAKISTAN	FSC Turkey issued on		7.0.
	(ELI-00247	10-07-2020		3
20.	TRI-TECH	Foras Bilg. Elekt.	Binefes	Approved subject to submission of
	INTERNATIONA	Medikal san ve Tic ltd.	Ventilator SP 100	copy of Form 7A.
	L	Sti		
	10-C, 6TH Sunset	Ostim OSB Mahallesi	Class c	
	Commercial Lane,	1269. adde, No:35	N. "6,"	
	Phase 2 EXT,	06374 Ankara/ Turkey	*Oh	
	DHA, KARACHI,	ECC Tuelcovices de l'	C	
	PAKISTAN (FLL 00247	FSC Turkey issued on 10-07-2020		
21.	(ELI-00247	Foras Bilg. Elekt.	Binefes	Deferred for.
41.	TRI-TECH INTERNATIONA	Medikal san ve Tic ltd.	Ventilator	
	L	Sti	(ICU Ventilator DEM	1. clarification of BiNefes DEM T19
	10-C, 6TH Sunset	Ostim OSB Mahallesi	T-19)	not mentioned on FSC Turkey, FSC
	Commercial Lane,	1269. adde, No:35	1-17)	Spain and FQA.
	Phase 2 EXT,	06374 Ankara/ Turkey	Class C	2. submission of copy of Form 7A.
	DHA, KARACHI,	OOSITIMIKALA TULKEY	C1055 C	
	PAKISTAN	FSC Turkey issued on		
	(ELI-00247	10-07-2020		
	(1 2 0 7 2020	1	İ

22.	TRI-TECH	Xuzhou Yongkang	Younker	Rejected due to following reasons.
,	INTERNATIONA	Electronic Science	Patient Monitor	Trojocioù duo to 10110 Wing 10410 Mississi
	L	Technology Co., Ltd		1. address of manufacturer on FSC
	10-C, 6TH Sunset	4F Building C8, 40	Class C	(Xuzhou Yongkang Electronic
	Commercial Lane,	Jingshan Road,		Science Technology Co., Ltd,
	Phase 2 EXT,	Economic and		1 st &2 nd Floor, , 6#01, 6#02, No.6
	DHA, KARACHI,	Technological		Building 1st Phase Ecnomic
	PAKISTAN	Development Zone,		S
	(ELI-00247	Xuzhou, China		development manufacturing Zone,
				LIANDO U Valley, No.6 Leye Road,
		FSC original valid till		Zuzhou ETDZ 221000 P.R. China) is
		13-03-2023	1121 22	different from address on LOA
				(Xuzhou Yongkang Electronic
			000 111 6	Science Technology Co., Ltd 4F
			G, 10, 70%	Building C8, 40 Jingshan Road,
				Economic and Technological
		200	110	Development Zone, Xuzhou, China).
			Osciol Jose	2. Original free sale certificate not
			700	provided
		701	40.	3. The name of the device on FSC is
		3510		different from applied device.
23.	NI Healthcare	Vincent Medical and	Vincent / inspired	Rejected due to following reasons.
23.	Products (Pvt)	Manufacturing Co.	Humidifier VBH20	1. The device name Vincent /
	Ltd., Office No.	Ltd.	Trumumer v B1120	inspired Humidifier is not given in
	•		II: 4:£:	FSC.
	A, Unit 10, Survey	Flat/RM B2, 7/F. Hang	Humidifier	
	No. 263 Damlotte	Fung Industrial	G. G	2. The manufacturer address on FSC
	Road malir,	Building Phase 2, 2G	Class C	and FQA is different.
	Karachi	Hok Yuen St., Hung	Shelf life 5 Years	3. The device name not mentioned on
		Hom, Kowloon Hong	Fee 62,000/-	of FQA along with Notified Body
	(ELI-01117	Kong		confirmation letter.
				4. The applied product code/model
				not available in free sale certificate.
24.	NEW PAKISTAN	M/s NANTONG	Accurate pregnancy	Deferred for submission of
	TRADERS	EGENS	test kit	following.
	Office No. 306/I,	BIOTECHNOLOGY	L'AND CIN	1. Notarized LOA and ISO 13485.
	Trade Tower, Altaf	CO., LTD ADDRESS:	CLASS: B	2. valid original FSC
	Hussain Road,	Block A Fifteenth		3. valid CE /FSC of RRA
	New Challi,	Factory-building	Shelf life:	or indicate of the control of the co
	Karachi.	No.1692 Xinghu	2 years	
	ELI-00161	Avenue, Nantong	C	
		Economic &	Fee 25000:-	
	R&I	Technological		
	16/05/2022	Development Zone,		
		NANTONG, CHINA		
		900,		
		15		
		FSC original China		
		valid till 05-05-24		
25.	National	Medikokim Tibbi ve	Saugermed	Deferred for following:
	Enterprises,	Kimyevi Malzeme	Neurosurgical Pads	
	Office # 409, 4th			

	Floor, Al-Sehat	sanayi ve Ticaret		1. Firm has applied the product as
	Center, Annexe	Limited Sirketi		single on Form 7A while it has
	Regent Plaza			multiple codes.
	Shahrah-e-Faisal			2. Firm has applied both soft cotton
	Karachi			and pure cotton neurosurgical patties
	(ELI-00043)			in single application.
				3. according to DOC device is of
				class D while firm has applied as
				class C.
			. (4. valid FSC of RRA or valid Design
				Examination certificate
26.	Sawanki & Co.	Shenzhen Pango	Electronic Blood	Deferred for following reasons.
	Plot C-11, Sector	Medical electronic Co.,	Pressure Monitor	1. FSC of the china is not legalized.
	35-A, Korangi	Ltd.	G x0 200	2. Name of device on FSC is Arm
	Industrial Area,	No. 25, 1st Industry	Electronic Blood	blood Pressure Monitor (PG-
	Korangi karachi	Zone, Fenghuang road,	Pressure Monitor	800B10).
	Pakistan	Xikeng Village	N. 106/1,	3. FSC of RRA or CE Certificate not
	(ELI-00521)	Henggang Town, Longgang estrict	400	provided.
		Shenzhen 518115	C	4. Firm has submitted copy of Form
		Guangdong PR		7A without annexures.
		CHINA		
27.	Sawanki & Co.	Shenzhen Viatom	Blood Pressure	Deferred for following reasons.
	Plot C-11, Sector	Technology Co., Ltd.	Monitor (BP2)	1. FSC not original and legalized.
	35-A, Korangi	4E, Building 3,		2. Name of device on FSC is Arm
	Industrial Area,	Tingwei Industruial	Blood Pressure	blood Pressure Monitor (PG-
	Korangi karachi	Park, No. 6 Liufang	Monitor	800B10).
	Pakistan (ELI-00521)	Road, Block 67, Xin'an Street, Bao'an District,		3. FSC of RRA or CE Certificate not
	(ELI-00321)	Shenzhen 51801,		provided.
		Gaungdong PR		4. Firm has submitted copy of Form
		CHINA		7A without annexures.
28.	Sawanki & Co.	Feellife Mdeical Inc.	Air Mask, Air Mask II	Deferred (last opportunity) for:
	Plot C-11, Sector	Room 1903, Building	000 111 6	1. Submission of legalized FSC of
	35-A, Korangi	A, No. 9, Furong	UltraSonic Nebulizers	RRA mentioning applied product
	Industrial Area,	Road, Tantou	(Portal Mesh	and codes/model.
	Korangi karachi	Community Songgang	Nebulizer)	or CE marking certificate
	Pakistan (ELI-00521)	Street, Bao'an District, Shenzhen China	A. 70,	2. Clarification regarding
	(ELI-00321)	Shelizhen China	*0	manufacturing site address.
			C	3. Submission of legalized FSC
		619	7	(China).
29.	Rech International,	Tipmed Medical	Tipmed	Deferred for following reasons.
	247/B, Block-6	devices Manufacturing		1. CE and DE certificates are valid
	P.E.C.H.S Karachi	Ltd. Kamalpasa	Primary Hip	till 26.05.2024.
		Mahallesi 7401/1SOK.	prosthesis sys	2. Firm has attached statement of
	(ELI-00257	No. 16		Ministry of Health Turkey for
		Bornova/izmir/Turkey.	Class C	extension of these certificates instead
) · ·	Shelf life As per	of NB confirmation letter.
		Notarized LOA	stability study	3. As per DOC its class D medical
		submitted.	Fee 50,000/-	device.

30.	RECH International 247/B Block 6	Copy of Turkey notarized FSC issued on 23-02-2021 valid for three years. (Expired FSC submitted). Notarized FQA valid till 26-05-2024. Expired after submission. Notarized ISO submitted valid 13-07- 2024. Copy of FQA submitted till 26-05- 2024. Notarized design examination certificated submitted. Expired after submission on 26-05- 2024. Shandong Weigao Orthopedics Devices Company Limited	Bone Screw Bone Screw	4. ISO13485, CE certificate, DE certificate and LOA are not notarized. 4. Name of the manufacturer as per documents is TIPMED Tibbi Medikal Urunler Tic. San. Ltd.Sti. 5. Firm has not given clarification of Brand name and manufacturer name as per FSC. Deferred for 1. submission of legalized FSC and notarized ISO 13485, valid FQA.
	PECHS Yaseen Suleman Street	Address: NO.26 Xiangjiyang Road,	Class C	2. calrification of brand name. 3. clarification of screw type.
	Near Faran Hotel	tourist resort, Weihei	Shelf life 5 Years	5 Jan 19
	Shahrah e Faisal, Karachi, Pakistan	city Shandong Province, China	Fee 50,000/-	3.
	(ELI-00257	Copy of LOA submitted valid till 15-11-2027.	Olice 1505	
		Apostille Certificate for Exportation of Medical Products provided valid till 20-08-2025. Copy of FQA provided valid till 26-05-2024.	cio	
21	DEGU		D	
31.	RECH International	Biomet Orthopedics 56 East Bell Dr. PO Box	Persona Partial Knee	Rejected due to following reasons.
	247/B Block 6		Joint Replacement	

	PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257	587 Warsaw, Indiana USA	Orector 2025	1. Manufacturer name on FSC is Biomet, Inc., 56 East Bell Dr. PO Box 587 Warsaw, Indiana USA, on LOA is Biomet Orthopedics, 56 East Bell Dr. PO Box 587 Warsaw, Indiana USA, for authorization letterhead of Zimmer Biomet, 1800 West Center St. Warsa Indiana USA has been used and manufacturer on Form 7A is Biomet France, Plateau de lautangne 26000 valence France. 2. Form 7A is without annexure, signatures, stamp, date and stamp paper. 3. Firm has applied multiple products in single application.
32.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI- 00247 R & I Submission Date: 24.11.2022	MA. EL "SIEM. SRI" Via Veggioletta, 16/C IT29121 – Piacenza – Italy FSC Validity (13.05.2022) Italy ISO Valid Till (11.03.2024) EC Valid Till (06.05.2023) LOA Valid Till (15.03.2022)	EMERGENCY AND TRANSPORT LUNG VENTILTOR BA - 2001 Class C Shelf Life: 5 Years Codes/Sizes (mention as per FSC)	Approved BA -2001 MA-EL. Foirm will apply separately for rest of models.
33.	Applicant: M/s: TRI TECH INTERNATIONA L 10 C 6 SUNSET COMM LINE PHASE II DEFENCE HOUSING AUTHORITY KARACHI (ELI-00247) Fee details:	(Legal Manufacturer) Name: M/s Bistos, 7th Floor, A Bldg, Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon- gu, Sungnam-si, Gyeonggi-do, Korea. FSC Korea: issued on 30-01-2020 Letter of authorization:	Fetal Doppler System Model: BT-250 Class B Shelf life: 05 years EC Certificate: expired ISO 13485 Certificate validity: expired	Rejected due to following reason: 1. FQA, ISO 13485 and DOC are not notarized. 2. The name as per FQA and DOC is <u>Ultrasound Doppler System.</u> 3. Firm has not submitted Free sale ceryificate.

	Amount: PKR	26-06-2028		
	25000/-			
	Slip: 2006272			
	Dated: 09-07-2020			
34.	TRI-TECH	ELMASLAR	Lifetime Surgical	Approved.
	INTERNATIONA	IMALAT TIBBI	Aspirator	
	L	CIHAZLAR INS.	SA01HT	
	10-C, 6TH Sunset	TAS. ITH.IHR.SAN.		
	Commercial Lane,	Ve TIC.A.S.,		
	Phase 2 EXT,	1.ORGANIZE SAN.		
	DHA, KARACHI,	BOL.BABURSAH		
	PAKISTAN	CAD. NO:17	111 1111	·D.
	(ELI-00247	SINCAN/ ANKARA	0011. 1 (1	, 5 ,
		TURKIYE	000	3
35.	Samzco Trading	Legal Manufacturer:	Zeiss Contact Day 1	Rejected due to following reasons.
	Company,	Wohlk Contactlinsen	(Contact Lenses)	1. Firm has not clarified that applied
	Office No. 501,	GMBH		lens is spheric, toric or multifocal.
	Imperial Optical	BurgerMeister-Schade-	Codes & Sizes: As per	2. Device applied as Class c but as
	Center, Masjid	Str.12, 24232 Schon	FSC	per DOC its Class IIa (B).
	•	kirchen, Germany		*
	,	3500	Class-C	
	Khatta M. A Jinnah	FSC: not provided.		manufacturer credentials.
	Road, Karachi	V2 12	Shelf Life:	4. Firm has not submitted stability
	(ELI-00685)		05 years	studies.
			,	5. ISO 13485 and DOC not
	Dossier#4646-7A	600		notarized.
	Date:19-07-22			
		Up.		
36.	Samzco Trading	Legal Manufacturer:	Zeiss Contact Day 30	Rejected due to following reasons.
30.	Company,	Wohlk Contactlinsen	(Contact Lenses)	1. Firm has not clarified that applied
	Office No. 501,	GMBH	(Contact Echses)	lens is spheric, toric or multifocal.
		BurgerMeister-Schade-	Codes & Sizes: As per	-
	Imperial Optical	Str.12-6 24232 Schon	FSC FSC	2. Device applied as Class c but as
	Center, Masjid	kirchen, Germany		per DOC its Class IIa (B).
	Street, Ghari	and the state of t	A 40. 412	3. Firm has not submitted
	Khatta M. A Jinnah	FSC: not provided.	Class-C	manufacturer credentials.
	Road, Karachi	1 50. not provided.	Class C	4. Firm has not submitted stability
	(ELI-00685)		Shelf Life:	studies.
		, , ,	05 years	5. ISO 13485 and DOC not
	Dossier#4877-7A	401	55 ,0015	notarized.
	Date:07-07-22	3500		
		65, 7		
37.		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		MDB acceded the request of the firm
37.	SIND MEDICAL	DiaMed GmbH	HAM's ACID RED	to withdraw the application and
	STORES,	Pra Rond 23, 1785	CELL TEST IVD,	* *
	13-B, Block 6,	Cressier FR	REAGENT	Rejected application.
	PECHS,	Switzerland.	(FAMILY)	
	Shahrah e Faisal,	Switzerand.		
	Karachi – 75400,	Head Quarter (Parent	Class – B	
	PAKISTAN		C1035 - D	
	IANISIAN	Company):		

	Lic. No.ELI- 00010	Bio-Rad Laboratories Inc.,		
		1000 Alfred Nobel		
		Drive, Hercules,		
		California 94547- USA.		
		USA.		
		European HQ:		
		Bio-Rad Europe		OB.
		GmbH,		
		Holbeinstrasse 75,		
		4051 Basel, Switzerland.	112	0.0
		Switzeriand.	00,11	, D,
		FSC Switzerland	Osqii 1 (pr	
		Valid Till (18.10.2022)	, CO, OO	
		1000		
		ISO 13485:2016	0,.00,,	
		Certificate Valid till	00	
		(30.10.2021)	CL	
		LOA Valid until		
		(31.12.2020)		
38.	WIS International	Legal Manufacturer:	ZMD	Rejected for following reasons.
	(Pvt) Ltd,	Suzhou Sunan	Compression Bone	1. Manufacturer has submitted we
	Office no. 910, 9th	Zimmered Medical	Plates	are unable to provide DE certificate
	Floor, Business	Instrument Co., Ltd	Codes & Cines	due to conversion from MDD to
	Avenue Building,	South Jiankang Road, Hexing, Jinfeng Town,	Codes & Sizes: ZSQ01,	MDR nor submitted original valid
	plot No. 26-A,	Zhanjiagang, 215626	ZSQ01, ZSQ02,	legalized FSC of Reference country
	Block 6,	Jiangsu P.R. China	ZSQ03,	
	P.E.C.H.S, Karachi		ZSQ04,	2. Applicant has submitted that
	ELI NO. 00659	FSC China	ZSQ05,	address of the manufacturer has
	Dossier#313-C	issued 15-09-2022	ZSQ06,	changed and being updated in legal
	Date:30-11-22 Submitted Fee:		ZSQ07,	documents that will be submitted later when completed.
	50,000/-PKR		ZSQ08,	later when completed.
	Challan No.:		ZSQ09, ZSQ10,	
	646878823471	PO	ZSQ10, ZSQ11,	
	Evaluator:		ZSQ12,	
	DD-II		ZSQ13,	
	DD II	:iSI* (ZSQ14,	
		65, 73	CI D	
		P. I.	Class-D	
39.	Life Cares, M-20,	Manufacturer:	Shelf Life: 5 years FORTUNE	Rejected the case due to following
	Mezzanine Floor	FORTUNE MEDICAL	Stomach Gastric,	reasons.
	Falaknaz Plaza	INSTRUMENT	Chest Laryengeal	1. Firm has not submitted original
	Natha Khan	CORP.	Mask Tube	and valid FSC of country of origin
	Bridge, Shahra-e-	6F, NO. 29, SEC.2		china (Taiwan).
1	~	,	Í.	
1	Faisal, Karachi	JHONGJHENG E	Class C	

		DISTRICT, NEW TAIPEI CITY, 251 TAIWAN Copy of FSC issued by Mo Health & Welfare, Republic of China (Taiwan) No. 078737 dated 13-05-2020 ISO valid till 08-08- 2022 FQA/CE valid till 04- 09-2023	Shelf Life: Not provided Code:- Model (Type): 2020-0003, 2020-0004, 2020-0005, 2020-0008, 2020-0010, 2020-0012, 2020-0014, 2020-0016, 2020-0018, 2020-0018, 2020-6014, 2020-5516, 2020-6014, 2020-6516, 2020-6516, 2020-7514, 2020-7516, Fee submitted: Rs. 50,000/-	 Name of the product on FSC is Fortune Drainage Tubes and Accessories (Sterile). Firm has not submitted stability studies. Firm has not submitted Separate Application & fee for different types of products as per MDB decision.
40.	M/s. Noor international, 29-D, Block 6, PECHS, Karachi. ELI-00061. Evaluator: AD-VI	Legal Manufacturer: M/s Hitec Medical Co., Ltd, No.703, Hengnan RD 1328, Minhang District 201114, Shanghai, China. FSC China Valid Till (14-10-2021)	HITEC CARE Tracheobronchial Tube. Class-B. claimed shelf life: 05- years. Codes & Sizes as per FSC.	Rejected due to following reasons. 1. FSC (China) not issued by the concerned Heath regulatory Authority. 2. Address of manufacturer on FSC, FQA and application form is different. 3. copy of EU Quality Assurance Certificate and ISO 13485 not notarized. 4. The name of the manufacturer as per ISO and FQA is Jiangsu Hitec Medical Co. ltd.
41.	M/s. Noor international, 29-D, Block 6, PECHS, <u>Karachi</u> . ELI-00061. <u>Evaluator</u> : AD-VI	Legal Manufacturer: M/s Hitec Medical Co., Ltd, No.703, Hengnan RD 1328, Minhang District 201114, Shanghai, China. FSC China Valid Till (14-10-2021)	HITEC CARE Tracheostomy Tube. Class-B claimed shelf life: 05- years. Codes & Sizes as per FSC.	Rejected due to following reasons. 1. FSC (China) not issued by the concerned Heath regulatory Authority. 2. Address of manufacturer on FSC, FQA and application form is different. 3. copy of EU Quality Assurance Certificate and ISO 13485 not notarized.

			T	
				4. The name of the manufacturer as per ISO and FQA is Jiangsu Hitec Medical Co. ltd.
42.	M/s New Pakistan Traders, Office No. 306/I, Trade Tower, Altaf Hussain Road, New Challi, Karachi. (ELI-00161) 4469-P 16-05-2022	Legal Manufacturer: M/s Shanghai Kinmed Import & Export Co. Ltd, Suit L, 12th Floor, No.588 Yingkou Road, Shanghai, China FSC China Date of Issuance 06-12-2021 valid for 2 years	KBM Auto-Disable Syringe Class B Shelf life: 05 Years Sizes: 3ml, 5ml	Rejected as firm has not submitted original legalized free sale Certificate, notarized CE certificate, ISO 13485 as per decision of MDB taken in its 66 th meeting.
43.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI- 00247 R & I submission Date: 03.06.2024	Legal Manufacturer: Magnamed Tenologia Médica S/A. Rua Santa Monica 801/831, Cotia - São Paulo Brazil FSC Validity (11.11.2029) Brazil ISO Valid Till (27.12.2025) EC Valid Till (29.11.2022) LOA Valid Till (03.02.2028)	ICU Ventilator FLEXIMAG MAX 300 LUNG VENTILATOR NEONATE TO ADULT Class – C Shelf Life: Three Years Codes/Sizes (mention as pet FSC)	Approved subject to original FSC of RRA.
44.	Tri Tech International, Plot 10 C 6th Sunset St, Commercial Lane Phase 2 Ext Defence Housing Authority, Karachi, 75500 PAKISTAN Lic. No. ELI- 00247 R & I submission Date: 03.06.2024	Legal Manufacturer: Magnamed Tenologia Médica S/A. Rua Santa Monica 801/831, Cotia - São Paulo Brazil FSC Validity (11.11.2029) Brazil ISO Valid Till (27.12.2025) EC Valid Till (29.11.2022) LOA Valid Till (03.02.2028)	Lungs Ventilator OXYMAG EMERGENCY AND TRANSPORT VENTILATOR Class – C Shelf Life: Five years Codes/Sizes (mention as pet FSC)	Approved subject to original FSC of RRA.
45.	M/s United Healthcare, C-271,	Legal Manufacturer & Site: Zhejiang	Safety Aero Disposable	Approved subject to submission of original valid FSC.

	Ground Floor,	Rungiang Medical	Anesthesia Filter-	
	Gulshan-Jauhar,	Instrument Co., Ltd	NRFIT Filter	
	Block 24, Karachi	Address as per Form-	Class: D	
	(ELI-00907)	7A & China FSC:	MD group: Single	
	Plot No.330/A. 2 nd	599 Ruifeng Street,	Shelf life: 5 years	
	floor, block 3	Gaozhao District,	shen me. s years	
	DMCHS, Alamgir	Xiuzhou Jiaxing City	Codes & Sizes: AF-	
	Road, Karchi.	zhejiang, China	A-0.5	
	110 44, 1242 0111	Address as per FQA:		
	(ELI-00293)	No. 618 Dade Road,		(A) (A)
	()	Jiaxing Xiuzhou	Fee Challan No.:	
		District 314031 Jiaxing	322123110	0:50
		City, China	PKR: 62,000/-	.3.
		FSC:	G- 10/ 20/3	*
		(China) valid upto 26-	1 2C/2 0ON	
		03-2025	110	
		ISO 13485 Certificate	0), 6/,	
		validity:		
		06-05-2025		
		EC (FQA) Certificate		
		valid upto 06-05-2023		
		Design Examination		
		Certificate valid upto		
		11-12-2022		
		LOA Validity:		
		22-08-2029		
46.	M/s United	Legal Manufacturer &	Safety Aero	Approved subject to submission
	Healthcare, C-271,	Site: Zhejiang	Disposable	valid original FSC and fee for family.
	Ground Floor,	Runqiang Medical	Anesthesia Needle -	
	Gulshan-Jauhar,	Instrument Co., Ltd	NRFIT Needle	
	Block-24, Karachi	Address as per Form-	(Disposable	0.3
	(ELI-00907)	7A & China FSC:	Anesthesia Needle-	
	Plot No.330/A. 2 nd	599 Ruifeng Street,	NRFIT Needle)	"
	floor, block 3	Gaozhao District,	Class: D	
	DMCHS, Alamgir	Xiuzhou Jiaxing City	MD group: Family	
	Road, Karchi.	zhejiang, China	Shelf life: 5 years	
	(TT T 00000)	Address as per FQA:		
	(ELI-00293)	No. 618 Dade Road,	Codes & Sizes: AN-	
		Jiaxing Xiuzhou	E, AN-S, AN-N,AN-	
		District 314031 Jiaxing	E/SII	
		City, China		
		FSC:	E. Challer N	
		(China) valid upto 26-	Fee Challan No.:	
		03-2025	82294572303 DVD: 62.000/	
i l		ISO 13485 Certificate	PKR: 62,000/-	
		volidity		
	<	validity:		
		06-05-2025		

		Γ=		
		Design Examination		
		Certificate valid upto		
		11-12-2022		
		LOA Validity:		
		22-08-2029		
47.	M/s United	Legal Manufacturer &	Safety Aero	Approved subject to submission of
	Healthcare, C-271,	Site: Zhejiang	Anesthesia Epidural	valid original FSC.
	Ground Floor,	Runqiang Medical	Puncture Kit	
	Gulshan-Jauhar,	Instrument Co., Ltd	Class: D	
	Block-24, Karachi	Address as per Form-	MD group: Single	
	(ELI-00907)	7A & China FSC:	Shelf life: 5 years	
	Plot No.330/A. 2 nd	599 Ruifeng Street,		0:50
	floor, block 3	Gaozhao District,	Codes & Sizes: AS-E	.3.
	DMCHS, Alamgir	Xiuzhou Jiaxing City	Codes & Sizes. Tis E	3
	Road, Karchi.	zhejiang, China	Fee Challan No.:	
	Roda, Raiciii.	Address as per FQA:	366814753	
	(ELI-00293)	No. 618 Dade Road,	PKR: 62,000/-	
	(ELI-002/3)	Jiaxing Xiuzhou	1 KK. 02,000/-	
		District 314031 Jiaxing	AO V	
		City, China		
		FSC:		
		(China) valid upto 26-		
		03-2025		
		ISO 13485 Certificate		
		validity:		
		06-05-2025		
		EC (FQA) Certificate		
		valid upto 06-05-2023		
		Design Examination		5) A (X
		Certificate valid upto		
		11-12-2022		0
		LOA Validity:	000	<i>J</i>
		22-08-2029	G, "U, "U,	7
48.	Applicant Name:	Name of	Brand Name:	Deferred for following reasons;
		Manufacturer:	110	1. the device name on FQA is Vessel
	M/s. Universal		ENDOSCOPE	harvesting System. Clarification is
	Enterprises	M/s. Terumo	700	required
		Cardiovascular	Class: B	2. The code MCENDO550R not
	Address of	System		mentioned in FSC and LOA.
	Importer:	Corporation located at 125 blue		3. Firm has not submitted Brand
		ball Rd Elkton,	Shelf life: 03 Years	name.
	29 Block 3,	Maryland 21921,		4. clearly mention name, type and
	Overseas	USA,	Model:	model as per FSC of USFDA
	Cooperative	<i>SSI</i> 1,		_
	Housing Society,	Contract	MCENDO550	
	Stadium Road,	Manufacturing by:	MCENDO550R	
	Karachi.	M/s Olympus		
		Winter & Ibe		
		GmbH,		

	(ELI-00079)	Kuchnstrasse 61,		
		2045 Hamberg		
	R&I Date:	Germany,		
	08 November 2022	X O A XX 11 11.		
	Fee Challan No.:	LOA Validity:		
	3493585041 PKR:	October 12, 2023		
	25,000	FSC Validity:		
	Dated: 19-10-2022	19-07-2023		OW
	Tracking ID			5) 44'
	ZS4-HDW-DAD2			
49.	M/s Royal	Manufacturer:	CR-Type Catheter	Approved subject to provision of
	Medical,	F Care Systems NV,	(Radiofrequency	Original FSC
	Office No. 26th,	Oosterveldlaan 99, B-	thermocoagulation	"
	3rd Floor United	2610, Wilrijk, Belgium	probes) Class C	
	Trade Center, Plot	FSC Belgium Issued	Codes:	
	# 5, Block 6,	on 4-11-2020	CR30KAB	
	Gulshan-e-Iqbal Karachi (ELI-		CR45i CR40i	
	00691)		Shelf Life: 3 Years	
	Evaluator:		Shell Elic. 5 Tears	
	AD-IV	65 03		
	[4327]			
50.	M/s Royal	Manufacturer:	EVRF (Endo-Venous	Approved subject to provision of
	Medical,	F Care Systems NV,	Radiofrequency	Original FSC. Code as per FSC.
	Office No. 26th,	Oosterveldlaan 99, B-	Thermocoagulator)	
	3rd Floor United	2610, Wilrijk, Belgium	Class C	
	Trade Center, Plot	FSC Belgium Issued on 4-11-2020	Shelf Life: N/A	
	# 5, Block 6, Gulshan-e-Iqbal	011 4-11-2020	Life span: 8 Years	
	Karachi (ELI-			5) 1/2
	00691)			6.
	Evaluator:		411 ' (12.	03.5
	AD-IV		030 41 6	
	[4327]		C+ 10, US	ר (
51.	M/s Royal	Manufacturer:	HPR45i	Approved subject to provision of
	Medical,	F Care Systems NV,	(Radiofrequency	Original FSC. Code as per FSC.
	Office No. 26th,	Oosterveldlaan 99, B-	thermocoagulation	
	3rd Floor United Trade Center, Plot	2610, Wilrijk, Belgium FSC Belgium Issued	probe) Class C Shelf Life: 3 Years	
	# 5, Block 6,	on 4-11-2020	Shell Life. 5 Tears	
	Gulshan-e-Iqbal		7	
	Karachi (ELI-	V22, J3		
	00691)	Y V		
	Evaluator:	107,		
	AD-IV	600		
	[4327]			
52.	Royal Medical	Legal Manufacturer	Name of Device :	Deferred (final opportunity) to
	Office No. 26th,	Name: F Care Systems	Fistura Catheter	provide of Valid legalized FSC of
	3rd Floor United	NV	Codes/Models: 6F,	country of origin, notarized LOA
	Trade Center Plot	Complete Address:	7F, 8F, 9F	

	# 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: (ELI- 00691	Uitbreidingstraat 42- 46, BE-2600 Berchem, Belgium Telephone Number: +3234515145 Official Website: www.fcaresystems.co m	R&I Date: 7th August 2023	along with copy of application form & Fee slip.
53.	Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: (ELI- 00691	Legal Manufacturer Name: Bicakcilar Tibbi Cihazlar Sanayi ve. Tic. A.S. Address: Osmangazi Mah. Gazi Cad. No: 21 Esenyurt 34522, Istanbul – Turkey Telephone No.: +90 212 689 02 20 Email: info@bicakcilar.com Website: www.bicakcilar.com	Name of Device: Bicakcilar- Coronary Artery Perfusion Cannula Codes/Models: 330 0461 1 R&I Date: 7th August 2023	Deferred (final opportunity) to provide of Valid legalized FSC of country of origin and Design Examination certificate or FSC of any RRA, notarized LOA along with copy of application form & Fee slip.
54.	Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi Establishment License: (ELI- 00691	Legal Manufacturer Name: Bicakcilar Tibbi Cihazlar Sanayi ve. Tic. A.S. Address: Osmangazi Mah. Gazi Cad. No: 21 Esenyurt 34522, Istanbul – Turkey Telephone No.: +90 212 689 02 20 Email: info@bicakcilar.com Website: www.bicakcilar.com	Name of Device: Bicakcilar- Aortic Root Cannula/Needle Codes/Models: 330 0111 1 R&I Date: 7th August 2023	Deferred (final opportunity) to provide of Valid legalized FSC of country of origin and Design Examination certificate or FSC of any RRA, notarized LOA along with copy of application form & Fee slip.
55.	M/s: Usmanco International Address of Importer House No. 220, Block-3, S. Abdul Tawwab Road, Karachi. ELI: 00121 R&I Detail	Legal Manufacturing: Zhejiang Kindly Medical Devices Co. Ltd Legal Manufacturing Site: No. 758, 5 th Binhai Road Binhai Industrial Park Longwan District Wenzhou, Zhejiang.	Uflo Safety IV Catheter Class B Claimed Shelf Life:05-Years Codes/Size as per FSC.	Rejected as firm has not submitted FSC of RRA.

	01 02 2024	LOA	T	
	01-02-2024	LOA		
	Fee 25,000/	Validity: 06-06-2026		
	through slip no.	FSC:		
	12207147, dated	Validity: 23-06-2026		
	08-01-2024	<u>ISO13485:</u>		
		Validity: 31-10-2026		
56.	M/s: Usmanco	Legal Manufacturing:	Uflo Disposable	Rejected as firm has not submitted
	International	Zhejiang Kindly	Insulin Pen Needle	FSC of RRA.
	Address of	Medical Devices Co.	Disposable Insulin	
	Importer	Ltd	Pen Needle	5) AB
	House No. 220,	Legal Manufacturing		
	Block-3, S. Abdul	Site: No. 758, 5 th	CI D	0,00
	Tawwab Road,	Binhai Road Binhai	Class B	
	Karachi, Pakistan.	Industrial Park	Claimed Shelf	"
	ELI: 00121	Longwan District	Life:05-Years	
	R&I Detail	Wenzhou, Zhejiang.	Codes/Size as per	
	01-02-2024	LOA	FSC.	
	Fee 25,000/	Validity: 06-06-2026	700	
	through slip	FSC:	AO.	
	no.1062293790,	Validity: 23-06-2026		
	dated 08-01-2024	ISO13485:		
	ualeu 08-01-2024			
-7	NA/ II	Validity: 31-10-2026	HC · D' N II	D: (1 C: 1 (1 1)
57.	M/s: Usmanco	Legal Manufacturing:	UCut Biopsy Needle	Rejected as firm has not submitted
	International	Zhejiang Kindly	Class B	FSC of RRA.
	Address of	Medical Devices Co.	Class B Claimed Shelf	
	Importer	Ltd	Life:05-Years	
	House No. 220,	Legal Manufacturing		
	Block-3, S. Abdul	Site: No. 758, 5 th	Codes/Size as per FSC.	
	Tawwab Road,	Binhai Road Binhai	rsc.	5) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
	Karachi, Pakistan.	Industrial Park		
		Longwan District	7(1) (12)	0:3
	ELI: 00121	Wenzhou, Zhejiang.	200	3
	R&I Detail	<u>LOA</u>	G, "U, "U,	2
	01-02-2024	Validity: 06-06-2026		
	Fee 25,000/	FSC:	Olifector 5052	
	through slip no.	Validity: 23-06-2026		
	1751589259, dated	<u>ISO13485:</u>	100	
	08-01-2024	Validity: 31-10-2026	AO	
58.	M/s: Usmanco	Legal Manufacturing:	BFlo Scalp Vein Set	Rejected as firm has not submitted
	International	Zhejiang Kindly	•	FSC of RRA.
	Address of	Medical Devices Co.		
	Importer	Ltd	Class B	
	House No. 220,	Legal Manufacturing	Claimed Shelf	
	Block-3, S. Abdul	Site: No. 758, 5 th	Life:05-Years	
	Tawwab Road,	Binhai Road Binhai	Codes/Size as per	
	Karachi, Pakistan.	Industrial Park	FSC.	
	ELI: 00121			
		Longwan District		
	R&I Detail	Wenzhou, Zhejiang.		

	01-02-2024	LOA		
	Fee. 25,000/	Validity: 06-06-2026		
	through slip no.	FSC:		
	00107168190,	Validity: 23-06-2026		
	dated 08-01-2024	<u>ISO13485:</u>		
		Validity: 31-10-2026		
59.	Applicant:	(Legal Manufacturer)	Disposable Chest	Rejected for following reasons.
	M/s Safe Health	Name: M/S. Suzhou	Drainage Bottle	1. Firm has submitted MDR Cover
	Pakistan Bizcon.	Yaxin Medical	(System) Single	letter of contract as CE and
	Office No. 25, 2nd	Products Co., Ltd.	Chamber, Two	confirmation that manufacturer has
	Floor, Dilkusha	No. 12, Zhonghua	Chambers & Three	started process of certification as
	Chamber, Marston	Road, Mudu Town,	Chambers - Venous TM	Extension on CE.
	Road, Karachi	Suzhou, Peoples	000	2. Firm has submitted that it is class I
		Republic of China	Class-A	as per documents while contract
	(ELI- 00275)		CC OO	shows device on it is of class IIa.
		FSC Validity:	Letter of	3. Firm has not submitted revised
	Track ID:	08-10-2025	authorization:	Form 7A and fee for class B.
	PDS-58W-A1R8		Issuance date: 25-02-	4. Firm has submitted Disposable
		101	2024	Chest Drainage Bottle (System)
	Fee: PKR 5000/-		Expiry date: Not	Single Chamber, Two Chambers &
	Slip: 2043614	65,0	mentioned	Three Chambers in single
	Dated: 06-10-2020	N3 7.3	mentioned	application.
	24.04.00 10 2020		Shelf life: 05 years	application.
		70-3	Storage Conditions:	
		450	Room temperature	
			Room temperature	
60.	Applicant:	(Legal Manufacturer)	Disposable Feeding	Rejected due to following reasons.
00.	M/s Safe Health	Name: M/S. Suzhou	Bag Venous TM	1. Firm has submitted MDR Cover
	Pakistan Bizcon.	Yaxin Medical	500ml,1000 ml, 1200	letter of contract as CE and
	Office No. 25, 2nd	Products Co., Ltd.	ml & 1500 ml	confirmation that manufacturer has
	Floor, Dilkusha	No. 12, Zhonghua	Generic:	started process of certification as
	Chamber, Marston	Road, Mudu Town,	Enteral Feeding set	Extension on CE.
	•		Enteral recuing set	
	Road, Karachi	Suzhou, Peoples	Char (40) (1)	2. Firm has submitted explanation
	(FIII 00275)	Republic of China	Class-A	" <u>Disposable Chest Drainage Bottle</u>
	(ELI- 00275)	FSC Validity:		is class I, very low risk medical
	Track ID:	08-10-2025	01.1010 07	device, used as container for Enteral
	Track ID:		Shelf life: 05 years	Nutrition feeding".
	PDS-58W-A1R8	Letter of authorization:	Storage Conditions:	3. The cover letter of contract of
	Fee: PKR 5000/-	Issuance date: 25-02-	Room temperature	Suction Drainage System and Waste
	Slip: 8401979738	2024		liquid collection system is attached
	Dated: 09-09-2021	Expiry date:		instead of Disposable Feeding Bag
		Not mentioned		Venous TM .
		90,		
61.	National	Legal Manufacturer:	Primado2	Approved only Primado2 control
	Enterprises,	M/S Nakanishi Inc.,	~	Unit. Model as per FSC.
	409, 4th Floor, Al-	700 Shimohinata,	(Total Surgical	Firm will apply separately for other
	Sehat Centre	Kanuma-shi,	System cutting	medical devices.
	Annexe Reagent	Tochigi, 322-8666, Japan	Accessories sterile drills, sterile Burs,	
		i ianan	rarius sterile Biirs	

	D1 C1 1 -		C 1.1. 1 D 0	
	Plaza, Sharah-e-	ECC. I	Saw blades, Resps &	
	Faisal Karachi	FSC: Japan	files)	
	(ELI-00043)	Issued on: 24/03/2021	Cadaa & Cimaa Aaman	
	Dossier#1238c-7A	Issued on: 24/03/2021	Codes & Sizes: As per	
			FSC	
	Date:28-02-23		Class-C	
	Submitted Fee:		Class-C	
	25,000/-PKR		Shelf Life burs: 05	
	23,000/-FKK			
	Challan No.:		years	
	4265344687			
	Evaluator:			0.5
	DD-II		-00, 1	' 3'
62.	Tri Tech	MEDIANA.CO.LTD	AUTOMATED	Deferred for clarification that as per
02.	International,	132,	EXTERNAL	DOC its class C device and as per NB
	Plot 10 C 6th	Donghwagongdan-ro,	DEFIBRILLATOR	confirmation letter class D device
	Sunset St,	Munmak-eup,	HEART ON A-16-DS	along with Design Examination
	Commercial Lane	Wonju-si, Gangwon-	*O	certificate/FSC of RRA and
	Phase 2 Ext	do, 26365, Republic of		differential fee for class D.
	Defence Housing	Korea	Class C	
	Authority, Karachi,	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
	75500	FSC Validity	Shelf Life: 5 Years	
	PAKISTAN	(14.09.2023)		
	Lic. No. ELI-	Korea	Codes/Sizes	
	00247	ISO Valid Till	(mention as per FSC)	
		(29.10.2025)		<u> </u>
	R & I submission	EC Valid Till		
	Date: 03.06.2024	(05.11.2023)		Old.
		LOA Valid Till		
		(12.09.2028)		51
		(12.03.12020)		0.
63.	Tri Tech	MEDIANA.CO.LTD	DEFIBILLATOR /	Deferred for
05.				1. submission of FSC with device
	International,	132,	MONITOR D100	
	Plot 10 C 6th	Donghwagongdan-ro,		name on it.
	Sunset St,	Munmak-eup,	Class C	2. Clarification that as per DOC its
	Commercial Lane	Wonju-si, Gangwon-	G1 101 10 5 11	class C device and as per NB
	Phase 2 Ext	do, 26365, Republic of	Shelf Life: 5 Years	confirmation letter class D device
	Defence Housing	Korea	Ci	along with Design Examination
	Authority, Karachi,	15"	Codes/Sizes	certificate/FSC of RRA and
	75500	FSC Validity	(mention as pet FSC)	differential fee for class D.
	PAKISTAN	(14.09.2023)		
	Lic. No. ELI-	Korea		
	00247	ISO Valid Till		
		(29.10.2025)		
	R & I submission	EC Valid Till		
	Date: 03.06.2024	(05.11.2023)		
		LOA Valid Till		
		(12.09.2028)		
		(-2.07.2020)	1	

64.	Rech International,	Tipmed Medical	Tipmed	Rejected the case due to following
	247/B, Block-6	devices Manufacturing		reasons.
	P.E.C.H.S Karachi	Ltd. Kamalpasa	Internal metallic bone	1. The Spanish FSC (Export
	(ELI-00257	Mahallesi 7401/1SOK. No. 16	fixation devices	certificate Medical devices) issue date 14.04.2023 is not legalized.
	(ELI-00237	Bornova/izmir/Turkey	Class C	2. The name of the device as per FSC
		Bomova/izmm/Turkey	Shelf life As per	is Sterile and Non-Sterile Internal
		Notarized LOA	stability study	Metallic Bone Fixation devices
		submitted.	Fee 50,000/-	(Bone Plates and Screws), Bone Pins
				and Wires.
		Copy of Turkey	1/20 200	3. The name of the manufacturer as
		notarized FSC issued	2011/1/1	per FSC is TIPMED Tibbi Medikal
		on 23-02-2021 valid	000	Urunler Tic. San. Ltd.Sti. 4. FQA is not notarized and valid
		for three years. (Expired FSC	0.00	(26.05.2024).
		submitted).		5. ISO 13485:2016 not notarized.
		Sustained).	011	6. Firm has not submitted stability
		Valid ISO submitted	100	studies and clarification of brand
		However expired after	G	name.
		submission on 13-07-		
		2024. Expired after		
		submission. Notarized		
		FQA valid till 26-05- 2024. Expired after		
		submission.		
65.	Rech International,	Beijing Libeier Bio-	HK01	Rejected due to following reasons.
	247/B, Block-6	engineering Institute		1. copy of the submitted FSC (China)
	P.E.C.H.S Karachi	Co., Ltd. 12	Cannulated Screw,	is not apostille or legalized.
	(ELI-00257	Chuangxin Road, Changping Science	Nuts, Washer, Screw Plugs	2. LOA not notarized.3. NB extension approval letter not
	(ELI-00237	and Technology park,	Tugs	notarized.
		Changping Area,	Class C	4. Firm has not provided justification
		Beijing P.R.China	Shelf life As per	for applying multiple products as
		1000	stability study	system.
		Expired embassy	Fee 50,000/-	5. Firm has not submitted fee for the
		attested certificate for	00	system.
		exportation submitted	C	
		valid till 29.02.2024	7	
		Expired Notarized		
		LOA submitted valid		
		till 31 Dec 2023		
		Copy of ISO 13485		
		valid till 4.08.2026		
		Expired FQA		
		submitted valid till		
		26.05.2024		

66.	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block-24, Karachi (ELI-00907)	Legal Manufacturer & Site: Wellong Instruments Co., Ltd Address (as per form- 7A): 2F, 63 Linsen North Road Taipei, Taiwan. R.O.C. Address as per FSC: 5th Floor No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City, Taiwan, Republic of China. FSC Validity: 09-09-2025 (Taiwan) 09-03-2021 (France) ISO 13485 Certificate validity: 08-07-2027 EC (FQA) not provided Design Examination Certificate not provided. LOA Validity:	System Class: D MD group: Family Shelf life: Not mentioned Storage condition: Room Temperature Codes & Sizes: 06124, 06126, 06128, 06120, 06122, 06129,06140,06142, US-62 Fee Challan No.: 948088324 PKR: 62,000/-	Deferred following reasons. 1. Firm has submitted Form 7A without annexures and undertaking on stamp paper. 2. DE certificate and NB confirmation letter are not notarized. 3. DE certificate and NB confirmation letter bear original stamp of Rech International Karachi. 4. Name of device on FSC is different i.e BMI CSF Shunting System. 5. copy of the FSC is notarized, not legalized.
67.	Noor International Noor House 29-D Block 6 PECHS Karachi -75400 (ELI-00061	Tagumedica S.A., Av. Maquinarias No. 2414, Lima- Peru Notarized LOA valid till 27-10-2025. Apostille FSC of Peru valid till 30-10-2023. Notarized ISO 13485 valid till 25-10-2024.	Glicosorb Polyglycolic Acid Multifilament Absorbable Sterile Synthetic Sutures Premium Tagum / Glicosorb Sutures, Synthetic, Absorbable, Polyglycolic Acid Class D Shelf life 5 Years Fee 50,000/-	Rejected due to following reasons. 1. EC certificate issued by Paragon that is not found on NANDO Database. 2. Design Examination certificate issued by the manufacturer himself.
68.	Noor International Noor House, 29-D, Block-6, PECHS,	Keewell Medical Technology Co, Ltd., Xiananyi Industry Zone, Pingzhou Babhai	KPW 4000 Body Warmer	Deferred for following reasons.

	Karachi -75400	District Eachen City		1. copy of ISO 13485 of M/s
	(ELI-00061	District Foshan City	9018.1900	A •
	(ELI-00001	Guangdong Province 528251 P.R. China	9016.1900	Medicaptain Medical technology
		320231 F.K. Cillia		Co., Ltd. China attached.
				2. The name of the Device on FSC is
				Medical Mattress Patient
				Warming Unit while on Form 7A is
				KPW 4000 Body Warmer.
				3. The code KPW 4000 not
				mentioned on FSC.
				4. The device has control unit, Hose,
				Power Cord, Screw and Screw
				Driver, Clip of Hose and warming
			200 mil	blanket and has been applied as
			G, "U, "U,	single device.
				5. Firm has submitted Form 7A
		12010	160	without annexures and undertaking.
69.	Noor International	Keewell Medical	KPW 3000	Deferred for following reasons.
57.	Noor House, 29-D,	Technology Co, Ltd.,		1. copy of ISO 13485 of M/s
	Block-6, PECHS,	Xiananyi Industry	Body Warmer	Medicaptain Medical technology
	Karachi -75400	Zone, Pingzhou Babhai	100	Co., Ltd. China attached.
	(ELI-00061	District Foshan City	9018.1900	2. The name of the Device on FSC is
		Guangdong Province		Medical Mattress Patient
		528251 P.R. China		
				Warming Unit while on Form 7A is
		460		KPW 3000 Body Warmer.
				3. The FSC has multiple codes, but
		Un		firm has applied as single device.
		*		4. The device has control unit, Hose,
				Power Cord, Screw and Screw
			. (Driver, Clip of Hose and warming
				blanket and has been applied as
			7/1 (12)	single device.
				5. Firm has submitted Form 7A
			G- "U) "U)	without annexures and undertaking.
70.	Noor	R-Vent Medikal	BVM Resuscitator	Approved subject to submission of
	INTERNATIONA	Uretim A.S, Yazibasi	(0)	fee for family and valid CE
	L	Mah. Balkan Cad.		certificate.
	NOOR HOUSE	Iztipsan Apt. No: 33/1	Manual Resuscitator	Firm will apply separately for other
	29-D BLOCK 6	Torbali, Izmir, Turkey	AO*	products.
	PECHS	1610	Codes/ Models (9060,	-
	KARACHI -75400	65 Q	9070, 9080)	
	(ELI-00061	V2 U3		
71	Unique Vierel	Local Manufactures 0	Ontions Class	Ammovod
71.	Unique Visual	Legal Manufacturer &	Optiano Clean	Approved.
	System, L-18m	Site:	NEO PLUS	
	Block-17,	Office address:	Contact Lens Multi-	
	Gulshan-E-Iqbal,	Neo Vision Co., Ltd.	Purpose Solution	
	Karachi	Heungdeokjungang-ro,	(20%	
	(ELI-00449	Giheung-gu, Yongin-	polyhexamethylene	
			biguanide)	

		si, Gyeonggi-do, 120 U-Tower 17F, Korea. Factory: 129-1, Donghwagongdan-ro, Munmak-eup, Wonju- si, Gangwon-do, Korea FSC: Korea Date of Issuance: 17- 02-2023 ISO 13485 dated 25- 08-2027. EC (FQA) valid upto 25-08-2023 LOA dated 15-07- 2024.	Class-C MD group: Family Shelf life: Not mentioned Codes: 60mL & 130mL Fee Challan No.: 82298189944 PKR: 62000/-	3.5.1A.PM
72.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e- Faisal, Karachi (ELI-00077)	Manufacturer: Phenox GmbH, Meitner-Allee 31, D- 44801 Bochum, Germany FSC: Germany Issued: 1-9-21 ISO valid till 26-06- 2022 FQA/CE valid till 26- 05-2024 Deign Examination:26- 05-2024	pHLO AC Aspiration Catheter Family Intravascular recanalization device. Code: PHLO-72-115, PHLO-72-125, PHLO-72-135 Class D Shelf Life: 4 years Fee submitted: Rs. 50,000/-	Deferred for submission of valid original legalized FSC, notarized ISO, DE certificate and stability study.
73.	Unique Visual System, L-18m Block-17, Gulshan-E-Iqbal, Karachi (ELI-00449	Legal Manufacturer & Site: M/s Chalice Solution PTE LT No. 6, Zhongxing Road, Yunyang street, High-tech zone, Danyang city, China FSC: China 08-05-2026 ISO 13485 dated 18- 03-2027.	Optiano" Multi-Purpose Solution Contact Lens Multi-Purpose Solution (20% polyhexamethylene biguanide) Class-C MD group: Family Shelf life: 3 years Codes: 100mL, 360mL & 500mL	Deferred for clarification of applying multiple models (Model. HA & HA-T) in single application alonwith valid CE certificate /FSC of RRA

		EC (EOA)	CV/7/7000001 (00.04	
		EC (FQA) not	GXZZ20223160264	
		provided	(Model. HA & HA-	
		LOA dated 15-07-	T)	
		2024.	Fee Challan No.:	
			82298189944 PKR:	
			62000/-	
	a 7: 1: 0 a	arras erra		
74.	S. Ejazuddin & Co.	SYSMEX	Sysmex XR-series	Approved XR-10 XR-Series
	P.O. Box 5629,	CORPORATION	Automated	Automated Hematology Analyzer
	237-B, Block II,	1-5-1 Wakinohama-	Hematology	(code: CF730361) subject to
	PECHS, Shahrah-	Kaigandori, Chuo-ku,	Analyzers along with	submission of fee for system and
	e-Quaideen,	Kobe 651-0073, Japan	Accessories	Original FSC.
	Karachi	Telephone number:	&Components	Firm will apply separately for other
	ELI 00084	(+81) 78-265-0500 Fax	0011. 1 6.	
		number: (+81) 78-265-	1. XR-20 XR-Series	products.
		0524	Automated	
			Hematology Analyzer	
		SYSMEX	(code: BQ559485)	
		CORPORATION Ono	(Code. DQ337703)	
		Factory 17 Takumidai,	2. XR-10 XR-Series	
		Ono, Hyogo 675-1322	Automated	
		Japan	Hematology Analyzer	
		Sysmex Asia Pacific	(code: CF730361)	
		Pte Ltd 19 Jalan		
		Tukang Singapore	XR-Series Automated	
		619265	Hematology Analyzer	
		Streck 7002 S. 109th	is a multi-parameter	
		Street,La Vista NE,	automated	
		68128, USA	hematology analyzer	
		>	for classification	
			and quantification of	
			following parameters	3).5:1A.PM
			in whole blood and	
			body fluid as an aid to	0.D.
			diagnosis of patient	,2,
			populations	
			found in clinical	, -
			laboratories.	
		100,		
			• Whole blood:	
			WBC, RBC, HGB,	
		4.0	HCT, MCV, MCH,	
		:610	MCHC, PLT, RDW-	
		-6100	SD, RDW-CV,	
		1 5 0,0	MicroR, MacroR,	
		Y . V	PDW, MPV, P-LCR,	
		100	PCT,	
		7.0.	NRBC%, NRBC#,	
		Viegaja, 13	NEUT%, NEUT#,	
			LYMPH%,	
			LYMPH#, MONO%,	
			MONO#, EO%, EO#,	
			BASO%, BASO#,	
			IG%,	
	<u>l</u>	l .	1070,	

IG#, AS-LYMP%, AS-LYMP#, RE-LYMP%, RE-LYMP#, NEUT-RI, NEUT-GI, RET%, RET#, IRF, LFR, MFR, HFR, RET-He, RBC-He, Delta-He, HYPO-He, HYPER-He, IPF, IPF#, HPC%, HPC# • Body fluid (Cerebrospinal fluid, serous fluids (peritoneal, pleural), synovial fluids and CAPD (Continuous ambulatory peritoneal dialysis) fluid): WBC-BF, RBC-BF, TC-BF#, MN%, MN#, PMN%, PMN# Accessories & Components: CDR Assy No. 406 (code: AX506844) Pneumatic Unit PU-17 code: 01330061 BT-50 Transportation Unit (code: AN735871) TA-01 Automated **Tube Sorter** (Automated Tube Archiver) code: AT903180 TS-01 Automated Tube Sorter (Automated Tube Sorter) code: AU291973 **BT-40** Transportation Unit (code: BT080317) CV-50 Transportation Unit (code: AQ200900) CV-55 Transportation Unit (code: CU287365) CV-65 Transportation

75. Life Cares, M-20, Mezzanine Floor For Tune Mezzanine Floor Falaknaz Plaza Natha Khan Tu-40 Transportation Unit (code: AN617358) FORTUNE FORTUNE Urological Catheters (Family) + Silicone Suprapubic Catheter Class C Rejected due to following reason: 1. Firm has submitted copy of FSC issue date 6th December 2018 (Not valid).			Assistant Abdul	Unit (code: AN203513) CV-70 Transportation Unit (code: CC652805) Connection Unit for DI-60 CF-70 (code: AH699752) Automated Hematology Slide Preparation Unit SP- 50 (code: BX765805) Reservoir tank RR-20 (code: CT932479) Reservoir Tank RR- 10 (code: BC479026) Reservoir Tank RR- 10 (w/O DCL) (code: AP594052) Reagent Unit RU-20 (code: CY662767) SA-01 Sampler Unit (code: CM660381) SA-10 Sampler Unit (code: CP366273) SA-20 Sampler Unit (code: CM186605) SA-21 Sampler Unit (code: CM186605)	3.5.1A.PM
AN617358) 75. Life Cares, M-20, Manufacturer: FORTUNE Wezzanine Floor Falaknaz Plaza Natha Khan AN617358) FORTUNE Weblicated due to following reason: 1. Firm has submitted copy of FSC (Family) + Silicone issue date 6th December 2018 (Not valid).			Assistant	CV979713) Automated Tube Sorter TS-10 (code: BN168792) TU-40 Transportation	
Mezzanine Floor Falaknaz Plaza Natha Khan FORTUNE MEDICAL Urological Catheters (Family) + Silicone Suprapubic Catheter valid). 1. Firm has submitted copy of FSC issue date 6 th December 2018 (Not valid).	7.5		6997,	AN617358)	
Falaknaz Plaza INSTRUMENT (Family) + Silicone issue date 6 th December 2018 (Not Valid).	75.				•
Natha Khan CORP. Suprapubic Catheter valid).				-	
				•	
		Natha Khan	CORP.		valid).

	Bridge, Shahra-e- Faisal, Karachi (ELI-00077)	6F, NO. 29, SEC.2 JHONGJHENG E RD DANSHUEI DISTRICT, NEW TAIPEI CITY, 251 TAIWAN Copy of FSC issued by Mo Health & Welfare, Republic of China	Shelf Life: Not provided Fee submitted: Rs. 50,000/-	2. Address on FSC is different from applied manufacturer address.3. multiple products applied in single application
		(Taiwan) No. 078737 dated 13-05-2020 ISO valid till 08-08- 2022	Osdir 1011	3:5:
		FQA/CE valid till 04- 09-2023	Oilloel, L	
76.	Rech International,	SERF: 85 Avenue des	SERF	Deferred for following reasons.
	247/B, Block-6 P.E.C.H.S Karachi	Bruyères, 69150 DECINES-	Femoral Head	 copy of LOA is not notarized. copy of FSC (France) is not
	F.E.C.H.S Karaciii	CHARPIEU,	remoral nead	legalized.
	(ELI-00257	FRANCE	RM-30100001	3. As per FSC its class D but firm has
	(EEI 00237	TWINGE	RM-30100002	applied in class C.
		Copy of LOA valid till	RM-30100003	4. Justification of applying Multiple
		05-10-2027.	RM-30100005	codes as single application.
	,		RM-30100006	5. clarification of brand name and
		Copy of FSC provided issued on 23-12-2020.	RM-30100007	generic name in FSC, LOA and applied name.
		135ucu on 25-12-2020.	Class C	аррией папіс.
			Shelf life 5 Years	. 5 .
		_	Fee 50,000/-	10
			-Cin-00, h	
77.	M/s. RECH	Legal Manufacturer:	Brand: Surgical	Deferred (Last opportunity) for;
	International	Changzhou Kanghui	Instrument	1. submission of original notarized
	Address: 247/B, BLOCK 6	Medical Innovation	Generic:	LOA and Termination letter of
	P.E.C.H.S, Karachi	Co., Ltd. located at	Surgical Instrument	Medtronic Pakistan for all devices
	1.2.C.11.5, Karacili	No.11 North Changjiang Road,	Class A Shelf Life: N/A	approved in 78th MDB meeting.2. Justification for applying multiple
	ELI: 00257	xinbei Zone,	SHEII LHE, IV/A	devices in single application.
		Changzhou Jiangsu	Models:	do 1200 in single application.
	R&I details	213022, P.R. China.		
	Date: 17-08-2020	450	QXB-09, QXB-14, ,	
		FSC: Germany	QXB-16, QXB-23,	
	Slip no. 1979607	Validity: Not		
	PKR 5000/-	mentioned, issued in	QXB-37, QXB-39,	
	Dated: 17-08-2020	Oct. 2022	QXB41, QXB-49,	

				,
			QXB-51, QXB-52,	
		LOA	QXB-55, QXB-56,	
		Validity: 31/12/2025	QXB-57, QXB-58,	
			QXB-59,	
			QXB60,QXB-69,	
			QXB-76, QXB-90,	
			QXB-91, QXB-92,	
			QXB-93, QXB-94,	
			QXB-113, QXB-	
			-	
			114,QXB-138, QXB-	511.
			139, QXB-149	
				3
78.	4S International,	Balton Sp. Z.o.o	Valver®-	Deferred for following reasons.
	Suit No, 205, 2nd	ul. Nowy Swait 7/14	Valvuloplasty Balloon	1. Firm has not submitted copy of
	Floor, Al-Fiza	street 00-496 Warsaw	Catheter	application Form.
	Glass Tower,	Poland	allo to	2. FSC of RRA not submitted.
	Rashid Minhas		U. 6),	3. Firm has submitted NB
	Road, Karachi	, 4/		confirmation letter attached but FQA
		401		and DE certificate not attached.
	(ELI-00290	360		4. NB confirmation letter is not
		65,00		notarized.
79.	Shirazi Trading	Legal manufacturer &	Posijet	Approved.
13.	Company Private	-	1 Osijet	Approved.
		Manufacturing Site	(Auto EDC Inicoton)	
	Limited	Lemer Pax located at	(Auto FDG Injector)	
	444 6 4134	72, Rue De Lorraine	<i>a</i> , <i>a</i>	
	114-C, Al Murtaza	44240 La Chapelle Sur	Class C	
	Commercial Lane	Erdre France	~	ON
	3, Khayaban-e-		Shelf Life:	- X
	Iqbal, Phase 8,	Date of R&I:	06 years (service life)	
	D.H.A., Karachi.	25.04.2024		
			Codes/Sizes:	0:3
	Establishment	Embassy attested FSC:	Z1102909 (GMDN	3
	Licence No.: ELI-	Country: France	Code)	19
	000263	Issued on 21.01.2023	- Co - Co	
		(No Validity date)	00 1	
		Notarized LOA	V 700.	
		Validity: 31.12.2023	Z1102909 (GMDN Code)	
		, andity. 31.12.2023	C	
		Notarized CE	7	
		Certificate Validian 20 04 2027		
		Validity: 20.04.2027		
		Notarized ISO 13485		
		Validity: 17.04.2025		

80.	Shirazi Trading	Legal manufacturer	Carestation 750C	Deferred for following reasons.
	Company Private	Datex Ohmeda Inc.		1. LOA, ISO of manufacturing site
	Limited	located at 3030	(Anaesthesia	has been notarized by Rizwan
		Ohmeda Drive, P.O	Workstation, general	Advocate Karachi instead of country
	114-C, Al Murtaza	Box 7550, Madison	purpose)	of origin.
	Commercial Lane	WI 3707-7550, U.S.A.	,	2. not clarified the relationship b/w
	3, Khayaban-e-	,	Class C	legal manufacturer and
	Iqbal, Phase 8,	Manufacturing Site		manufacturing site.
	D.H.A., Karachi.	GE Medical Systems	Shelf Life:	
	2 (11) 1, 110100	(China) Co. Ltd.	07 years (service life)	
	Establishment	located at No.19,	o, j (311,111,111,111,111,111,111,111,111,111	
	Licence No.: ELI-	ChangJiang Road	Codes/Sizes: 37710	0.,0
	000263	Wuxi National Hi-tech	(GMDN Code)	, D ,
	000203	Development Zone,	(GMDIT Code)	1
		Jiangsu, China	CIO OIL	
		Jiangsu, Ciina	00	
		Date of R&I:		
		24.04.2024	700.	
		24.04.2024	XOV	
		FSC:		
		Embassy attested		
		Country: U.S.A.		
		Validity: 23.05.2025		
		Compact contificate for		
		Copy of certificate for		
		exportation		
		Country: China		
		Validity: 20.04.2024		- X-Y-
		FSC:		5)\ ^B
		Reference Country:	11/21 22	
		1		3.
		Validity: 23.05.2025	030 411 6	
		validity. 25.05.2025	Oilectol 5052	, -
		Notarized LOA	, 100, 10,	
		Issuance date Validity:		
		15.09.2023	N. 70, ,	
		13.09.2023	400	
		(portrait vsm)	C	
		CE FQA Certificate		
		Validity: 26.05.2024		
		valuity. 20.03.2024		
		ISO 13485		
		Validity: 10.07.2024		
		(U.S.A.)		
		(U.S.A.)		
		Validity: 07.05.2026		
		(China)		
		(Cilina)		
<u></u>				

81.	Shirazi Trading Company Private Limited 114-C, Al Murtaza Commercial Lane 3, Khayaban-e- Iqbal, Phase 8, D.H.A., Karachi. Establishment Licence No.: ELI- 000263	Legal manufacturer Medtron AG located at Hauptstra be 255 66128 Saarbrücken Germany Manufacturing Site: Medtron AG located at Kreisstraße 152, 66128 Saarbrücken, Germany Date of R&I: 12.02.2024 Embassy attested FSC: Country: Germany Issued on 07.09.2022 (No validity date) FSC: Reference Country: Germany Issued on 07.09.2022 (No validity date)	Accutron HP Model 832 (Contrast Media Injector) Class C Shelf Life: 10 years (service life) Codes/Sizes: 57997 (GMDN Code)	Deferred for following reasons. 1. LOA has authorized M/s shirazi Trading Company & Atlas Global FZE Karachi and Dubai as distributor for Pakistan. 2. LOA has been Notarized by Rizwan Advocate Karachi instead of country of origin. 3. Firm has submitted general statement for 10 years life time/ shelf life of Medtron products (Injectors, remort controls and interfaces) instead of service life/ shelf life studies Accutron HP-D Model 832.
		LOA Validity: issuance date 07.02.2024 EC Certificate of conformity Validity: 20.01.2024 ISO 13485	Oadir 1011	3;5;1A,PM
		Validity: 20.01.2025	Jilos Lo	
82.	Shirazi Trading	Legal manufacturer	Accutron HP-D	Deferred for following reasons.
	Company Private	Medtron AG located at	Model 833	1. LOA has authorized M/s shirazi
	Limited	Hauptstra be 255		Trading Company & Atlas Global
		66128 Saarbrücken	(Contrast Media	FZE Karachi and Dubai as
	114-C, Al Murtaza	Germany	Injector)	distributor for Pakistan.
	Commercial Lane			2. LOA has been Notarized by
	3, Khayaban-e-	Manufacturing Site:	Class C	Rizwan Advocate Karachi instead of
	Iqbal, Phase 8,	Medtron AG located at	G1 167 16	country of origin.
	D.H.A., Karachi.	Kreisstraße 152, 66128	Shelf Life:	3. Firm has submitted general
	T 4 111 1	Saarbrücken, Germany	10 years (service life)	statement for 10 years life time/shelf
	Establishment	Data af DOI	C-1/C' 27201	life of Medtron products (Injectors,
	Licence No.: ELI-	Date of R&I:	Codes/Sizes: 37291	remort controls and interfaces)
	000263	12.02.2024	(GMDN Code)	

83.	M/s United	Embassy attested FSC: Country: Germany Issued on 07.09.2022 (No validity date) LOA Validity: issuance date 07.02.2024 EC Certificate of conformity Validity: 20.01.2024 ISO 13485 Validity: 20.01.2025 Legal Manufacturer	BMI External	instead of service life/ shelf life studies Accutron HP-D Model 833. Rejected due to following reasons.
63.	Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block-24, Karachi (ELI-00907)	& Site: Wellong Instruments Co., Ltd Address (as per form- 7A): 2F, 63 Linsen North Road Taipei, Taiwan. R.O.C. Address as per FSC: 5th Floor No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New	Drainage Monitoring System Class: D MD group: Family Shelf life: Not mentioned Storage condition: Room Temperature Codes & Sizes: 06128, 06140, 08182 Fee Challan No.: 2516483568 PKR: 62,000/-	1. Firm has submitted Form 7A without annexures and undertaking on stamp paper. 2. DE certificate and NB confirmation letter are not notarized. 3. The name and applied codes not mentioned on FSC. 4. copy of the FSC is notarized, not legalized.

0.4	Indian Darkham	T 1 N/L C 4	TDDI	A
84.	Imtiaz Brothers,	Legal Manufacturer:	TPRI	Approved in class B subject to
	Suite No. 7B, 2nd	Tianjin Plastics	Disposable Extra	change of brand name as same brand
	Floor, Abrar	Research Institute Co.,	Corporeal Circuit	name already issued to another firm.
	Business Center,	Ltd	Tube with Membrane	
	25 Main Wahdat	No. 24 Keda 1 Road,	Oxygenator (Infant)	
	Road, Lahore -	TEDA (Jinnan)		
	54600, Pakistan.	Microelectronics Park,	Class-D	
		Jinnan District, Tianjin,		Old,
	ELI-00133	People's Republic of	Shelf Life: 3 Years	
	5969-P	China, 300350		Sisila PM
	62,000/-		Model:	
		FSC: China.	Extra Corporeal	3.
		Date of Issuance: 13-	Circuit Tube with	
		05-2024 valid for 2	Membrane	'
		years LOA validity 31-	Oxygenator for Infant	
		12-2025		
		ISO 13485 validity 30-	N. 76,,	
		09-2026	400	
		CE certificate validity	C	
		26-05-2024 with		
		extension notification.		
85.	Imtiaz Brothers,	Legal Manufacturer:	TPRI	Approved in class B subject to
	Suite No. 7B, 2nd	Tianjin Plastics	Disposable Extra	change of brand name as same brand
	Floor, Abrar	Research Institute Co.,	Corporeal Circuit	name already issued to another firm.
	Business Center,	Ltd	Tube with Membrane	
	25 Main Wahdat		Oxygenator	
	Road, Lahore -	TEDA (Jinnan)	(Pediatric)	
	54600, Pakistan.	Microelectronics Park,		
		Jinnan District, Tianjin,	Class-D	5) A D:
	ELI-00133	People's Republic of		9 '2: \
	5970-P	China, 300350	Shelf Life: 3 Years	05:3
	62,000/-		030. 11	
		FSC: China.	Model:	"
		Date of Issuance: 13-	Extra Corporeal	
		05-2024 valid for 2	Circuit Tube with	
		years LOA validity 31-	Membrane	
		12-2025	Oxygenator for	
		ISO 13485 validity 30-	Pediatric	
		09-2026		
		CE certificate validity		
		26-05-2024 with		
		extension notification.		
86.	Imtiaz Brothers,	Legal Manufacturer:	TPRI Disposable	Approved in class B subject to
	Office Address	Tianjin Plastics	Extra Corporeal	change of brand name as same brand
	Suite No. 7B, 2nd	Research Institute Co.,	Circuit Tube -	name already issued to another firm.
	Floor, Abrar	Ltd, No. 24 Keda 1 Road, TEDA (Jinnan)	Cardioplegia Delivery System	
	Business Center,	Microelectronics Park,	System	
		Jinnan district, Tianjin,	Class-D	
		omman district, manifili,	C1400 D	

	25 Main Wahdat Road, Lahore. ELI-00133	People's Republic of China. FSC: China. Issuance: 13-05-2024	Shelf Life: 3 Year Codes as per FSC	
	5410-P 62,000/-	valid for 2 years.		
87.	Imtiaz Brothers, Office Address Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore. ELI-00133	Legal Manufacturer: Tianjin Plastics Research Institute Co., Ltd, No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan district, Tianjin, People's Republic of China.	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Adult) Class-D Shelf Life: 3 Year	Approved in class B subject to change of brand name as same brand name already issued to another firm.
	5130-P 62,000/-	FSC: China. Issuance: 13-05-2024 valid for 2 years.	Codes as per FSC	

Item No. II: <u>DEFERRED CASES OF LOCAL MANUFACTURING.</u>

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	Anax Associates Pvt Ltd.	Medpro By-Pass Drape Pack	Approved.
	Plot # 15, HDR Industrial Estate Next to	Class A	. 1
	Zaamin City Gajjumatah Lahore	Shelf Life: 3 Years	
	(ELM-000)	Fee: 6000	
	[610-6L]	Fee Slip No. 3511949383	
	Approved Section:	9qil (Mi. 3:2.	
	PPEs (Surgical & Non-Surgical Face mask	0.01, 0.00,	
	section and Protective suits/Surgical Gowns	-CI- 00	
	and Surgical Drape.	0 1	
2.	Anax Associates Pvt Ltd.	Medpro Cardiovascular Drape Pack	Approved.
	Plot # 15, HDR Industrial Estate Next to	Class A	
	Zaamin City Gajjumatah Lahore	Shelf Life: 3 Years	
	(ELM-000)	Fee: 6000	
	[610-6L]	Fee Slip No. 01997387	
	Approved Section:		
	PPEs (Surgical & Non-Surgical Face mask		
	section and Protective suits/Surgical Gowns		
	and Surgical Drape.		
3.	Anax Associates Pvt Ltd.	Medpro Advance Delivery Drape	Approved.
	Plot # 15, HDR Industrial Estate Next to	Pack	
	Zaamin City Gajjumatah Lahore		
	(ELM-000)	Class A	

	[610-6L]	Shelf Life: 3 Years	
		Fee: Fee Not attached	
	Prescribed fee slip not attached with		
	dossier.		
	Approved Section:		
	PPEs (Surgical & Non-Surgical Face mask section and Protective suits/Surgical Gowns and Surgical Drape.	(S)(A	SKI
4.	Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-000) [610-6L]	Medpro Liver Transplant Drape Pack Class A Shelf Life: 3 Years Fee: Fee Not attached	Approved.
	Prescribed fee slip not attached with dossier.	300 Not allicine	
	Approved Section:	Cr	
	PPEs (Surgical & Non-Surgical Face mask section and Protective suits/Surgical Gowns and Surgical Drape.		

Case No.1

Name
Sure Bio- Diagnostics & Pharmaceuticals
Address of Importer
EE-10, Defence View Phase-II, Near Igra University Shaheed-e-Millat
Express Way, Karachi.
Establishment License No. ELI-00084
LEGAL MANUFACTEURER
M/s. Wuhan Easy Diagnosis Biomedicine Co,. Ltd.
Company Address: Room 3 & 4, 2 nd floor, Bldg 25, Phase 3.1
Wuhan Optics Valley International Biopharmaceutical Enterprise
Accelerator. No.388, Gaoxin 2 nd RD, East Lake Hi-Tech
Development Zone, 430074 Wuhan, China
Contact: +86-27-65523649
Website: www.easydiagnosis.com
Easy Diagnosis Biomedicine D-Dimer (cluster of D Dimer,
Cystatin C, Ferritin (Fer) Test, Gastrin 17, Procalcitonin (PCT) Test
Kit, PGI/PGIIcombo test kit, S100-β protein (S100-β) Test Kit,
Serum Amyloid A (SAA) Test Kit, β Human Chorionic
Gonadotropin (β-HCG) Test Kit, Beta 2 Microglobulin (β2-MG)
Test Kit)
FSC:
China

	Validity: 18 Jan 2026
Date of application received along with	Date of R&I
Fee	14 May 2024
	Fee Amount & Fee Submission Date:
	Rs.25000
	16-05-2024
	Deposit Slip No: 584233359304
Class of medical device	В
Stability data/ service life	Shelf Life: 24 months
Documents submitted	qii (Mi, 3:2.
Marketing Authorization Letter:	Marketing Authorization Letter: (copy)
	Validity Date: 07-12-2024
Production Quality Management	101 CC 00
System Certificate (ISO 13485)	Production Quality Management System Certificate (Iso 13485)
	Validity Date: 26-01-2027
Full Quality Assurance Certificate or	
Equivalent:	*31 - 610
	Full Quality Assurance Certificate or Equivalent:
. 6	N/A
Design Examination	
X	
Declaration of Conformity (Doc):	Design Examination
	Not provided
	Declaration of Conformity (Doc):
5 · ·	Class B
Decision	The Board Approved above products as the firm has submitted separate
	application form 7A along with separate fee subject to submission of
	original legalized FSC of RRA.

Case No. 2

Name of product	Free Style Optium NEO Blood Glucose and Ketone Monitoring System		
	Registration No:	MDIR-0000664	
	Date of Registration:	11/09/2019	
D.C.	Class:	С	
	Brief Description: Glucos	se and Ketone Monitoring System	
Name and Address of	Abbot Laboratories (Pak	istan) Ltd.,	
Importer	Opposite radio Pakistan Tr	ansmission Center,	
	Hyderabad Road, landhi, Karachi. (ELI-00019)		
Name	Abbot Diabetes Care Ltd.,		
Address of Manufacturer	Range Road, Witney, OXON,		
	OX29 0YL, UK.		

Purpose/Request	M/s Abbot laboratory (Pakistan) ltd. Vide DRAP R&I 26892 dated 28			
	August 2025 has submitted under Rule 19(5) of MDR 2017 has that above			
	stated product has been discontinued from the legal manufacturer.			
Rule19(5) of MDR 2017	The manufacture or import of any medical device shall not, without prior			
	approval of the MDB, be discontinued for such period which may result in its			
	shortage:			
	Provided that in circumstances beyond control of a manufacturer or importer			
	of a medical device, which may lead to reduction in production or import of			
	that medical device, the circumstances may be intimated to the MDB. In case			
	of failure to comply, the enlistment or registration holder, as the case may be,			
	shall be held responsible for creating willful shortage leading to its black			
	marketing and the enlistment or registration may be suspended or cancelled			
	as the MDB may deem fit, after giving to the enlistment or registration holder			
	the opportunity of being heard.			
Remarks	Firm has not stated the reason for discontinuation.			
Decision of MDB	MDB decided to give personal hearing to the M/s Abbot Laboratories			
	(Pakistan) Ltd.			

Case No. 3

Name of Product	Brief Description	Class	Registration No.	Registration Date
i-STATE 6+ Cartridge	Intended for use in vitro quantification of sodium, potassium, chloride, glucose, BUN/Urea, Hct in arterial, venous, or capillary whole blood	С	MDIR-0002053	31.12.2020
i-STATE EC4+ Cartridge	Intended for use in vitro quantification of sodium, potassium, glucose and packed red blood cell volume fraction in arterial, venous, or capillary whole blood	C	MDIR-0002050	31.12.2020
ISTATE E3+ Cartridge	Intended for use in vitro quantification of sodium, potassium, glucose and packed red blood cell volume fraction in arterial, venous, or capillary whole blood	C	MDIR-0002450	07.04.2021
i-STATE CG+ Cartridge	Intended for use in vitro quantification of carbon dioxide partial pressure, oxygen partial pressure, pH, and lactate in venous, or capillary whole blood	С	MDIR-0002052	31.12.2020
Name and Address of Importer	Abbot Laboratories (Pakistan) Lo Opposite radio Pakistan Transmissi Hyderabad Road, landhi, Karachi.	on Center,))	
Name Address of Manufacturer	Abbot Point of care Inc., 100 and 200 Abbot Park Road, Abbot Park, IL, 60064 USA.			
Purpose/Request	M/s abbot laboratory (Pakistan) ltd. Vide DRAP R&I <u>26893</u> dated 28 August 2025 has submitted under Rule 19(5) of MDR 2017 has that above stated product has been discontinued from the legal manufacturer.			

Rule19(5) of MDR 2017	The manufacture or import of any medical device shall not, without prior			
Kule19(3) 01 WIDK 2017				
	approval of the MDB, be discontinued for such period which may result in its			
	shortage:			
	Provided that in circumstances beyond control of a manufacturer or importer			
	of a medical device, which may lead to reduction in production or import of			
	that medical device, the circumstances may be intimated to the MDB. In case			
	of failure to comply, the enlistment or registration holder, as the case may be,			
	shall be held responsible for creating willful shortage leading to its black			
	marketing and the enlistment or registration may be suspended or cancelled			
	as the MDB may deem fit, after giving to the enlistment or registration holder			
	the opportunity of being heard.			
Remarks	Firm has not stated the reason for discontinuation.			
Decision of MDB	MDB decided to give personal hearing to the M/s Abbot Laboratories			
	(Pakistan) Ltd.			

(Pakistan) Ltd.					
Case No. 4	"110-60,00	9			
Firm name	Request				
M/S Zybio Inc., No. 45. Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China	The FOREIGN MANUFACTURER vide DRAP R&I No. 3162 dated 29.08.2025 has submitted original letter (not notarized) that We. M/S Zybio Inc., a company incorporated in China located at No. 45. Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China hereby states that we had duly applied for the registration of the products listed in the attached document in Pakistan, authorizing ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED as our sole distributor for the import and sale of these products in the country. It has come to our attention that another company. Ayyan Moleculer Products, 43/11, FCC villas Muratib Ali Road, Gulberg-IV, Lahore (ELI-00721) has illegally used our documents without our consent or authorization to apply for the registration of the same products under our brand name. Disturbingly, they have obtained registration certificates for these products through this unauthorized action. We humbly request DRAP to immediately cancel their registrations for these products and take appropriate action in accordance with the relevant laws and regulations, as their actions constitute a clear violation of our intellectual property and distribution rights.				
Details of the products enclosed wi		Class	D N -	D 1-4-	
Product Name Zybio Nucleic Acid Detection Kit (Magnetic Bead Method) (RNA/DNA Extraction Kit)	Model B-200, T-200 (B-2008T/Kit 16T/Kit, 20T/Kit, 32T/Kit T-200: 32T/Kit, 96T/Kit)	B B	Reg. No MDIR-0007907	Reg. date 25.02.2025	
Zybio cluster for C-reactive proteins (immunoturbidimetric method)	CRP kit (CRP RI, CRP R2. CRP Calibrator, CRP Control)	В	MDIR-0007908	25.02.2025	
Zybio cluster for liver function tests	Total bilirubin, Alanine aminotransferase, aspartate aminotransferase, direct bilirubin	В	MDIR-0007909	25.02.2025	
Zybio cluster for Substrates	Urea, glucose, triglyceride, uric acid	В	MDIR-0007910	25.02.2025	

Zybio cluster for enzymes	Lipase, alkaline phosphatase, lactate	В	MDIR-0007912	25.02.2025	
	dehydrogenase, gamma glutamyl				
	transferase				
Zybio cluster for transport proteins	Albumin, glycated hemoglobin, total	В	MDIR-0007913	25.02.2025	
	protein				
Zybio MG (Magnesium kit)		В	MDIR-0007914	25.02.2025	
Zybio Hematology analyzer	Z50	A	MDIE-0000969	25.02.2025	
Zybio Chemistry Analyzer	EXC200	A	MDIE 0000968	25.02.2025	
Zybio Diluent Z5 DN, LYSE Z5	Z5 DN, Z5 LD, Z5 LB	A	MDIE 0000964	25.02.2025	
LD, LYSE Z5 LB	25.				
Zybio Hematology Analyzer	Z3 CRP	A	MDIE-0000966	25.02.2025	
Zybio probe cleanser	0000	A	MDIE-0000967	25.02.2025	
Zybio Diluent LYSE	20Lx1,10Lx1	A	MDIE-0000965	25.02.2025	
Zybio Lyse	500mL/Bottle, 250mL/Bottle	A	MDIE-0000965	25.02.2025	
Decision of MDB	The board decided to call both firms for personal hearing alongwith valid				
	Notarized Letter of authorization and valid Notarized termination letter, as the				
	case may be, issued by foreign manufacturer M/S Zybio Inc., China before further				
	processing the case.	·	· ·		

CASE NO.5

Name	M/s DKT Pakistan (Pvt.) Limited, RJ, Building, 4th Floor, Plot No. 37-C,		
Address of Importer	Stadium Lane, Comm. Area, Phase V, DHA, Karachi		
	ELI-00515 dated 06-02-2020		
Request Title	Change of Management		
Existing Management	Syed Sadaqat Ali Jafr, 79-Shah Taj Colony, Walton Road, Lahore CNIC: 42201-0312901-9		
	Muhammad Dawar Waraich, House No. 77, Gali No. 10, MohallahKhayaban-e-Badar, Phase 6, DHA, Karachi CNIC: 42301-3088394-9		
	Mr. Christopher Houston, 3614-Quesada Street NW Washington DC, USA P.No.483712287		
Proposed Management	Mr. Christopher Houston, California, USA P.No.567674939 Mr. Georgios Papachristou, Flat No.2401, Pearl Tower II, Emaar, DHA Phase VIII, Karachi.		
	P.No.AT1147253		
Remarks	 Application on Form-2. Fee of Rs.12,500/- (for change of management. Copies of Passports of proprietors. Undertaking and Declaration on stamp paper signed by Mr. Fawaded 		

	Jokhio, Director Business Development not by Proprietors.
	SECP documents (Form-29) does not show any entry of outgoing and
	incoming proprietors.
MDB Decision in 76th Meeting	Deferred for provision of the following:
	 SECP documents (Form-29 or any other document) duly verified by SECP which indicate exit of the outgoing Directors & entry of the incoming Directors. Authorization of Mr. Fawaded Jokhio as signatory for legal documents such Declaration, Undertaking & Form-2 etc. by the management/ owner of the company.
	The Board also advised to take legal opinion if foreigner (non-Pakistani) Directors can be the approved as Director wherein no Pakistani citizen is in the management (as Director as per SECP).
Opinion from Legal Affairs division.	DRAP has no authority to register a person as director in company. It is domain of the SECP to incorporate a foreign national as Director. If SECP registered a foreigner as director in a company and the company submitted the certified copy of Form-29 with foreign national directors, then the same may be processed in accordance with law.
Remarks	Firm has not replied to the above decision of MDB
Decision of MDB	The Board deferred the case and directed the firm to submit. 1. SCEP documents (Form-29 or any other document) duly verified by SECP which indicate exit of the outgoing Directors & entry of the incoming Directors. 2. Authorization of Mr. Fawaded Jokhio as signatory for legal documents such Declaration, Undertaking & Form-2 etc. by the management/ owner of the company.
Remarks	Abdul Gadir, (MIS). 5:1A.P. is sistant Director, 2025, 3:5:1A.P. is sistant Director,

ADDITIONAL AGENDA

DEFERRED CASES OF IMPORT

S#	Importer Name	Manufacturer	Name of MD / Class /	Decision
		Details	Codes / Shelf life / etc.	
1.	Kokab Enterprises	Manufacturer:	Belzer UW Cold	Decision of MDB. The MDB
	No. G-56, Billys Shoppers	Preservation	Storage Solution	decided to give opportunity to
	Galleria, Gulistan-e-	Solutions Inc.		M/s Kokab Enterprises No. G-
	jauhar, Block 18, Karachi	1099 Proctor Drive,	1(5)	56, Billys Shoppers Galleria,
		Elkhorn, WI 53121	Class D	Gulistan-e-jauhar, Block 18,
	(ELI-00544)	USA	911 112 3	Karachi, to:
			Shelf life 24 months	
	Evaluator:	\ G	, 70, ⁷ 0,5,	I. Define the role as
	AD-IV		Co. UO	manufacturer of M/s
	[3599]	1000011	0 , 1	Carnamedica Spolka z
		VA O		Organiczona
			70	Odpowiedzialnoscia ul.
		40, 41	9	Olszynki Grochowskiej
		3500		21 lok, U6, 04-281
		65, 03		Warszana, Poland and
				Preservation Solutions Inc.,
		1		USA and link between
		700		them.
		50		II. Submit original valid
				notarized authorization
				letter from manufacturer
				III. Original notarized
			.6)	cancellation of LOA of M/s
				Healthline
			711 " (12, 3)	Pharmaceuticals, Lahore.
			30. 11	IV. Firm will also submit
		, G	, *O, *U.S.,	complete copy of the
			~C/~ ~O/	initially submitted file.
2.	M/s Zenith International,	Legal	Perfect Disposable	Approved in class D subject to
		Manufacturer &	Spinal Needle	submission of differential fee
	Room# 104, Tahir Plaza,	Site: Zhejiang	(Quincke Bevel type	for family.
	A/20, Block 7&8,	runqing Medical	Class: C	
	KCHSU, Karachi	Instrument Co., Ltd	MD group: Single	
	(ELI-00090)	Address as per	Shelf life: 5 years	
		Form-7A & China	-	
		FSC:	Codes & Sizes	
		599 Ruifeng Street,	(guage):	
		Gaozhao District,	18,19,20,21,22,23,24,2	
		Xiuzhou Jiaxing City	5,26 & 27.	
		zhejiang, China	,	
		Address as per	Fee Challan No.:	
		FQA:	6193522908	
		rya.	0173344300	

		No. 618 Dade Road, Jiaxing Xiuzhou District 314031 Jiaxing City, China FSC Validity 18-09-2026 (China) valid upto 26-03- 2025 FSC (Spain) Date of Issuance 10- 10-2024 ISO 13485 Certificate validity: 06-05-2025 EC (FQA) Certificate valid	PKR: 62,000/- Dated: 12-12-2024	S. A. P. M.
3.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	upto 06-05-2023 LOA Validity: 29-04-2029 Manufacturer: The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. FSC: UK issue date 16.08.2022 valid till 19-08-2027 (embassy attested Submitted in Optilite® Freelite® Kappa Free Kit)	Optilite® Freelite® Lambda Free Kit Class C Shelf Life: 18 months Code:- LK018.OPT Date of Submission: 31-05-2023 Fee submitted: Rs. 50,000/- Storage temperature: Store at temperature 2- 8°C	Approved.
4.	M/s Labserv, House No. B-165/2 Block 3A Gulistan e Jauhar, Scheme 36, Karachi. Lic. No. ELI-00105	Manufacturer: The Binding Site Group Limited, 8 Calthrope Road Edgbaston, Birmingham, B15 1QT, United Kingdom. FSC: UK issue date 16.08.2022 valid till 19-08-2027	Optilite® Freelite® Kappa Free Kit Class C Shelf Life: 18 months Code:- LK016.OPT Date of Submission: 31-05-2023 Fee submitted: Rs. 50,000/-	Approved.

	(embassy attested	Storage temperature:	
	Submitted	Store at temperature 2-	
		8°C	

CASE NO. 5

Name	Name	
Address of Importer	M/S Briogene Pvt Ltd	
	Address of Importer	
	196-A, Sindhi, Muslim Cooperative Housing Society, Shahrah-e-Faisal,	
	Karachi	
Detail of ELM/ELI	ELI-00015	
Name	(LEGAL MANUFACTEURER)	
Address of	Qiagen GmbH, Qiagen Strasse 1, 40724, Helden, Germany	
Manufacturer	(Manufacturing site)	
	Veracyte SAS, 163, Avenue de Luminy, 13009, Marseille, France	
Brand Name	IPSOGEN® BCR-ABL 1 MBCR IS-MMR DX Kit Cat # 670823 (24)	
Date of application	Date	
received along with	21 December 2023	
Fee	Fee	
	Rs. 50,000/ through slip no. 14537699678, dated 14.12.2023	
Class of medical device	C	
Stability data/ service life	Shelf Life: 36 months	
Decision	Deferred for submission of valid, Notarized LOA (with device name as applied) and notarized valid ISO 13485 plant of France.	

	applied) and notarized valid ISO 13485 plant of France.			
	LOCAL MANUFACTURING CASES Hafiz Muhammad Asif Iqbal (Deputy Director-VII)			
Sr.	Name & Address of Establishment	Name of Medical Devices With	Decision	
No.		Size		
1.	M/s Global Health Care Private Limited,	Yonker Syringe Pump	Board approved the	
	Plot No. 3A, N4, RCC Industrial Area		device in Class C subject	
	Rawat, Islamabad	Class: B	to submission of	
		Shelf Life: 5 Years	differential fee of class C	
		Fee: 25000	device as per S.R.O.	
	Approved Sections:	Fee Slip No. 6864370075	1399(I)/2025 dated 1st	
	1. Assembling Filling Packaging,		August, 2025.	
	Labelling & Testing of Reagents Kits			
	2. Cutting Assembling Packaging Labelling			
	& Testing of Rapid Test Kits			
	3. Assembling Section (Patient Monitor,			
	Vital Sign Monitor, ECG Machine			

	I I I I I I I I I I I I I I I I I I I		
	Ultrasound, Arm Blood Pressure		
	Monitor, Nebulizer, Infrared		
	Thermometer, Syringe Infusion Pump &		
	Pulse Oximeter)		
2.	M/s Global Health Care Private Limited,	Periomed Ultrasound Machine	Approved
	Plot No. 3A, N4, RCC Industrial Area		
	Rawat, Islamabad	Class: B	
		Shelf Life: 5 Years	
		Fee: 25000	
	Approved Sections:	Fee Slip No. 71930338981	N. 1
	1. Assembling Filling Packaging,	1,51	
	Labelling & Testing of Reagents Kits		
	2. Cutting Assembling Packaging Labelling	911 / (1, 3, 2, 2)	
	& Testing of Rapid Test Kits	030 (1)	
	Assembling Section (Patient Monitor, Vital	G, *0, *U;,	
	Sign Monitor, ECG Machine Ultrasound,	CC OO	
	Arm Blood Pressure Monitor, Nebulizer,		
	Infrared Thermometer, Syringe Infusion		
	Pump & Pulse Oximeter)	700	
3.	M/s Global Health Care Private Limited,	Yonker ECG Machine	Approved
	Plot No. 3A, N4, RCC Industrial Area	C	rr · · · · ·
	Rawat, Islamabad	Class: B	
	(2° 0'3	Shelf Life: 5 Years	
	Approved Sections:	Fee: 25000	
	1. Assembling Filling Packaging,	Fee Slip No. 41815703	
	Labelling & Testing of Reagents Kits	and the state of	
	2.Cutting Assembling Packaging Labelling		
	& Testing of Rapid Test Kits		
	3. Assembling Section (Patient Monitor,		
	Vital Sign Monitor, ECG Machine		OB.
	Ultrasound, Arm Blood Pressure		A. X
	Monitor, Nebulizer, Infrared	(6)	VK.
	Thermometer, Syringe Infusion Pump &		
	Pulse Oximeter)		
4.	M/s Global Health Care Private Limited,	Yonker Nebulizer	Approved
7.	Plot No. 3A, N4, RCC Industrial Area	Tonker redunzer	Approved
	Rawat, Islamabad	Class: B	
	Kawat, Islamabau	Shelf Life: 5 Years	
	Annayad Sactions	Fee: 25000	
	Approved Sections: 1. Assembling Filling Packaging,	Fee Slip No. 653047191	
	Labelling & Testing of Reagents Kits	1 CC 511p 1vo. 05504/151	
	2.Cutting Assembling Packaging Labelling	C	
	& Testing of Rapid Test Kits	7	
	3. Assembling Section (Patient Monitor,		
	· · · · · · · · · · · · · · · · · · ·		
	Vital Sign Monitor, ECG Machine		
	Ultrasound, Arm Blood Pressure		
	Monitor, Nebulizer, Infrared		
	Thermometer, Syringe Infusion Pump &		
<u> </u>	Pulse Oximeter)	W 1 D1 1D 37	D 1
5.	M/s Global Health Care Private Limited,	Yonker Blood Pressure Monitor	Board approved the
	Plot No. 3A, N4, RCC Industrial Area	Class: B	device in Class C subject to submission of
	Rawat, Islamabad		to submission of

		Shelf Life: 5 Years	differential fee of class C
	Approved Sections:	Fee: 25000	device as per S.R.O.
	1. Assembling Filling Packaging,	Fee Slip No. 33245310951	1399(I)/2025 dated 1st
	Labelling & Testing of Reagents Kits	1 ce ship 1 to. 332 + 3310 / 31	August, 2025.
	2.Cutting Assembling Packaging Labelling		1145451, 2025.
	& Testing of Rapid Test Kits		
	3. Assembling Section (Patient Monitor,		
	Vital Sign Monitor, ECG Machine		
	Ultrasound, Arm Blood Pressure		
	Monitor, Nebulizer, Infrared		
	Thermometer, Syringe Infusion Pump &	.61 4	Dk .
	Pulse Oximeter)		•
6.	M/s Global Health Care Private Limited,	Yonker Infusion Pump	Board approved the
0.	Plot No. 3A, N4, RCC Industrial Area	Tomes unasion Tamp	device in Class C subject
	Rawat, Islamabad	G, "U, "U, D,	to submission of
	2.u. // u., 2.2u. i.u. u.	Class: B	differential fee of class C
	Approved Sections:	Shelf Life: 5 Years	device as per S.R.O.
	1. Assembling Filling Packaging,	Fee: 25000	1399(I)/2025 dated 1st
	Labelling & Testing of Reagents Kits	Fee Slip No. 7683296653	August, 2025.
	2. Cutting Assembling Packaging Labelling	XO*	
	& Testing of Rapid Test Kits	0-	
	3. Assembling Section (Patient Monitor,	/	
	Vital Sign Monitor, ECG Machine		
	Ultrasound, Arm Blood Pressure		
	Monitor, Nebulizer, Infrared		
	Thermometer, Syringe Infusion Pump &		
	Pulse Oximeter)		
7.	M/s Global Health Care Private Limited,	Yonker Patient Monitor	Approved
	Plot No. 3A, N4, RCC Industrial Area		
	Rawat, Islamabad		X
		Class: B	Dx *
	Approved Sections:	Shelf Life: 5 Years	
	1. Assembling Filling Packaging,	Fee: 25000	
	Labelling & Testing of Reagents Kits	Fee Slip No. 812356052443	
	2. Cutting Assembling Packaging Labelling	G, "U, U,	
	& Testing of Rapid Test Kits 3. Assembling Section (Patient Monitor,	- Ci - Oi	
	Vital Sign Monitor, ECG Machine	Direct 20	
	Ultrasound, Arm Blood Pressure		
	Monitor, Nebulizer, Infrared	700	
	Thermometer, Syringe Infusion Pump &	XO*	
	Pulse Oximeter)	0.	
8.	M/s Global Health Care Private Limited,	Enzymes	Deferred for the
	Plot No. 3A, N4, RCC Industrial Area	<i>J</i>	submission of the
	Rawat, Islamabad	α-Amylase (α-AMY) Assay	justification of grouping
	123	Kit, Creatine Kinase (CK)	Multiple kits of different
	Approved Sections:	Assay Kit, Creatine Kinase MB	class as Cluster and
	1. Assembling Filling Packaging,	(CK-MB) Assay Kit and	Brand name of the
	Labelling & Testing of Reagents	Lactate Dehydrogenase (LDH)	product
	Kits		=
	2. Cutting Assembling Packaging Labelling	Assay Kit	
	& Testing of Rapid Test Kits	Shelf Life: α-Amylase (α-	
	1	Short Bire. w-runyiase (w-	

	3. Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)	AMY) Assay Kit and Creatine Kinase MB (CK-MB) Assay Kit: 12 months Creatine Kinase (CK) Assay Kit and Lactate Dehydrogenase: 13 months Class: B R & I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 3815349909 Fee Submitted on: 02/06/2025	APM
9.	M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad Approved Sections: 1. Assembling Filling Packaging, Labelling & Testing of Reagents Kits 2. Cutting Assembling Packaging Labelling & Testing of Rapid Test Kits 3. Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)	Liver Function Tests Alanine Aminotransferase (ALT) Assay Kit, Aspartate Aminotransferase (AST)/SGOT) Assay Kit, Alkaline Phosphatase (ALP) Assay Kit, γ- Glutamyltransferase (GGT) Assay Kit, Total Bilirubin (TBIL) Assay Kit, Direct Bilirubin (DBIL) Assay Kit Shelf Life: 12 Months Class: B R & I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 69798237	Deferred for the submission of the justification of grouping multiple kits in single application and Brand name of the product
10.	M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad Approved Sections: 1. Assembling Filling Packaging, Labelling & Testing of Reagents Kits	Serology Tests Antistreptolysin O (ASO) Assay Kit, Rheumatoid Factor (RF) Assay Kit, C-reactive Protein (CRP) Assay Kit Shelf Life: 13 months	Deferred for the submission of the justification of grouping multiple kits in single application and Brand name of the product

	2. Cutting Assembling Packaging Labelling	Class: B	
	& Testing of Rapid Test Kits 3. Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine	R & I Details: File submitted on 05/06/2025	
	Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump &	Rs. 25,000/-	
	Pulse Oximeter)	Slip No: 44445638	
11.	M/s Global Health Care Private Limited,	Lipid Profile Test	Deferred for the
	Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad	Total Cholesterol (CHO) Assay Kit and Triglycerides (TG)	submission of the justification of grouping multiple kits in single application and
	Approved Sections:	Assay Kit	Brand name of the
	1. Assembling Filling Packaging,	Shelf Life: 12 months	product
	Labelling & Testing of Reagents Kits	Class: B	
	2. Cutting Assembling Packaging Labelling& Testing of Rapid Test Kits3. Assembling Section (Patient Monitor,	R & I Details: File submitted on 05/06/2025	
	Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure	Rs. 25,000/-	
	Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)	Slip No: 863511594841	
12.	M/s Global Health Care Private Limited,	Renal Function Tests	Deferred for the
12.	Plot No. 3A, N4, RCC Industrial Area	Renai Function Tests	submission of the
	Rawat, Islamabad	Creatinine (CREA-E) Assay	justification of grouping
	Nawat, Islamabaa	Kit, Urea (UREA) Assay Kit,	multiple kits in single
	*	Albumin (ALB) Assay Kit,	application and
	Approved Sections:	Total Protein (TP) Assay Kit,	Brand name of the
	1. Assembling Filling Packaging,	Uric Acid (UA) Assay Kit,	product
	Labelling & Testing of Reagents	Urine Microalbumin (UMA)	_
	Kits	Assay Kit)	
	2. Cutting Assembling Packaging Labelling & Testing of Rapid Test Kits	G, "U, "U, 3,	
	3. Assembling Section (Patient Monitor,	Shelf Life: 12 months	
	Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure	Class: B	
	Monitor, Nebulizer, Infrared	R & I Details: File submitted on	
	Thermometer, Syringe Infusion Pump &	05/06/2025	
	Pulse Oximeter)	Rs. 25,000/-	
	182 U.B	Slip No: 09464377012	

Item No. V: MISCELLANEOUS CASES.

Deputy Director-I (Saadat Ali Khan)

Case No.1: M/S Briogene Pvt Ltd, Karachi

The following products of Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e-Faisal, Karachi was approved in 78th meeting of MDB subject to submission of requisite Fee as per SRO 1324(I)/2024 dated 30th August, 2024. The details are as under:

Manufacturer	Products details	Decision of 78th meeting
		of MDB
Thermo Fisher Scientific Oy,	Brand Name	Approved both types
Ratastie 2,FI-01620 Vantaa, Finland	Indiko Plus	subject to submission of
	Indiko Plus with ISH	revised form-7A and
FSC Country of Origin: Finland	Generic Name;	differential fee as the
Date of Issuance: 12-Sep-2024	Indiko Plus 98640000	product fall in Class B and
ISO 13485	Indiko Plus with ISE 98641000	form and fee for Indiko
Expiry: 31-3-2027.	Class A	Plus with ISH.
	Shelf Life: N/A	
Date of submission: 14th July 2023	Codes / Sizes (if any): 98640000,	
Fee submitted: PKR 5,000/-	98641000	
Tracking id:	LOA validity:	
SLA-QB8-L6NS	27th January 2026	

Now the firm has submitted that the applied product is fall in Class-A, for this purpose the firm provided copy of Declaration of Conformity (DOC) wherein the applied product is classified in IVD General. The firm also provided copy of document 'Statement Concerning validity of IVDD EC Declaration of Conformity during the EU IVDR transition Period", wherein it has been mentioned that the applied products are classified as Class A product.

Decision: the Board approved both the products Indiko Plus 98640000 and Indiko Plus with ISE 98641000 in Class A. Firm will submit separate fee of Class A for Indiko Plus with ISE 98641000.

The meeting ended with vote of thanks to and from the Chair.
