

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

DECISIONS OF 101ST MEETING OF THE MEDICAL DEVICE BOARD (MDB)
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:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
3.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
5.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member
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 Engineer	Co-Opted Expert (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 / Codes / Shelf life / etc.	Decision
1.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#0583362272	M/s Taidoc Technology 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 04-03-2024 wherein the product (TD-4255) is mentioned as Blood Glucose Monitoring System. (Copy) ISO Certificate: 01-03-2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy)	Clever Chek Glucometer TD-4255 Glucometer Applied as: Single Class-C Shelf life: 7 years Models: -TD-4255	Rejected due to following reasons: 1. Brand Name of product applied is different in application form, free sale certificate of Germany 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.
2.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore	M/s Taidoc Technology Corporation, B1-7F, No. 127, Wugong 2 nd Road Wugu District,	Clever Chek Glucometer Strips TD-4255 Glucometer Strips	Rejected due to following reasons: 1. Brand Name of product applied is different in application form, free sale certificate of Germany and in 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-4255) is mentioned as Blood Glucose Monitoring System. (Copy) ISO Certificate: 01-03-2026 (Copy) EC Certificate (FQA): 26-05-2025 (Copy)	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.
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#690230281078	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 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)		
6.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#8074211565	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) EC Certificate (FQA): 26-05-2025 (Copy)	CC Super Glucometer Strips TD-4267 (as per Form-7A) CC Fast Strips TD-4267 (as per covering letter & fee slip etc.) Glucometer Applied as: Single Class-C Shelf life: :- 25.6 months 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.
7.	Muslim Scientific Corporation Address:- 3,Syed Moj Darya Road Lahore (ELI-00431) Date of R& I 11-04-2025 Fee: PKR 62,000/- Slip#05298657872	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 not provided. ISO Certificate validity 01-03-2026 (Copy)	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.

		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	<u>Legal Manufacturer:</u> 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.	<u>Applicant Name:</u> Muslim Medical Services, 1 st Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore ELI-00373 Date of R&I 13-02-2025 <u>Fee Details:</u> Paid Fee: 31,000/- Fee Challan No: 603857485 Dated:	<u>Legal Manufacturer:</u> 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.	<u>Applicant Name:</u> Muslim Medical Services, 1 st Floor of Sky Star Travels, 3-Syed Moj Darya Road, Lahore ELI-00373 Date of R&I 13-02-2025 <u>Fee Details:</u> Paid Fee: 31,000/- Fee Challan No: 603857485 Dated:	<u>Legal Manufacturer:</u> Beurer GmbH, SoeflingerStrasse 218, 89077 Ulm Germany <u>LOA Validity:</u> 31-12-2025 <u>FSC: Germany</u> <u>Issue date:</u> 23-01-2025 <u>ISO Validity:</u> 29-11-2026 EC Certificate Validity: 26-05-2024	<u>Beurer Nebulizer</u> 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	<u>Legal manufacturer:</u> 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/-	<u>Legal Manufacturer:</u> 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/-	<u>Legal Manufacturer:</u> 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/-	<u>Legal Manufacturer:</u> 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.

15.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal- e-Haq Road, Blue Area, Islamabad. ELI-00183 1511-Ibd 6,000/-	<u>Legal Manufacturer:</u> 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 Adhesive Adhesive for skin grafting Class-A Shelf Life: 4 Years Codes: 2.9190	approved
16.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal- e-Haq Road, Blue Area, Islamabad. ELI-00183 1507-Ibd 6,000/-	<u>Legal Manufacturer:</u> 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 Microgratf gauze Sterile woven Guaze Pad Class-A Shelf life: 4 years Codes: 2.2/10, 2.3/10, 2.3/40, 2.4/10, 2.4/40, 2.6/10, 2.6/40, 2.9/10, 2.9/40	approved
17.	Medequips SMC Pvt Ltd, 30-Shahrah E Quaid E Azam, Lahore, 54000, Pakistan. ELI-00362 7023-P	<u>Legal Manufacturer:</u> MEDISONO LLC. 3016 NW 82nd Avenue, Doral, FL 33122, USA. FSC: USA. Date of Validity: 23- 10-2026. LOA issuance 05-12- 2024 ISO 13485 missing. 510k No. K231659 for P11 Plus	MS12 Digital Color Doppler Ultrasound System and P11 Plus Digital Color Doppler Ultrasound System (Digital Color Doppler Ultrasound System) Class-B Service life: 7 years Model as per FSC	Rejected due to reason that firm has not submitted. 1. ISO 13485:2016 certificate. 2. Fee for the system. 3. Justification for applying two devices MS12 Digital Color Doppler Ultrasound System and P11 Plus Digital Color Doppler Ultrasound System in single application.
18.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) Date of R&I	<u>Legal Manufacturer:</u> Roche Molecular Systems Inc. 1080 US Highway 202 South Branchburg, NJ 08876 USA <u>Manufacturing Site:</u>	Cobas MPXV Class: D Fees: 50,000/- Shelf life: 1. 11 months at 2 - 8°C	Deferred for personal hearing. Firm has to submit the FSC of country of origin and Design Examination certificate.

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

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

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

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

	PECHS Yaseen Suleman Street Near Faran Hotel Shahrah e Faisal, Karachi, Pakistan (ELI-00257)	587 Warsaw, Indiana USA		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 VENTILATOR 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 INTERNATIONAL 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 25000/- Slip: 2006272 Dated: 09-07-2020	26-06-2028		
34.	TRI-TECH INTERNATIONAL 10-C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, KARACHI, PAKISTAN (ELI-00247)	ELMASLAR IMALAT TIBBI CIHAZLAR INS. TAS. ITH.IHR.SAN. Ve TIC.A.S., 1.ORGANIZE SAN. BOL.BABURSAH CAD. NO:17 SINCAN/ ANKARA TURKIYE	Lifetime Surgical Aspirator SA01HT	Approved.
35.	Samzco Trading Company, Office No. 501,, Imperial Optical Center, Masjid Street, Ghari Khatta M. A Jinnah Road, Karachi (ELI-00685) Dossier#4646-7A Date:19-07-22	Legal Manufacturer: Wohlk Contactlinsen GMBH BurgerMeister-Schade- Str.12, 24232 Schon kirchen, Germany FSC: not provided.	Zeiss Contact Day 1 (Contact Lenses) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Rejected due to following reasons. 1. Firm has not clarified that applied lens is spheric, toric or multifocal. 2. Device applied as Class c but as per DOC its Class IIa (B). 3. Firm has not submitted manufacturer credentials. 4. Firm has not submitted stability studies. 5. ISO 13485 and DOC not notarized.
36.	Samzco Trading Company, Office No. 501,, Imperial Optical Center, Masjid Street, Ghari Khatta M. A Jinnah Road, Karachi (ELI-00685) Dossier#4877-7A Date:07-07-22	Legal Manufacturer: Wohlk Contactlinsen GMBH BurgerMeister-Schade- Str.12-6 24232 Schon kirchen, Germany FSC: not provided.	Zeiss Contact Day 30 (Contact Lenses) Codes & Sizes: As per FSC Class-C Shelf Life: 05 years	Rejected due to following reasons. 1. Firm has not clarified that applied lens is spheric, toric or multifocal. 2. Device applied as Class c but as per DOC its Class IIa (B). 3. Firm has not submitted manufacturer credentials. 4. Firm has not submitted stability studies. 5. ISO 13485 and DOC not notarized.
37.	SIND MEDICAL STORES, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi – 75400, PAKISTAN	DiaMed GmbH Pra Rond 23, 1785 Cressier FR Switzerland. <u>Head Quarter (Parent Company):</u>	HAM's ACID RED CELL TEST IVD, REAGENT (FAMILY) Class – B	MDB acceded the request of the firm to withdraw the application and Rejected application.

	Lic. No.ELI-00010	Bio-Rad Laboratories Inc., 1000 Alfred Nobel Drive, Hercules, California 94547-USA. <u>European HQ:</u> Bio-Rad Europe GmbH, Holbeinstrasse 75, 4051 Basel, Switzerland. FSC Switzerland Valid Till (18.10.2022) ISO 13485:2016 Certificate Valid till (30.10.2021) LOA Valid until (31.12.2020)		
38.	WIS International (Pvt) Ltd, Office no. 910, 9th Floor, Business Avenue Building, plot No. 26-A, Block 6, P.E.C.H.S, Karachi ELI NO. 00659 Dossier#313-C Date:30-11-22 Submitted Fee: 50,000/-PKR Challan No.: 646878823471 Evaluator: DD-II	Legal Manufacturer: Suzhou Sunan Zimmered Medical Instrument Co., Ltd South Jiankang Road, Hexing, Jinfeng Town, Zhanjiagang, 215626 Jiangsu P.R. China FSC China issued 15-09-2022	ZMD Compression Bone Plates Codes & Sizes: ZSQ01, ZSQ02, ZSQ03, ZSQ04, ZSQ05, ZSQ06, ZSQ07, ZSQ08, ZSQ09, ZSQ10, ZSQ11, ZSQ12, ZSQ13, ZSQ14, Class-D Shelf Life: 5 years	Rejected for following reasons. 1. Manufacturer has submitted we are unable to provide DE certificate due to conversion from MDD to MDR nor submitted original valid legalized FSC of Reference country 2. Applicant has submitted that address of the manufacturer has changed and being updated in legal documents that will be submitted later when completed.
39.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi (ELI-00077)	Manufacturer: FORTUNE MEDICAL INSTRUMENT CORP. 6F, NO. 29, SEC.2 JHONGJHENG E RD.. DANSHUEI	FORTUNE Stomach Gastric, Chest Laryngeal Mask Tube Class C	Rejected the case due to following reasons. 1. Firm has not submitted original and valid FSC of country of origin china (Taiwan).

		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, 2020-0006, 2020-0008, 2020-0010, 2020-0012, 2020-0014, 2020-0016, 2020-0018, 2020-0020, 2020-5514, 2020-5516, 2020-6014, 2020-6016, 2020-6514, 2020-6516, 2020-7014, 2020-7016, 2020-7514, 2020-7516, Fee submitted: Rs. 50,000/-	2. Name of the product on FSC is Fortune Drainage Tubes and Accessories (Sterile). 3. Firm has not submitted stability studies. 4. 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 Health 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 Health 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.
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	<u>Legal Manufacturer:</u> 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 per 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	<u>Legal Manufacturer:</u> 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 per 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, Gulshan Jauhar, Block 24, Karachi (ELI-00907) Plot No.330/A. 2nd floor, block 3 DMCHS, Alamgir Road, Karchi. (ELI-00293)	Runqiang Medical Instrument Co., Ltd Address as per Form- 7A & China FSC: 599 Ruifeng Street, Gaozhao District, Xiuzhou Jiaying City zhejiang, China Address as per FQA: No. 618 Dade Road, Jiaying Xiuzhou District 314031 Jiaying 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 Certificate valid upto 11-12-2022 LOA Validity: 22-08-2029	Anesthesia Filter- NRFIT Filter Class: D MD group: Single Shelf life: 5 years Codes & Sizes: AF- A-0.5 Fee Challan No.: 322123110 PKR: 62,000/-	
46.	M/s United Healthcare, C-271, Ground Floor, Gulshan Jauhar, Block 24, Karachi (ELI-00907) Plot No.330/A. 2nd floor, block 3 DMCHS, Alamgir Road, Karchi. (ELI-00293)	Legal Manufacturer & Site: Zhejiang Runqiang Medical Instrument Co., Ltd Address as per Form- 7A & China FSC: 599 Ruifeng Street, Gaozhao District, Xiuzhou Jiaying City zhejiang, China Address as per FQA: No. 618 Dade Road, Jiaying Xiuzhou District 314031 Jiaying City, China FSC: (China) valid upto 26- 03-2025 ISO 13485 Certificate validity: 06-05-2025 EC (FQA) Certificate valid upto 06-05-2023	Safety Aero Disposable Anesthesia Needle - NRFIT Needle (Disposable Anesthesia Needle- NRFIT Needle) Class: D MD group: Family Shelf life: 5 years Codes & Sizes: AN- E, AN-S, AN-N,AN- E/SII Fee Challan No.: 82294572303 PKR: 62,000/-	Approved subject to submission valid original FSC and fee for family.

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

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

	# 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	<u>Legal Manufacturing:</u> Zhejiang Kindly Medical Devices Co. Ltd <u>Legal Manufacturing</u> <u>Site:</u> 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 Fee 25,000/ through slip no. 12207147, dated 08-01-2024	<u>LOA</u> Validity: 06-06-2026 <u>FSC:</u> Validity: 23-06-2026 <u>ISO13485:</u> Validity: 31-10-2026		
56.	M/s: Usmanco International Address of Importer House No. 220, Block-3, S. Abdul Tawwab Road, Karachi, Pakistan. ELI: 00121 R&I Detail 01-02-2024 Fee 25,000/ through slip no.1062293790, dated 08-01-2024	<u>Legal Manufacturing:</u> Zhejiang Kindly Medical Devices Co. Ltd <u>Legal Manufacturing</u> <u>Site:</u> No. 758, 5 th Binhai Road Binhai Industrial Park Longwan District Wenzhou, Zhejiang. <u>LOA</u> Validity: 06-06-2026 <u>FSC:</u> Validity: 23-06-2026 <u>ISO13485:</u> Validity: 31-10-2026	Uflo Disposable Insulin Pen Needle Disposable Insulin Pen Needle Class B Claimed Shelf Life:05-Years Codes/Size as per FSC.	Rejected as firm has not submitted FSC of RRA.
57.	M/s: Usmanco International Address of Importer House No. 220, Block-3, S. Abdul Tawwab Road, Karachi, Pakistan. ELI: 00121 R&I Detail 01-02-2024 Fee 25,000/ through slip no. 1751589259, dated 08-01-2024	<u>Legal Manufacturing:</u> Zhejiang Kindly Medical Devices Co. Ltd <u>Legal Manufacturing</u> <u>Site:</u> No. 758, 5 th Binhai Road Binhai Industrial Park Longwan District Wenzhou, Zhejiang. <u>LOA</u> Validity: 06-06-2026 <u>FSC:</u> Validity: 23-06-2026 <u>ISO13485:</u> Validity: 31-10-2026	UCut Biopsy Needle Class B Claimed Shelf Life:05-Years Codes/Size as per FSC.	Rejected as firm has not submitted FSC of RRA.
58.	M/s: Usmanco International Address of Importer House No. 220, Block-3, S. Abdul Tawwab Road, Karachi, Pakistan. ELI: 00121 R&I Detail	<u>Legal Manufacturing:</u> Zhejiang Kindly Medical Devices Co. Ltd <u>Legal Manufacturing</u> <u>Site:</u> No. 758, 5 th Binhai Road Binhai Industrial Park Longwan District Wenzhou, Zhejiang.	BFlo Scalp Vein Set Class B Claimed Shelf Life:05-Years Codes/Size as per FSC.	Rejected as firm has not submitted FSC of RRA.

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

	Plaza, Sharah-e-Faisal Karachi (ELI-00043) Dossier#1238c-7A Date:28-02-23 Submitted Fee: 25,000/-PKR Challan No.: 4265344687 Evaluator: DD-II	FSC: Japan Issued on: 24/03/2021	Saw blades, Resps & files) Codes & Sizes: As per FSC Class-C Shelf Life burs : 05 years	
62.	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	MEDIANA.CO.LTD 132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea FSC Validity (14.09.2023) Korea ISO Valid Till (29.10.2025) EC Valid Till (05.11.2023) LOA Valid Till (12.09.2028)	AUTOMATED EXTERNAL DEFIBRILLATOR HEART ON A-16-DS Class C Shelf Life: 5 Years Codes/Sizes (mention as per FSC)	Deferred for clarification that as per DOC its class C device and as per NB confirmation letter class D device along with Design Examination certificate/FSC of RRA and differential fee for class D.
63.	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	MEDIANA.CO.LTD 132, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365, Republic of Korea FSC Validity (14.09.2023) Korea ISO Valid Till (29.10.2025) EC Valid Till (05.11.2023) LOA Valid Till (12.09.2028)	DEFIBILLATOR / MONITOR D100 Class C Shelf Life: 5 Years Codes/Sizes (mention as pet FSC)	Deferred for 1. submission of FSC with device name on it. 2. Clarification that as per DOC its class C device and as per NB confirmation letter class D device along with Design Examination certificate/FSC of RRA and differential fee for class D.

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

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: 26-07-2026	BMI Shunting 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 <u>BMI CSF Shunting System</u>. 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 (ELI-00061)	District Foshan City Guangdong Province 528251 P.R. China	9018.1900	1. copy of ISO 13485 of M/s Medicaptain Medical technology 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 blanket and has been applied as single device. 5. Firm has submitted Form 7A without annexures and undertaking.
69.	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061)	Keewell Medical Technology Co, Ltd., Xiananyi Industry Zone, Pingzhou Babhai District Foshan City Guangdong Province 528251 P.R. China	KPW 3000 Body Warmer 9018.1900	Deferred for following reasons. 1. copy of ISO 13485 of M/s Medicaptain Medical technology Co., Ltd. China attached. 2. The name of the Device on FSC is Medical Mattress Patient Warming Unit while on Form 7A is KPW 3000 Body Warmer. 3. The FSC has multiple codes, but 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 single device. 5. Firm has submitted Form 7A without annexures and undertaking.
70.	Noor INTERNATIONAL NOOR HOUSE 29-D BLOCK 6 PECHS KARACHI -75400 (ELI-00061)	R-Vent Medikal Uretim A.S, Yazibasi Mah. Balkan Cad. Iztipsan Apt. No: 33/1 Torbalı, Izmir, Turkey	BVM Resuscitator Manual Resuscitator Codes/ Models (9060, 9070, 9080)	Approved subject to submission of fee for family and valid CE certificate. Firm will apply separately for other products.
71.	Unique Visual System, L-18m Block-17, Gulshan-E-Iqbal, Karachi (ELI-00449)	Legal Manufacturer & Site: Office address: Neo Vision Co., Ltd. Heungdeokjungang-ro, Giheung-gu, Yongin-	Optiano Clean NEO PLUS Contact Lens Multi- Purpose Solution (20% polyhexamethylene biguanide)	Approved.

		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/-	
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 alongwith valid CE certificate /FSC of RRA

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

			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	
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			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: BP758948) SA-31 Sampler Unit (code: AH258209) ST-40 Transportation Unit (code: CJ256159) ST-41 Transportation Unit (code: AX575334) ST-42 Transportation Unit (code: CV979713) Automated Tube Sorter TS-10 (code: BN168792) TU-40 Transportation Unit (code: AN617358)	
75.	Life Cares, M-20, Mezzanine Floor Falaknaz Plaza Natha Khan	Manufacturer: FORTUNE MEDICAL INSTRUMENT CORP.	FORTUNE Urological Catheters (Family) + Silicone Suprapubic Catheter Class C	Rejected due to following reason: 1. Firm has submitted copy of FSC issue date 6 th December 2018 (Not valid).

	Bridge, Shakra-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 (Taiwan) No. 078737 dated 13-05-2020 ISO valid till 08-08-2022 FQA/CE valid till 04-09-2023	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
76.	Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)	SERF : 85 Avenue des Bruyères, 69150 DECINES-CHARPIEU, FRANCE Copy of LOA valid till 05-10-2027. Copy of FSC provided issued on 23-12-2020.	SERF Femoral Head RM-30100001 RM-30100002 RM-30100003 RM-30100005 RM-30100006 RM-30100007 Class C Shelf life 5 Years Fee 50,000/-	Deferred for following reasons. 1. copy of LOA is not notarized. 2. copy of FSC (France) is not legalized. 3. As per FSC its class D but firm has applied in class C. 4. Justification of applying Multiple codes as single application. 5. clarification of brand name and generic name in FSC, LOA and applied name.
77.	M/s. RECH International Address: 247/B, BLOCK 6 P.E.C.H.S, Karachi ELI: 00257 R&I details Date: 17-08-2020 Slip no. 1979607 PKR 5000/- Dated: 17-08-2020	<u>Legal Manufacturer:</u> Changzhou Kanghui Medical Innovation Co., Ltd. located at No.11 North Changjiang Road, xinbei Zone, Changzhou Jiangsu 213022, P.R. China. FSC: Germany Validity: Not mentioned, issued in Oct. 2022	Brand: Surgical Instrument Generic: Surgical Instrument Class A Shelf Life: N/A Models: QXB-09, QXB-14, , QXB-16, QXB-23, QXB-24, QXB-25, , QXB-37, QXB-39, QXB-41, QXB-49,	Deferred (Last opportunity) for; 1. submission of original notarized LOA and Termination letter of Medtronic Pakistan for all devices approved in 78 th MDB meeting. 2. Justification for applying multiple devices in single application.

		LOA Validity: 31/12/2025	QXB-51, QXB-52, QXB-55, QXB-56, 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- 139, QXB-149	
78.	4S International, Suit No, 205, 2nd Floor, Al-Fiza Glass Tower, Rashid Minhas Road, Karachi (ELI-00290	Balton Sp. Z.o.o ul. Nowy Swait 7/14 street 00-496 Warsaw Poland	Valver®- Valvuloplasty Balloon Catheter	Deferred for following reasons. 1. Firm has not submitted copy of application Form. 2. FSC of RRA not submitted. 3. Firm has submitted NB confirmation letter attached but FQA and DE certificate not attached. 4. NB confirmation letter is not notarized.
79.	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	<u>Legal manufacturer & Manufacturing Site</u> Lemer Pax located at 72, Rue De Lorraine 44240 La Chapelle Sur Erdre France Date of R&I: 25.04.2024 <u>Embassy attested FSC:</u> Country: France Issued on 21.01.2023 (No Validity date) <u>Notarized LOA</u> Validity: 31.12.2023 <u>Notarized CE Certificate</u> Validity: 20.04.2027 <u>Notarized ISO 13485</u> Validity: 17.04.2025	Posijet (Auto FDG Injector) Class C Shelf Life: 06 years (service life) Codes/Sizes: Z1102909 (GMDN Code)	Approved.

80.	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	<u>Legal manufacturer</u> Datex Ohmeda Inc. located at 3030 Ohmeda Drive, P.O Box 7550, Madison WI 3707-7550, U.S.A. <u>Manufacturing Site</u> GE Medical Systems (China) Co. Ltd. located at No.19, ChangJiang Road Wuxi National Hi-tech Development Zone, Jiangsu, China Date of R&I: 24.04.2024 <u>FSC:</u> Embassy attested Country: U.S.A. Validity: 23.05.2025 Copy of certificate for exportation Country: China Validity: 20.04.2024 FSC: Reference Country: U.S.A. Validity: 23.05.2025 <u>Notarized LOA</u> Issuance date Validity: 15.09.2023 (portrait vsm) <u>CE FQA Certificate</u> Validity: 26.05.2024 <u>ISO 13485</u> Validity: 10.07.2024 (U.S.A.) Validity: 07.05.2026 (China)	Carestation 750C (Anaesthesia Workstation, general purpose) Class C Shelf Life: 07 years (service life) Codes/Sizes: 37710 (GMDN Code)	Deferred for following reasons. 1. LOA, ISO of manufacturing site has been notarized by Rizwan Advocate Karachi instead of country of origin. 2. not clarified the relationship b/w legal manufacturer and manufacturing site.
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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	<u>Legal manufacturer</u> 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 <u>Embassy attested FSC:</u> Country: Germany Issued on 07.09.2022 (No validity date) FSC: Reference Country: Germany Issued on 07.09.2022 (No validity date) <u>LOA</u> Validity: issuance date 07.02.2024 <u>EC Certificate of conformity</u> Validity: 20.01.2024 <u>ISO 13485</u> Validity: 20.01.2025	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.
82.	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	<u>Legal manufacturer</u> 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	Accutron HP-D Model 833 (Contrast Media Injector) Class C Shelf Life: 10 years (service life) Codes/Sizes: 37291 (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)

		<u>Embassy attested FSC:</u> Country: Germany Issued on 07.09.2022 (No validity date) <u>LOA</u> Validity: issuance date 07.02.2024 <u>EC Certificate of conformity</u> Validity: 20.01.2024 <u>ISO 13485</u> Validity: 20.01.2025		instead of service life/ shelf life studies Accutron HP-D Model 833.
83.	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: 26-07-2026	BMI External 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/-	Rejected due to 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. The name and applied codes not mentioned on FSC. 4. copy of the FSC is notarized, not legalized.

84.	Imtiaz Brothers, Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore - 54600, Pakistan. ELI-00133 5969-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan District, Tianjin, People's Republic of China, 300350 FSC: China. Date of Issuance: 13- 05-2024 valid for 2 years LOA validity 31- 12-2025 ISO 13485 validity 30- 09-2026 CE certificate validity 26-05-2024 with extension notification.	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Infant) Class-D Shelf Life: 3 Years Model: Extra Corporeal Circuit Tube with Membrane Oxygenator for Infant	Approved in class B subject to change of brand name as same brand name already issued to another firm.
85.	Imtiaz Brothers, Suite No. 7B, 2nd Floor, Abrar Business Center, 25 Main Wahdat Road, Lahore - 54600, Pakistan. ELI-00133 5970-P 62,000/-	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan District, Tianjin, People's Republic of China, 300350 FSC: China. Date of Issuance: 13- 05-2024 valid for 2 years LOA validity 31- 12-2025 ISO 13485 validity 30- 09-2026 CE certificate validity 26-05-2024 with extension notification.	TPRI Disposable Extra Corporeal Circuit Tube with Membrane Oxygenator (Pediatric) Class-D Shelf Life: 3 Years Model: Extra Corporeal Circuit Tube with Membrane Oxygenator for Pediatric	Approved in class B subject to change of brand name as same brand name already issued to another firm.
86.	Imtiaz Brothers, Office Address Suite No. 7B, 2nd Floor, Abrar Business Center,	<u>Legal Manufacturer:</u> Tianjin Plastics Research Institute Co., Ltd, No. 24 Keda 1 Road, TEDA (Jinnan) Microelectronics Park, Jinnan district, Tianjin,	TPRI Disposable Extra Corporeal Circuit Tube - Cardioplegia Delivery System Class-D	Approved in class B subject to change of brand name as same brand name already issued to another firm.

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

Item No. II: DEFERRED CASES OF LOCAL MANUFACTURING.

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

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

Case No.1

Name Address of Importer	Name Sure Bio- Diagnostics & Pharmaceuticals Address of Importer EE-10, Defence View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi.
Detail of ELM/ELI	Establishment License No. ELI-00084
Name Address of Manufacturer	LEGAL MANUFACTURER 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
Brand Name	Easy Diagnosis Biomedicine D-Dimer (cluster of D Dimer, Cystatin C, Ferritin (Fer) Test, Gastrin 17, Procalcitonin (PCT) Test Kit, PGI/PGI combo 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)
Country of origin FSC	FSC: China

	Validity: 18 Jan 2026
Date of application received along with Fee	Date of R&I 14 May 2024 Fee Amount & Fee Submission Date: Rs.25000 16-05-2024 Deposit Slip No: 584233359304
Class of medical device	B
Stability data/ service life	Shelf Life: 24 months
Documents submitted	
Marketing Authorization Letter:	Marketing Authorization Letter: (copy) Validity Date: 07-12-2024
Production Quality Management System Certificate (ISO 13485)	Production Quality Management System Certificate (Iso 13485) Validity Date: 26-01-2027
Full Quality Assurance Certificate or Equivalent:	Full Quality Assurance Certificate or Equivalent: N/A
Design Examination	Design Examination Not provided
Declaration of Conformity (Doc):	Declaration of Conformity (Doc): 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 Class: C Brief Description: Glucose and Ketone Monitoring System
Name and Address of Importer	Abbot Laboratories (Pakistan) Ltd., Opposite radio Pakistan Transmission Center, Hyderabad Road, landhi, Karachi. (ELI-00019)
Name Address of Manufacturer	Abbot Diabetes Care Ltd., Range Road, Witney, OXON, OX29 0YL, UK.

Purpose/Request	M/s Abbot laboratory (Pakistan) ltd. Vide DRAP R&I <u>26892</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 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	C	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	C	MDIR-0002052	31.12.2020
Name and Address of Importer	Abbot Laboratories (Pakistan) Ltd., Opposite radio Pakistan Transmission Center, Hyderabad Road, landhi, Karachi. (ELI-00019)			
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 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. 4

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 with the letter is as following

Product Name	Model	Class	Reg. No	Reg. date
Zybio Nucleic Acid Detection Kit (Magnetic Bead Method) (RNA/DNA Extraction Kit)	B-200, T-200 (B-2008T/Kit 16T/Kit, 20T/Kit, 32T/Kit T-200: 32T/Kit, 96T/Kit)	B	MDIR-0007907	25.02.2025
Zybio cluster for C-reactive proteins (immunoturbidimetric method)	CRP kit (CRP RI, CRP R2. CRP Calibrator, CRP Control)	B	MDIR-0007908	25.02.2025
Zybio cluster for liver function tests	Total bilirubin, Alanine aminotransferase, aspartate aminotransferase, direct bilirubin	B	MDIR-0007909	25.02.2025
Zybio cluster for Substrates	Urea, glucose, triglyceride, uric acid	B	MDIR-0007910	25.02.2025

Zybio cluster for enzymes	Lipase, alkaline phosphatase, lactate dehydrogenase, gamma glutamyl transferase	B	MDIR-0007912	25.02.2025
Zybio cluster for transport proteins	Albumin, glycated hemoglobin, total protein	B	MDIR-0007913	25.02.2025
Zybio MG (Magnesium kit)		B	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 LD, LYSE Z5 LB	Z5 DN, Z5 LD, Z5 LB	A	MDIE 0000964	25.02.2025
Zybio Hematology Analyzer	Z3 CRP	A	MDIE-0000966	25.02.2025
Zybio probe cleanser		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 Address of Importer	M/s DKT Pakistan (Pvt.) Limited, RJ, Building, 4 th Floor, Plot No. 37-C, 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: 1. SECP 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. 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.	<u>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.</u>
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.

ADDITIONAL AGENDA**DEFERRED CASES OF IMPORT**

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Kokab Enterprises No. G-56, Billys Shoppers Galleria, Gulistan-e-jauhar, Block 18, Karachi (ELI-00544) Evaluator: AD-IV [3599]	Manufacturer: Preservation Solutions Inc. 1099 Proctor Drive, Elkhorn, WI 53121 USA	Belzer UW Cold Storage Solution Class D Shelf life 24 months	Decision of MDB. The MDB decided to give opportunity to M/s Kokab Enterprises No. G-56, Billys Shoppers Galleria, Gulistan-e-jauhar, Block 18, Karachi, to: I. Define the role as manufacturer of M/s Carnamedica Spolka z Odpowiedzialnoscia ul. Olszynki Grochowskiej 21 lok, U6, 04-281 Warszana, Poland and Preservation Solutions Inc., USA and link between them. II. Submit original valid notarized authorization letter from manufacturer III. Original notarized cancellation of LOA of M/s Healthline Pharmaceuticals, Lahore. IV. Firm will also submit complete copy of the initially submitted file.
2.	M/s Zenith International, Room# 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090)	Legal Manufacturer & Site: Zhejiang runqing Medical Instrument Co., Ltd Address as per Form-7A & China FSC: 599 Ruifeng Street, Gaozhao District, Xiuzhou Jiaxing City zhejiang, China Address as per FQA:	Perfect Disposable Spinal Needle (Quincke Bevel type) Class: C MD group: Single Shelf life: 5 years Codes & Sizes (guage): 18,19,20,21,22,23,24,25,26 & 27. Fee Challan No.: 6193522908	Approved in class D subject to submission of differential fee for family.

		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 upto 06-05-2023 LOA Validity: 29-04-2029	PKR: 62,000/- Dated: 12-12-2024	
3.	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 Calthroe 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 Calthroe 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 Submitted	Storage temperature: Store at temperature 2-8°C	
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CASE NO. 5

Name Address of Importer	Name 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 Address of Manufacturer	(LEGAL MANUFACTUREUR) Qiagen GmbH, Qiagen Strasse 1, 40724, Helden, Germany (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 received along with Fee	Date 21 December 2023 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.

LOCAL MANUFACTURING CASES

Hafiz Muhammad Asif Iqbal (Deputy Director-VII)

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
1.	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	Yonker Syringe Pump Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 6864370075	Board approved the device in Class C subject to submission of differential fee of class C device as per S.R.O. 1399(I)/2025 dated 1st August, 2025.

	Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)		
2.	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 Assembling Section (Patient Monitor, Vital Sign Monitor, ECG Machine Ultrasound, Arm Blood Pressure Monitor, Nebulizer, Infrared Thermometer, Syringe Infusion Pump & Pulse Oximeter)	Periomed Ultrasound Machine Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 71930338981	Approved
3.	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)	Yonker ECG Machine Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 41815703	Approved
4.	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)	Yonker Nebulizer Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 653047191	Approved
5.	M/s Global Health Care Private Limited, Plot No. 3A, N4, RCC Industrial Area Rawat, Islamabad	Yonker Blood Pressure Monitor Class: B	Board approved the device in Class C subject to submission of

	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)	Shelf Life: 5 Years Fee: 25000 Fee Slip No. 33245310951	differential fee of class C device as per S.R.O. 1399(I)/2025 dated 1st August, 2025.
6.	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)	Yonker Infusion Pump Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 7683296653	Board approved the device in Class C subject to submission of differential fee of class C device as per S.R.O. 1399(I)/2025 dated 1st August, 2025.
7.	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)	Yonker Patient Monitor Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 812356052443	Approved
8.	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	Enzymes α -Amylase (α -AMY) Assay Kit, Creatine Kinase (CK) Assay Kit, Creatine Kinase MB (CK-MB) Assay Kit and Lactate Dehydrogenase (LDH) Assay Kit Shelf Life: α -Amylase (α -	Deferred for the submission of the justification of grouping Multiple kits of different class as Cluster and Brand name of the product

	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	
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 & 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)	Class: B R & I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 44445638	
11.	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)	Lipid Profile Test Total Cholesterol (CHO) Assay Kit and Triglycerides (TG) Assay Kit Shelf Life: 12 months Class: B R & I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 863511594841	Deferred for the submission of the justification of grouping multiple kits in single application and Brand name of the product
12.	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)	Renal Function Tests Creatinine (CREA-E) Assay Kit, Urea (UREA) Assay Kit, Albumin (ALB) Assay Kit, Total Protein (TP) Assay Kit, Uric Acid (UA) Assay Kit, Urine Microalbumin (UMA) Assay Kit) Shelf Life: 12 months Class: B R & I Details: File submitted on 05/06/2025 Rs. 25,000/- Slip No: 09464377012	Deferred for the submission of the justification of grouping multiple kits in single application and Brand name of the product

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

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.

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