

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

DECISIONS OF 137th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 30TH AND 31ST July 2026 (MANUAL APPLICATIONS PART-II)

137th 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 30th & 31st July 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S#	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
3.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
4.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
5.	Dr. Farid Khan, Senior Consultant Neurosurgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
7.	Prof. Dr. Syed Mohsin Naveed Abbas, Consultant Nephrologist & Transplant Physician, Head of Department of Nephrology & Dialysis, Cantt General Hospital, Rawalpindi.	Member (attended meeting through videolink)
8.	Mrs. Tazeen S Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co -Opted Expert (attended meeting through videolink)
9.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

Sr.No.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Asif Jalil	Deputy Director
10.	Ms. Minahil Javed	Internee
11.	Ms. Hajira Abid	Internee

Evaluator: Mr. Muhammad Amin (Deputy Director)

Item No. I(A): APPROVAL OF SITES FOR ESTABLISHMENT OF MANUFACTURING UNIT OF MEDICAL DEVICES.

Subject: Grant of establishment license to manufacture medical devices in residential area.

Pursuant to DRAP's policy decision dated 10 September 2021 (File No. 16-4/2019-MD) establishment licenses for the manufacture of medical devices were restricted/ not allowed in residential areas. Therefore, the case was referred to Authority by Medical Devices Board considering increased number of such applications from manufacturers particularly surgical instrument manufactures of Sialkot. The **Authority in 223rd meeting held on 10th July 2026 decided as under:**

“The Authority observed that the Medical Devices Rules, 2017 (MDR, 2017) do not specify any restrictive conditions regarding the location of manufacturing premises. It was further highlighted that such requirements are not mandated internationally, as global standards permit medical device manufacturing facilities to be located outside designated industrial areas, provided they meet environmental and quality controls, based upon the risk-based classification. Moreover, it was observed that some surgical instrument manufacturers in Pakistan are already successfully exporting to stringently regulated global markets and complying with international quality systems on their existing premises.

The Authority directed the Medical Devices Board (MDB) to process establishment license applications by evaluating each application based on the technical requirements, risk-based classification, manufacturing and quality control standards associated with the medical devices/being produced, ensuring that safety and quality standards are maintained”.

Accordingly, following deferred cases are presented before the MDB since these sites are in residential area.

S. No.	Name of Firm and Address	Decision
1.	M/s Bridge Surgical, Khan Mehal road, Sialkot	The board deliberated on the matter in the light of decision of Authority taken in its 223 rd meeting held on 10 th July 2026 and accordingly decided to approve the site with the advice to fulfil legal as well as technical requirements, manufacturing and quality
	Intended Items to be	

	manufactured: Orthopedic instruments & implants	control standards associated with the medical devices/being produced, ensuring that safety and quality standards are maintained by the applicant. The applicant is advised to obtain regulatory approvals from environment and building control authorities/municipal administration /provincial government.
2.	A.D.M INSTRUMENTS Office Address: STREET 1 MOHALLAH KOTLI MANALIAN GHOD PUR SIALKOT Factory Address: STREET 1 KOTLI MANALIAN GHOD PUR , Sialkot Tracking ID: MDSV-20260126-24733 Intended Items to be manufactured: GENERAL SURGERY INSTRUMENTS 2) ORTHOPADIC SURGERY INSTRUMENTS 3) GYNECOLOGY SURGERY INSTRUMENTS 4) SPINE SURGERY INSTRUMENTS 5) NEURO SURGERY INSTRUMENTS 6) CARIC SURGERY INSTRUMENTS	The board deliberated on the matter in the light of decision of Authority taken in its 223rd meeting held on 10th July 2026 and accordingly decided to approve the site with the advice to fulfil legal as well as technical requirements, manufacturing and quality control standards associated with the medical devices/being produced, ensuring that safety and quality standards are maintained by the applicant. The applicant is advised to obtain regulatory approvals from environment and building control authorities/municipal administration /provincial government.
3.	Bioactive Diagnostic Systems Office Address: 3C/B first floor chouburji centre multan road Factory Address: 80ft band road , Lahore Tracking ID: MDSV-20260331-30857 Intended Items to be manufactured: Repacking of ready to use bulk imported Class A and Class B Reagents Diluent for hematology Analyzer	The board deliberated on the matter in the light of decision of Authority taken in its 223rd meeting held on 10th July 2026 and accordingly decided to approve the site with the advice to fulfil legal as well as technical requirements, manufacturing and quality control standards associated with the medical devices/being produced, ensuring that safety and quality standards are maintained by the applicant. The applicant is advised to obtain regulatory approvals from environment and building control authorities/municipal administration /provincial government.

	Lyse for hematology analyzer Rinse for Hematology analyzer Glucose reagent ALT reagent AST reagent ALP reagent Bilirubin Reagent Calcium reagent creatinine reagent Cholesterol reagent triglycerides reagent Uric Acid reagent Urea reagent Albumin reagent HDL reagent LDL reagent	
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Item No. I(B): RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES:

I. FRESH RENEWAL CASES:

S. No	Name of Establishment	Production In charge	Quality Control In charge	Decision
1	M/s National Absorbent Mills Co, : Plot No. A-37, S.I.T.E., Manghopir Road, Karachi	Mrs. Tuba Nasim Pharm D	Mr. Liaquat Ali M.Se. Analytical Chemistry	Deferred. The board deferred the application of the firm for approval of tech staff and additional section. The firm shall submit requisite fee in the head of change of particulars for both the cases and supporting documents for consideration of the board.

II. DEFERRED RENEWAL CASES OF ELM:

S.#	Name of Establishment	Production In charge	Quality Control In charge	Decision
I.	M/s General Pharma, Office/godown: Farm Road, 3-KM, G.T. Road Manhes (KotliWagha),	Miss Shama Pharm D	Mr. Muhammad Saeed Pharm-B, M.Phil	Approved. The board observed that the firm has complied with all the conditions of license including fee for grant of additional section (POP Bandage) and production in charge

	Kamoke, District Gujranwala. ELM-0038			with relevant documents. The board therefore decided to grant renewal of establishment license to manufacture medical devices for the following sections. a. Cotton wool section b. Cotton open wave Bandage section c. Cotton Crepe Bandage section d. Gauze section (Sterile & Non Sterile) e. X-ray detectable Abdominal Pad Section f. Paraffin Wax Gauze Section g. POP Bandage Section
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III. TRANSFER OF LICENSE FROM DRUG MANUFACTURING LICENCE (DML) TO ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES (ELM):

Deferred Case:

S. No	Name and Address of Establishment	Name of Production In charge	Name of QC In charge	Decision
1.	M/s Umer Usman Surgical cotton industries, Factory Address: Faisalabad Road Kot Sai Singh, Jhang.	Rana Tauseef Mehmood B-Pharm	Muhammad Waqas Khan Pharma D	Approved. The board noticed that as per decision of the board the firm has submitted renewal application for establishment license to manufacture medical devices for the next period (17-09-2025 to 16-09-2030) with applicable late fee as defined under medical devices rules 2017. The board deliberated on the matter in the light of inspection report and decided to approve conversion of license from Drug Manufacturing License to Establishment License to Manufacture Medical Devices for the below mentioned section for the period 17-09-2025 to 16-09-2030. a. Cotton Wool Section (Non sterile) b. Cotton Bandage Section (Non Sterile)

				c. Crepe Bandage Section (Non Sterile)
				d. Absorbent Gauze Section (Sterile & Non Sterile)

Item No. I(C): GRANT OF ADDITIONAL SECTION TO MANUFACTURE MEDICAL DEVICES
M/s BQ Pharma & Medical Devices (Pvt) Ltd., Plot No. 43-A, Industrial Estate
Hayatabad , Peshawar.

S.#	Name of Establishment	Production In charge	Quality Control In charge	Name of Panel Inspector (s)	Recommendations by the panel.	Decision
1.	M/s BQ Pharma & Medical Devices (Pvt) Ltd., Plot No. 43-A, Industrial Estate Hayatabad , Peshawar. ELM-0066	Atta Ullah Shah	Muhammad Sadiq	Faisal Shahzad Additional Director, DRAP, Peshawar & Shahid Nawaz Latif, FID-II, DRAP, Peshawar.	Rapid Test KIT Assembly Hall. The designated assembly hall for rapid test kit assembly is located within the existing manufacturing premises and is physically separated from other production areas with a buffer. Assembly hall is also provided with HVAC having HEPA filters for provision of controlled Environmental conditions suitable for medical device assembly. The designated assembly hall contains the following instruments; 1. Strip cutter machine. 2. Sheet Strip inserting machine. 3. Cassette sealer machine. 4. Cassette printer machine. 5. Pressing table for cassette pressing 6. Cassette pouch packing. Already available moulding machines installed for plastic blood collection tube section will be used for manufacturing of cassettes with different mould. With reference to testing facility for In-Vitro Diagnostic (IVD) medical devices, there are number of different types of rapid testing IVDs. The testing requirements for IVDs are	Deferred. The board observed that the firm has not obtained approval of both production and QC incharge as per established procedure. The board therefore decided to defer the case for approval of both the qualified persons with applicable fee and supporting documents.

				product-specific and vary depending on the intended use, design, performance characteristics, and applicable standards of each medical device along with microbiological testing. Therefore, the adequacy and suitability of the testing facilities needs to specified by Medical Devices Board and if required, to be verified separately by technical experts/panel through field inspection for each IVD product before granting market approval to establish meeting the requirements of essential principles of safety and performance. Based on the inspection findings, it is the proposed that Rapid Test Kit Assembly Hall is recommended as an additional manufacturing section under the existing manufacturing licence of M/s BQ Pharma for the assembly, packaging, labelling, and related manufacturing activities of Rapid Test Kits subject to compliance with applicable regulatory requirements for device specific testing facilities to ensure its performance. Remarks: The firm has changed both production incharge & QC incharge but no evidence of approval provided.	
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Item No. I(D): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

FRESH CASES ELI

S.#	Name of Establishment	Name of Qualified Technical Person	Cold Chain (Yes/No)	Decision
1.	M/s Mays Marketing Enterprises Office: 2 nd Floor, House No. 46/E/2, Block-6, PECHS, Karachi Godown: Room No. G02, Plot No. 42, Darulaman Housing Society Block 7 & 8, Karachi.	New Qualified Person: Ms. Mariam Gul Siddiqui Pharm D	Yes	Approved

Item No. I(E): APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

(FRESH RENEWAL CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Angel Medical Services, Office/godown: House No 7/4 Drigh Road Cantt Bazar Korangi Shah Faisal Town Karachi.	Muhammad Ahsan Pharm D	Kaleem Sharoon CEO	Approved For room temp products.
2.	M/s Focus Surgical Office/godown: 11 Hearn Road, Krishan Nagar, Islampura, Lahore.	Hamza Elahi Pharm D	Mr. Muhammad Jawad Raza Mr. Awais Tariq Mr. Muhammad Umer Shahzad Mughal	Approved For room temp products.
3.	M/s Spero Enterprises, Office/godown: Ground floor, Ho. NO. A-336, Block NO. 5, Gulshan e Iqbal under KDA Scheme NO. 24, Karachi.	Amjad Shakeel Pharm D	Usman Tanzeel CEO	Approved For room temp products.
4.	M/s Meditron Medical Systems, Office/godown: 88-A, Johar town, Lahore.	Shela Iftikhar B Pharmacy	Muhammad Arshad CEO	Approved For room temp products.
5.	M/s Rehman Medicine Co., Office: Shop No. 1 & 2, First Floor, H.J Centre, Kutchi Gali No.2, Karachi. Godown: Suite # 2, Ground Floor, Cambel Street, SR-7, Shahrah-e-Liaquat, Karachi	Mr. Ravish Kumar Pharm D	Mr. Abdul Rehman Soomro CEO	Approved For room temp products.

6.	M/s Mediline technology, Office /godown: Suite No. 411, 4 th floor, Pak medical center, Khyber bazaar, Peshawar. ELI-00555	Engr Ali Ahmad Biomedical Engineer	Khalid Khan Ashfaq ahmad	Approved For room temp products.
7.	M/s Rehab Initiative, Office/godown: Sadaat Plaza, Thanda Pani, main Lehtar Road Islamabad ELI-00229	Mr .Ahmar Iftikhar Pharm D	Mr.Ihtisham Ahmed Mr.Bakht Sawrar Mr.Akhtar Waheed Mr.Mohammad Sohail Ayaz khan Mr.Imram Latif khan	Approved For room temp products.
8.	M/s JD Professional Healthcare Services (SMC-PVT) Ltd, Office/godown: 3rd Floor, 310/311, Rania Mall, Bank Road, Saddar, Rawalpindi ELI-00560	Ahsan Ilyas Pharm D	Malik Abdul Wadood CEO	Approved For room temp products.
9.	M/s Lab Line, Office / godown: 98, National Medicine Market, Arambagh Road, Karachi ELI-00437	Ms. Banita Maryam Chohan Msc Microbiology	Mr. Jahangir Abbas Chishty CEO	Approved For room temp products.
10.	M/s Gulf Marketing International, Office / godown: 11B/2 Mohallah Satellite town, Abdullah Jan Masjid Street Near Kali Tanki, Said Pur Road Rawalpindi.	Malik Muhammad Zaman MLT	Muhammad Shafiq CEO	Deferred. The board deferred the case for approval of qualified person as required under medical devices rules 2017.

Item No. I(F): APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

(DEFERRED CASES FOR RENEWAL OF -ELI):

Sr. No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s A.S Enterprises, Office/ New Godown: 03-Mozang Road, Lahore ELI-00190	Previous Qualified Person: Waqar Akram Pharm D New Qualified Person: Muhammad Azhar Javad	Shafi-ud-Din CEO	Approved For room temp products.

2.	M/s Cure Traders (SMC) Pvt. Ltd., Office/Godown: House No. 236, Street No. 1, Sector F-8, Phase-6, Hayatabad Peshawar (ELI-00491)	Muhammad Faraz Shah Pharm D	Muhammad Rafiq	Approved For room temp products.
3.	M/s Akram brothers & Co, Office/Godown: 89-D, jail Road, Lahore ELI-00324	Amina Saeed Pharm D	Rana Muhammad Akram Khan	Approved For room temp products.

Licensing Additional Agenda

Item No. I(G): RENEWAL OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICE.

S.NO.	Name of Firm	Renewal Due Date	Decision
1.	M/s Medimages Services, Office/Godown: Suite No. 5/B Peshawar Medical Centre, Shoba Bazar, Peshawar. ELI No. 00548	12-02-2025	The board observed that the license of the firm was declared invalid in 129 meeting of MDB inadvertently due to an error/ discrepancy in data. Therefore, it was decided to revoke earlier decision of the board and establishment license to import medical devices issued in favor of M/s Medimages Services, Office/Godown: Suite No. 5/B Peshawar Medical Centre, Shoba Bazar, Peshawar ELI No. 00548 (approved in 114 th MDB) is declared valid for the period 12-02-2025 to 11-02-2030.

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

Evaluator: Hafiz Muhammad Asif Iqbal (Deputy Director)

Evaluator: HAJIRA ABID (Intern-2)

IMPORT DEFERRED CASES:

Sr No.	Importer name	Manufacture details	Name of MD/Class/Code/ Shelf life/etc.	Decision
1.	M/s Medtronic Pakistan Private Limited Date of submission	Legal Manufacturer: 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com	Medtronic Slitter Adjustable Slitter 6232ADJ Universal Slitter II	Approved

	2 nd December 2025	+1 763 514 4000 Manufacturing site: Contract Manufacturer DONATELLE, 501 Country Rd, E-2 Extension, New Brington, MN USA55112	6230UNI Shelf life: 2 years Class: D Single	
2	Name M/s Medtronic Pakistan (Pvt) Ltd Ocean Tower, 21 st Floor, Plot # G-3, Khayaban-e-Iqbal, Block 09, Clifton, Karachi ELI-00273 Date of Dossier: 09-09-2024 Fee Amount & Fee Submission Date: Rs.50,000/-	Legal Manufacturer M/s Cardio Tek B.V. Dr. Nolenslaan 107B 6136 GL Sittard, The Netherlands	EP Tracer system Class C FSC: The Netherlands Validity: Not Provid Marketing Authorization Letter: Issuance Date: not provided Copy Production Quality Management System Certificate (ISO 13485) Validity Date: 02 nd December, 2026 Full Quality Assurance Certificate or Equivalent: Validity Date: 26 th May, 2024	Deferred for submission of valid notarized LOA issued from legal manufacturer as M/s ACP has already applied for the same product with LOA issued by the legal manufacturer i.e. M/s Cardio Tek B.V. Dr. Nolenslaan 107B 6136 GL Sittard, The Netherlands.
3	Applicant Name: M/s. NI healthcare Products Pvt Ltd. Address: Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 14-03-2025 Rs. 31,000/- Slip# 07733267928	Legal Manufacturer: Jiangsu Hitec Medical Co. Ltd., Jiangxin Road North, Tongzhou Bay River Sea Joint Development Demonstration Zone, Jiangsu Province, China FSC: Validity: 27-12-2026 LOA Validity: 17-12-2027 CE Certificate Validity: 08-04-2029 ISO 13485	Brand Name: DYCO Suction Connecting Tube with Yankauer handle Class B Shelf Life: 5 years Codes/Sizes (If any) Sizes: with Yankauer handle 8.2mm 9.0mm 9.7mm 10.0mm 10.7mm 11.2mm	Rejected on the ground: Code: A060102 not mentioned on brochure and the firm has submitted the name DYCO+ while the product with name DYCO is already registered.

		Validity: 27-02-2027	Code: A060102 Surgical Drainage Connection Medical tubes	
4	NI healthcare Products Pvt Ltd Office No. A, Unit 10 Survey No. 263, Damlotte Road District Malir, Karachi (ELI-01117) Date of R&I 31-12-2024 Fee Details: Paid Fee: 31,000/- Challan No. 57245832	Legal manufacturer (as per Form-7A) Vincent Medical Manufacturing Co., Ltd Flat/RM B2, 7/F. Hang Fung Industrial Building Phase 2, 2G Hok Yuen St., Hung Hom, Kowloon, Hong Kong. Manufacturing Site (as per form-7A): Site No.1: Vincent Medical (Dongguan) Technology Company Limited RM 101 and 201, Block 10, 1st Taoyuan Road, Songshan Lake Zone, 523 808 Dongguan, Guangdong, China. Site No.2: Vincent Medical (Dong Guan) Manufacturing Co., Ltd 11 ShaBu Street, Qiao Long District, Tang Xia Town, 523730 Dong Guan City, Guangdong Province, China. Legal manufacturer & manufacturing Site (as per FSC (china): Vincent Medical (Dong Guan) Manufacturing Co., Ltd 11 ShaBu Street, Qiao Long District, Tang Xia Town, 523730 Dong Guan City, Guangdong Province, China. LOA Type: Scan copy of non-notarized copy. Validity: 01-12-2026	Vincent /Inspired Humidification Chambers Applied as Family. Class-B Service Life: 5 Yrs Model/Codes/Size: VHC10, VHC20, VHC25, VHC50	Approved model VHC25.

		FSC Type: Scan copy of non-notarized copy Issued By: issuance authority is mentioned in Chinese language. Validity: 28-12-2025 ISO 13485: Type: Scan copy of non-notarized copy Validity: 16-04-2027 CE Certificate: Type: Scan copy of non-notarized copy Validity: 26-05-2024		
5	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju-cho, Adachi-ku, Tokyo 120-0035, Japan Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory LOA valid till 31.12.2027 FSC Japan Issue date 01.01.2025	TOP-5530 Syringe Pump 9018.1900 Class C Shelf life 6 years	Approved model TOP-5530 Syringe Pump
6	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju- Nakai-Cho, Adachi-Ku Tokyo 120-0035, Japan Inside Country of Origin: Top Corporation Koshigaya Factory, 40-34 Noborito-cho, Koshigaya-shi Saitama, Japan Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory FSC issue date: 22-01-2025	Infusion Pump MJ-210 Class C Shelf life 6 years	Approved model Infusion Pump MJ-210

7	Noor International, 29-D, Block 6, PECHS, Karachi (ELI-00061) Date of R&I 28-02-2025 Fee Details: Paid Fee: 62,000/- Challan No. 2463026582	Legal Manufacturer Top Corporation 19-10 Senju Nakai-cho, Adachi-ku, Tokyo 120- 0035, Japan. Manufacturing Site as per FSC: 1st Site: Meditop Corporation (Malaysia) SDN. BHD. Plant-2 N03, Persiaran Usahawan Taman IKS, Seksyen 9,43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia. 2nd Site: Top corporation Koshigaya Factory, 40-34 Noborito-cho, Koshigaya-shi, saitama,, Japan. LOA Type: Scan copy of non- notarized copy. Validity: 31-12-2027 FSC Type: Scan copy of non- notarized copy Issued By: Japan Issuance Date: 15-12-2020 Validity: not mentioned. • ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-03-2026 & ISO 13485 for Malaysia site valid upto 31-08-2027 • EC (FQA) Type: Scan copy of non- notarized copy Validity: 26-05-2024	TOP-S500 Syringe Pump Applied as Single. Class-C Service Life: 6 years Model: S500	Approved model TOP-S500 Syringe Pump
8	M/s. Reliable Medical Supply, Office No. 204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar.	Name of Manufacturer: Hebei Kanging Medical Devices Co. Ltd., 5th Floor, Building A-2, Guohietang Medical Equipment Industrial Park, No.509 Taihang South Street,	Brand name: Single-Use Container for Human Venous Blood Specimen Collection Generic Name: Blood Collection Tube	Approved single Model EDTA K2 with Brand name Reliable Medical.

	(ELI- 00618) R&I detail 27-06-2025 Fee: 6,000/- Slip: 5224087764	Shijiazhuang Hitech Zone, China. • LOA Type: Copy Notarization: Not Notarized Issue Date: 03-06-2025 Validity: Not mentioned • FSC Type: Copy Issued By: MPA Legalization: Not legalized Validity: 12-05-2027 • ISO Certificate Type: Copy Notarization: Not Notarized Validity: 22-05-2028	Applied as: Single Class: A Model/Codes/Sizes (as per application & FSC): Multiple Types have been mentioned in Form (Plain, Gel Clot etc.) Shelf life: 3 Years	
9	Applicant Name: Batla Impex, Shop No. 40 Namco Center, Cambell Street, Karachi (ELI-00170) Date of R&I 14-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 5369944260	M/s Hangzhou Valued Medtech Co. Ltd.,289#, Gaojia Road, Tonglu County Zhejiang China LOA Validity: Validity not provided. FSC: China Validity: 17-01-2025	Super Non-Absorbable Surgical Suture with Needle Class-B Shelf life: 05 years Models/ Specification:	REJECTED on following grounds: Firm hasn't submitted LOA , FSC , CE certificate , NO class justification and fee submission.
10	Applicant Name: Batla Impex, Shop No. 40 Namco Center, Cambell Street, Karachi (ELI-00170) Date of R&I 14-04-2025 Fee Details: Paid Fee: 31,000/- 8137827346	M/s Super Health Medical (Qingdao) Co., Ltd., No. 236 Heyuan Road, High-Tech Zone Qingdao, China LOA Validity: 17-02-2030 FSC: China Validity: 27-04-2025 ISO Validity: 29-03-2026 EC Certificate:	B Care I.V Cannula Class-B Shelf life: 05 years Models/ Specification:14G, 16G, 18G, 20G, 22G, 24G, 26G	REJECTED on following grounds: Firm hasn't submitted original, notarized LOA and FSC No Clarification of multiple sizes of IV cannula

		Validity:		
11	M/s Radiant Medical Private Limited 06-Sher Shah Block New Garden Town Lahore, Pakistan (ELI-00135) R&I Date: 21-4-2025 CMS tracking ID: WN6-SDZ-374Z Fee: 62,000/-	Manufacturer Name: M/s Asclepion Laser Technologies GmbH Address: Brüsseler Str. 10, 07747 Jena, Germany LOA Notarization: Yes Issued: 31-12-2026 • FSC Legalized: Yes Issued by: German Authority Issued: 01-07-2024 ISO – Certificate: Notarization: yes Valid till: 02-12-2027 EC Certificate: Valid till 26-05-2024	Brand Name: MultiPulse Pro 40/60 CO2 Laser Surgical Instrument Generic Name: CO2 Laser Surgical Instrument Applied as: Family Class: C Models/Code/sizes (as per FSC & application: MD 1402 Shelf life N/A	Approved model MultiPulse Pro 40/60
12	M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi. ELI-00197 Date of R&I 23-01-2023 Fee Details: Paid Fee: 5,000/- Challan No. 54653978285	Legal Manufacturer M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany. Manufacturing Site M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance date: 29-06-2022 Validity: Not mentioned.	Cuvette Racks & Ball for 800 Tests Assay Stirring Set Applied as Single: Class-A Shelf life: 4 Years Codes/Model/Sizes 050210	Approved model 050210

		• ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-11-2023		
13	M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi. ELI-00197 Date of R&I 23-01-2023 Fee Details: Paid Fee: 5,000/- Challan No. 3421866301	Legal Manufacturer M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany. Manufacturing Site M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance date: 29-06-2022 Validity: Not mentioned. • ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-11-2023	Cuvette Racks for 2.320 Tests Assay Stirring Set Applied as Single: Class-A Shelf life: 4 Years Codes/Model/Sizes 54420	Rejected on following grounds: Applied product Cuvette Racks for 2.320 Tests is not mention on LOA product list
14	M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi. ELI-00197 Date of R&I 23-01-2023 Fee Details: Paid Fee: 5,000/-	Legal Manufacturer M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany. Manufacturing Site M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany.	Cuvette Racks 8-Fold CP for 2.320 Tests Assay Stirring Set Applied as Single: Class-A Shelf life: 4 Years Codes/Model/Sizes 54520	Rejected on following grounds: Applied product Cuvette Racks 8-Fold CP for 2.320 Tests is not mention on LOA product list

	Challan No. 525775824070	LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance date: 29-06-2022 Validity: Not mentioned. • ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-11-2023		
15	M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi. ELI-00197 Date of R&I 23-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 11354502	M/s. BIOLABO S.A.S. Les Hautes Rives, 02160 Maizy, France. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued by: CCI France Issuance date: 01-06-2025 Validity: Not mentioned. • ISO 13485: Type: Scan copy of non-notarized copy Validity: 23-12-2024	BE FIB Reagent for quantitative determination of Fibrinogen (FIB) in human plasma. Applied as: SINGLE Class-B Shelf life: 3 Years Codes/Model/Sizes 771300 & 771301	Approved single model 771300
16	M/s Muller & Phipps, Uzma Court, Main Clifton Road Karachi ELI-00030 R&I Details 19-08-2020. Fee of Rs. 5,000/- Fee Challan No. 0829160 dated 06-08-2020	Legal Manufacturer (as per Form-7A): ConvaTec Limited First Avenue Deeside Industrial Park Deeside, Flintshire, CH5 2NU, UK. Manufacturing Site (as per Form-7A): PharmaPac (UK) Ltd. Unit 22, Valley Road Business Park, Bidston, Wirral, CH41 7EL.UK.	Stomahesive Protective Powder Class A Applied as Single. Shelf life: 3 years Code/sizes: 025510	Deferred with final opportunity on following grounds: Applied product not mentioned on FSC; stability study report Not provided.

		Manufacturer Name as per FSC (UK): ConvaTec Limited Letter of Authorization: Type: Scan copy of notarized copy. Date of issuance: 29-07-2024 Validity: 28-01-2026 FSC Type: Scan copy of notarized copy Issued By: MHRA, UK Date of Issuance: 14-05-2015 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 03-01-2026		
17	Coral Pharmaceuticals, A - 85 S.M.C.H.S, Karachi. Lic. No.: ELI-00065. Date of R&I 13-01-2022 Fee Details: Paid Fee: 25,000/- Challan No. 79800146234	Dyneke Pty Ltd 9 Circuit Drive, Hendon, SA 5014, Australia. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued by: TGA Australia Issuance Date: 24-11-2021 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 19-04-2025.	Chromic Gut Chromic Catgut Applied as. Family Class-D Service Life: 5 yrs. Model/Codes/Size:	Approved as family Codes ACG197 ACG169 ACG297 ACG298 ACG097 ACG2069 ACG3065 ACG4060 USP SIZES + NEEDLE SIZE 1-40mm 1-30mm 2-40mm 2-48mm 0-40mm 2/0-30mm 3/0-20mm 4/0-16mm
18	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached.	M/s. Tomato M&C Co. Ltd 15-11, Suworam-gil, Seotan-myeon, Pyeongtaek-si, Gyeonggi-do, Republic of Korea 17704 LOA:	Tomato Super Splint Orthopedic Bandage Class A Applied as Family. Shelf life: Code/Model/Size:	Rejected on following grounds: Firm hasn't submitted LOA And Not valid fee challan

	Tracking ID: LAP-1ZW-NJ78	Type: Scan copy of notarized copy. Date of issuance: 01-11-2020 Validity: 01-11-2025 FSC Type: Scan copy of notarized copy Issued by: Mo FDS Korea Issuance Date: 22-02-2021 Validity: not mentioned ISO 13485: Valid upto 16-05-2022	3" x 12" 3" x 35" 4" x 15" 4" x 30"	
19	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: 1SW-X88-AEQ8	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Seton Collafoam Cervical Collar Class A Applied as Single. Shelf life: 5 years Code/Model/Size: S, M, L	Approved single size SETON21003 - Medium
20	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: X8Z-NAX-SZE7	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027	Seton Polysling Polysling Class A Applied as Single. Shelf life: 5 years Code/Model/Size: Seton21015	Approved model Seton21015

		FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.		
21	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: X8Z-NAX-SZE7	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Seton Skin Traction Kit Skin Traction Kit (Adhesive) Class A Applied as Single. Shelf life: 5 years Code/Model/Size: Child, Adult	Approved single model /size ; Seton21010-CHILD
22	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: HE9-D9Q-LRWH	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy	Seton Stockinette Tubular Bandage Stockinette Tubular Bandage Class A Applied as Single. Shelf life: 5 years Code/Model/Size: (cmxm) 5x20, 7.5x20, 10x20	Approved single code Seton21002- 5x20 cm

		Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.		
23	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: HE9-D9Q-LRWH	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Seton Tubigrip Tubular Support Bandage Tubular Bandage Class A Applied as Single. Shelf life: 5 years Code/Model/Size:	Approved single model Seton Tubigrip Tubular Support bandages models SETON 21001-B
24	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: THA-GJL-E84B	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024	Seton Wrist Brace Right & Left Wrist Orthosis Class A Applied as Single. Shelf life: 5 years Code/Model/Size:	Approved model SETON21005-Medium-right

		ISO 13485: Not attached.		
25	Applicant: M/s. Zybion Medical Pakistan (SMC- PRIVATE) Limited. Address: House No 323, Street No 66, Sector I/8/3, Islamabad. ELI:01195 R&I Date: 13-06-2024 Fee details: Fee: PKR 25000/- Slip: 2223481930	(Legal Manufacturer) M/s Zybion Inc. Floor1 to floor 5, building 30, No.6 of taikang road, block C of Jianqiao Industrial Par, Daduko District, 400082 Chongqing, PEOPLES'S REPUBLIC OF CHINA FSC (China) Validity: 10-06-2025	Brand Name: Zybion Generic: TSH Assay (Immunofluorescence) Sizes: 25 T/Kit Class-B Letter of authorization: Validity: 23-11-2028 Shelf life: 18 months ISO 13485 certificate validity: 24-02-2025	Rejected on following grounds Firm has again submitted expired fee challan.
26	CARDIAC CARE, 848- C, Shadman - 1 Lahore-54610, PakistanELI - 00070 R&I Date: 04.10.2022 Fee: 25000/- Slip # 09392061 This evaluation is based on the on- line data submitted through E-App. Tracking ID: B73- 2NS-PR4P	Legal Manufacturer: VYGON Germany GmbH, Prager Ring 100, 52070 Aachen, Germany LOA Type: scanned copy Notarization: Yes Validity: 31.12.2026 FSC Type: scanned copy Issued by: Cologne Regional Government, Germany Legalization: No Issue date: 04.12.2024 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 23.03.2025 CE certificate Type: scanned copy Notarization: No Validity: 19.12.2022 Extended till 31.12.2028	Brand Name: Premicath Generic Name: Neonatal PICC Applied as: Single Class: B Models/Code/sizes (as per FSC & application: 1261.080, 1261.102, 1261.152, 1261.153, 1261.20, 1261.201, 1261.203, 1261.205, 1261.206, 1261.207, 1261.208, 1261.21, 1261.22, 1261.302, 1261.306, 1261.307 Shelf Life: 5 years	Rejected on following grounds Firm has not submitted LOA , FSC , FORM 7A.
27	Cardiac Care 848-C Shadman-I Lahore. ELI-00070 5984-P 31,000/-	Legal Manufacturer: EUROSETS S.r.l. Strada Statale 12, n°143 41036 Medolla (MO) Italy. FSC: Italy. Date of Issuance: 12-07-	HORIZON AF PLUS Oxygenator Class-B Shelf Life: 3.5 years	Rejected on following grounds Firm hasn't provided clarification regarding original documents submission in R&I.

		2024. LOA validity 31-12-2026 ISO 13485 validity 24-08-2025 CE certificate validity 26-05-2024 with extension notification.	Model: AG5300	
28	Applicant Name: Biomedical Star Enterprises, Plot No. E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes) ELI-01186 (yes) Date of R&I 26-05-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 86456446	Name of Manufacturer: GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi (yes) Manufacturing site: Ikitelli Osb Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes) LOA Validity: 30-12-2029 (Copy) (yes) FSC: Turkey Validity: 1-03-2027 (yes) APOSTILLE ATTACHED ISO Validity: 24-08-2025 (yes) notarized EU QA/ EC Certificate Validity: 27-05-2024 notarized EU Design examination Certificate notarized Validity: 27-05-2024 Extension letter given	Brand name: S&J PA Sterile Surgical Suture Generic Name: Non-Absorbable Polypropylene Surgical Suture Class-C Single Shelf life: 5 years Models/ Specification	Approved model Polyamide PA monofilament Non Absorbable Suture 75cm 2-Black 40mm 1/2 Circle Round needle
29	Applicant Name: Biomedical Star Enterprises, Plot No. E-2 Office G-16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes) ELI-01186 (yes) Date of R&I 26-05-2025 (yes)	Name of Manufacturer: GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi (yes) Manufacturing site: Ikitelli Osb Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes) GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area, 361006 Xiamen China	Brand name: S&J PDO Sterile Surgical Suture Generic Name: Absorbable Polydioxanone Monofilament Surgical Suture Class-D Shelf life: 5 years single Models/ Specification	Approved model PDO monofilament Absorbable Suture 75cm 2-PURPLE 40mm 1/2 Circle Round needle

	Fee Details: Paid Fee: 62,000/- 6670451321 (yes)	LOA Validity: 30-12-2029 (Copy) (yes) FSC: Turkey Validity: 1-03-2027 (Copy) (yes) APOSTILLE ATTACHED(copy) ISO Validity: 24-08-2025 (Copy) (yes) EU QA/ EC Certificate Validity: 27-05-2024 (yes)		
30	Applicant Name: Biomedical Star Enterprises, Plot No. E-2 Office G- 16 Dhedhi Business Avenue Estate Avenue Road Site, Karachi (yes) ELI-01186 (yes) Date of R&I 26-05-2025 (yes) Fee Details: Paid Fee: 62,000/- 7587015702 (yes)	Name of Manufacturer: GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi (yes) Manufacturing site: Ikitelli Osib Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes) GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area, 361006 Xiamen China LOA Validity: 30-12-2029 (Original) (yes) FSC: Turkey Validity: 1-03-2027 (Original) (yes) not original APOSTILLE ATTACHED(copy) ISO Validity: 24-08-2025 (Copy) (yes) EU QA/ EC Certificate Validity: 27-05-2024 (yes) copy	Brand name: S&J PE Sterile Surgical Suture Generic Name: Non- Absorbable Polyester Surgical Suture Class-C single Shelf life: 5 year Models/ Specification	Approved model Polyester PE braided 2-0,26cm, 1/2 Round non absorbable, 75cm suture
31	Applicant Name: Biomedical Star Enterprises, Plot No. E-2 Office G- 16 Dhedhi Business	Name of Manufacturer: GMD Group Medikal Sanayi ve Ticaret Anonim Sirketi	Brand name: S&J PGLA Rapid Sterile Surgical Suture Generic Name:	Approved model PGLA Rapid 4-0, 16mm,3/8 reverse sharp 75cm suture

	Avenue Estate Avenue Road Site, Karachi (yes) ELI-01186 (yes) Date of R&I 26-05-2025 (yes) Fee Details: Paid Fee: 62,000/- 7587015702 (no)	Manufacturing site: Ikitelli Osob Mah. Lsdok Sosyal Tesis 2 Sk. B Blok 1 B 7 Basaksehir Istanbul, Turkiye (yes) GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area, 361006 Xiamen China LOA Validity: 30-12-2029 (Copy) (yes) FSC: Turkey Validity: 1-03-2027 (Copy) (yes) APOSTILLE ATTACHED(copy) ISO Validity: 24-08-2025 (Copy) (yes) EU QA/ EC Certificate Validity: 27-05-2024 (yes) copy	Absorbable Polyglactin 910 Rapid Surgical Suture Class-D Single Shelf life: 5 years Models/ Specification	
32	Biomedical Star Enterprises, Plot E-2 Office G- 16 Dhedhi Business Avenue Estate Avenue Road SITE Karachi (ELI-01186)	Tianchang City Anrui Medical Equipment Co., Ltd Renhe Industrial District 239331 Tianchang city Anhui Province, China	Biofit Powder Free Latex Surgical Gloves Powder Free Latex Surgical Gloves Class B	Rejected on following grounds: valid FSC is not submitted.
33	Biomedical Star Enterprises, Plot E-2 Office G- 16 Dhedhi Business Avenue Estate Avenue Road SITE Karachi (ELI-01186)	Tianchang City Annrui Medical Equipment Co., Ltd Renhe Industrial District 239331 Tianchang city Anhui Province, China	Biofit Powdered Latex Surgical Gloves Powdered Latex Surgical Gloves Class B	Rejected on following grounds: Not valid FSC is submitted.

LOCAL DEFERRED CASES

1	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055)	B.T Plain Catgut Suture Class: D Shelf Life: 60 Months Fee: 25000 Fee Slip No. 793975159758 Sizes: 0,1,2,2/0,3/0,4/0,	Approved
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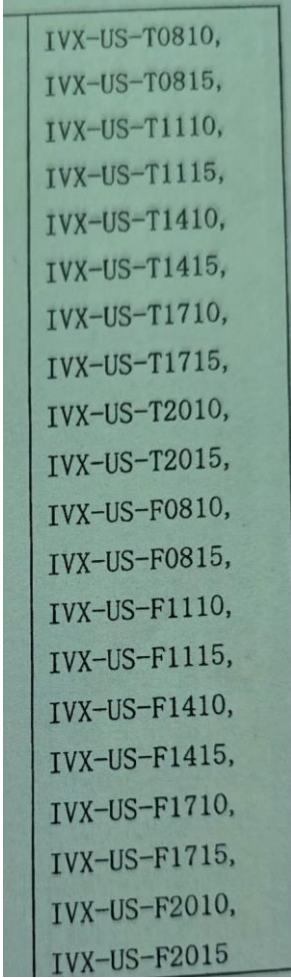
DEFERRED IMPORT CASES:

Sr. No.	Importer name	Manufacture details	Name of MD/Class/Code/Shelf life/etc	Decision
1	M/s Ferozsons Laboratories Limited (ELI-00120) Date of R&I 14-02-2025 Fee Details: Paid Fee: 62,000/- Challan No. 9550075802	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA. Manufacturing Site: Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112 USA. Contract Manufacturing Site: Dedicated Computing LLC, N26 W23880 Commerce Circle Waukesha, Wisconsin 53188 USA. LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025-4 FSC Type: Scan copy of non-notarized copy Issued By: HPRA Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non-notarized copy Validity: 01-09-2026 • EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024	Lab system Pro EP Recording System, LABSYSTEM PRO EP Recording System, LS10K Win 10 Computer, V4.0 SW Applied as Single. Class-C Service Life: N/A Model/Codes/Size:	Approved as Lab System Pro EP Recording with code M00420020810

2.	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/-	Rejected on the following grounds Firm hasn't clarified the grouping Multiple screw types are applied in a single application The anatomical region or intended area of use for the screws is not specified.
3.	Rech International, 247/B, Block-6 P.E.C.H.S Karachi (ELI-00257)	Tipmed Medical devices Manufacturing Ltd. Kamalpasa Mahalleesi 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). 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.	Tipmed Primary Hip prosthesis sys Class C Shelf life As per stability study Fee 50,000/-	Rejected on the following grounds Firm hasn't clarified the grouping The anatomical region or intended area of use is not specified.
4.	BNS Trading Est. Office No. 339, 3rd Floor, Landmark Plaza, Jail Road, Lahore (ELI-00583) R&I Date: 08-	Name of Manufacturer: Jiangsu Kangjin Medical Instruments Co., Ltd., Address: No. 56, Changzheng Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China LOA:	Brand Name: 3S Safe Transfusion Set Generic Name: Transfusion Set Applied as: Kit Class: B Models/Code/sizes (as per FSC & application Model:	Approved the model TS-T1. The firm is advised to submit valid FSC.

	07-2025 Fee: 31,000/- Slip # 90655129.	Type: Copy Notarization: Yes Validity: 13-05-2028 FSC: Type: Copy Issued By: Provincial Supervision Body Legalization: Apostille Validity: 17-08-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 01-02-2025 Copy of EC certificate also submitted	TS-T1 TS-T2 TS-T3 TS-T4 Shelf life: 5 years	
5.	BNS Trading Est. Office No. 339, 3rd Floor, Landmark Plaza, Jail Road, Lahore (ELI-00583) R&I Date: 08-07-2025 Fee: 31,000/- Slip # 6580023410.	Name of Manufacturer: Jiangsu Kangjin Medical Instruments Co., Ltd., Address: No. 56, Changzheng Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China LOA: Type: Original Notarization: Yes Validity: 13-05-2028 FSC: Type: Original Issued By: Jiangsu Provincial Drug Administration Legalization: Apostille Validity: 17-08-2025 ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-01-2028 Notarized Copy of EC certificate also submitted	Brand Name: 3S Safe Infusion Set Generic Name: Infusion Set Applied as: Kit Class: B Models/Code/sizes (as per FSC & application Model): IS-M-A1 IS-M-A2 IS-M-A2-3 IS-M-A3-3 IS-M-A21 IS-M-A22 Shelf life: 5 years	Approved the model IS-M-A1. The firm is advised to submit valid FSC.
6.	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09-07-2025 Fee: Rs. 31,000 vide deposit slip no. 155273695	Name of Manufacturer: Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Copy Notarization: Apostille Validity: 20-05-2028 • FSC:	Brand Name: Innovex Ureteral Stents Generic Name: Urological Ureteral Stents Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Several models have been applied in FSC Shelf Life: 3 years	Rejected on the following grounds The firm submitted expired FSC in response of deferment in 102nd meeting. Multiple models applied while grouping as single.

		Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 04-11-2027		
7.	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09- 07-2025 Fee: Rs. 6,000 vide deposit slip no. 448108026709	Name of Manufacturer: Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Copy Notarization: Apostille Validity: 20-05-2028 • FSC: Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 04-11-2027	Brand Name: Innovex Urological Sampler Sets Generic Name: Urological Sampler Sets Applied as: Single Class: A Models/Code/sizes (as per FSC & application IVX-NB-150 Shelf Life: 3 years	Rejected on the following grounds The firm submitted expired FSC in response of deferment in 102nd meeting.
8.	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09- 07-2025 Fee: Rs. 31,000 vide deposit slip no. 7103137035	Name of Manufacturer: Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Copy Notarization: Apostille Validity: 20-05-2028 • FSC: Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate:	Brand Name: Innovex Urological Stone extraction baskets Generic Name: Urological Stone extraction baskets Applied as: Single Class: B Models/Code/sizes (as per FSC & application	Rejected on the following grounds The firm submitted expired FSC in response of deferment in 102nd meeting.

		Type: Copy Notarization: Apostille Validity: 04-11-2027 EU certificate for Quality management system has been submitted		
			Shelf Life: 3 years	
9	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09-07-2025 Fee: Rs. 31,000 vide deposit slip no. 075994978304	Name of Manufacturer: GuangDong Baihe Medical Technology Company China Address: No. 89 Taiyuan East Road Nanhi Foshan 528225 Guangdong Province China LOA Type: Original Notarization: Notarized Validity: 5 years • FSC: Type: Original Issued By: Provincial Supervision Body Legalization: Apostille Validity: 22-07-2026 ISO – Certificate: Type: Original	Brand Name: ABLE Disposable Urology Guide Wire Generic Name: Disposable Urological Guidewire Applied as: family Class: B Models/Code/sizes (as per FSC & application) TS-J-150-035, TS-J-180-035, TS-J-260-035, TS-J-150-038, TS-J-180-038, TS-J-260-038	Approved

		Notarization: Notarized Validity: 06-08-2027 Notarized copy of EC certificate valid till 26-05-2024 has been submitted.		
			Shelf Life: 3 years	
10	M/s. Moon Enterprises, 324, Rewaz Garden Lahore (ELI-00356) R&I Date: 03-06-2025 Fee: 50,000/- Slip # 7060554145	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd., Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China LOA Type: Copy Notarization: Apostille Issue Date: 01-01-2025 Validity: 01-01-2030 • FSC Type: Copy Issued By: Shandong Association for Medical Device Industry Legalization: Apostille Validity: 07-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025 CE Certificate: Type: Copy Legalization: Notarized Validity: 26-05-2026 Issued by: TUV Rheinland LGA Products GmbH, Germany.	Brand Name: WZ ® Generic Name: Disposable sterile Blood Infusion set (with Needle)-all sizes Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model): FSC and LOA does not mention any particular sizes or models Shelf Life: 5 years	Approved with codes W-IS-GA ,W-IS-GB,W-IS-GC ,W-IS-GD
11	M/s. Moon Enterprises, 324, Rewaz Garden Lahore (ELI-00356) R&I Date: 03-06-2025 Fee: 50000/- Slip # 6757456105898	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd., Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China LOA Type: Original Notarization: Apostille Issue Date: 01-01-2025 Validity: 01-01-2030	Brand Name: WZ ® Generic Name: Disposable sterile blood transfusion set (with needle) Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model): Specifications: With	Approved codes/sizes W-TS-A, W-TS-B, W-TS-C, W-TS-D

		The submitted LOA does not include name of applied product • FSC Type: Original Issued By: Shandong Association for Medical Device Industry Legalization: Apostille Validity: 07-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025 CE Certificate: Type: Copy Legalization: Notarized Validity: 26-05-2026 Issued by: TUV Rheinald LGA Products GmbH, Germany.	needles (all sizes) Shelf Life: 5 years	
12	M/s. Moon Enterprises, 324, Rewaz Garden Lahore (ELI-00356) R&I Date: 03-06-2025 Fee: 50000/- Slip # 2739623925	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd., Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China LOA Type: Copy Notarization: Apostille Issue Date: 01-01-2025 Validity: 01-01-2030 • FSC Type: Copy Issued By: Shandong Association for Medical Device Industry Legalization: Apostille Validity: 07-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025 CE Certificate: Type: Copy Legalization: Notarized Validity: 26-05-2026 Issued by: TUV Rheinald	Brand Name: WZ ® Generic Name: Intravenous infusion set with Burette Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model): Specifications: With needles BS-100ml-G • 100ml without check valve, Normal PVC • 100ml with check valve, Normal PVC • 100ml with check valve, PVC DEHP FREE • 100ml without check valve, PVC DEHP Free. BS -150ml-G • 150ml without check vale, normal PVC	Approved as BS-100-G, BS-150-G

		LGA Products GmbH, Germany.	• 150ml with check valve, Normal PVC • 150ml with check valve, PVC DEHP free • 150ml without check valve, PVC DEHP free	
			Shelf Life: 5 years	
13	M/s. Moon Enterprises, 324, Rewaz Garden Lahore (ELI-00356) R&I Date: 03-06-2025 Fee: 31,000/- Slip # 309953150993	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd., Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China LOA Type: Copy Notarization: Apostille Issue Date: 01-01-2025 Validity: 01-01-2030 • FSC Type: Copy Issued By: Shandong Association for Medical Device Industry Legalization: Apostille Validity: 07-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025 CE Certificate: Type: Copy Legalization: Notarized Validity: 26-05-2026 Issued by: TUV Rheinald LGA Products GmbH, Germany.	Brand Name: WZ ® Generic Name: Disposable sterile Insulin Syringe Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model): U-100 (1ml) Shelf Life: 5 years	Approved as 0.5ML,1ML
14	M/s. Moon Enterprises, 324, Rewaz Garden Lahore (ELI-00356) R&I Date: 03-06-2025 Fee: 50000/- Slip #	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd., Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China LOA Type: Copy Notarization: Apostille	Brand Name: WZ ® Generic Name: Disposable sterile Syringe (Included Auto-Destruct / Auto Disable Type with Needle) Applied as: Family	Approved as Auto-Destruct / Auto Disable Type with Needle codes/sizes 1ML,2ml,3ml,5ml,10ml, only.

	5692872003	Issue Date: 01-01-2025 Validity: 01-01-2030 • FSC Type: Copy Issued By: Shandong Association for Medical Device Industry Legalization: Apostille Validity: 07-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025 CE Certificate: Type: Copy Legalization: Notarized Validity: 26-05-2026 Issued by: TUV Rheinald LGA Products GmbH, Germany.	Class: B Models/Code/sizes (as per FSC & application Model): 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 50ml Shelf Life: 5 years	
15	Al-Kareem Medical Technologies, 41 AlFirdous Avenue Faiz Road Old Muslim Town, Lahore (ELI-00653	WilAmed Gawerbepark Barthelmeasaurach Aurachhohe 5-7 91126 Kammerstein Germany	Brand name: WILAmed Generic name: respiratory gas humidifier Applied as : set Class: B SHELF LIFE: n/a	Rejected on following grounds: Form 7a not signed and stamped Applied Product not mentioned on FSC
16	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20096; 07-Jul-2025 Fee: 31,000/- Slip # 9109518754	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of	Brand Name: Exomind Generic Name: Transcranial Magnetic Stimulation (TMS) Applied as: System Class: B Models/Code/sizes (as per FSC & application Model): Exomind Exomind Applicator (BTL-699-AP-M-2) Shelf Life: 5 years	Approved

LOCAL DEFERRED CASES:

1	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055) Date of R&I 23-04-2024 Fee Details: Paid Fee: 20,000/- Challan No. 47610803513	Surgical Sutures Section Ligatures Section GMP certificate valid up to 08-09-2023.	BT-Polypropylene Suture Propylene blue monofilament non-absorbable Suture Applied as Single. Class-B Service Life: 5 Yrs Model/Codes/Size: 0,1,2,2/0,3/0,4/0,5/0,6/0,7/0,8/0	Approved
2	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055) Date of R&I 23-04-2024 Fee Details: Paid Fee: 20,000/- Challan No. 182667518	Surgical Sutures Section Ligatures Section GMP certificate valid up to 08-09-2023.	BT-PGA SUTURE Synthetic Absorbable Suture Braided Polyglycolic Acid Applied as Single. Class-B Service Life: 5 Yrs Model/Codes/Size: 0,1,2,2/0,3/0,4/0,5/0,6/0,7/0,8/0	Approved

**MANUFACTURING SITE ADDRESS OF ALREADY APPROVED MEDICAL DEVICES OF
M/S MATRIX PHARMA (PVT) LIMITED, KARACHI FOR IMPORT.**

S.No	Name of Firm	Name of Manufacturer	Name of Medical Device	Decision of 13 th meeting of MDB
1	M/s Matrix Pharma (Pvt) Ltd., Plot No. 12, Sector 15, Korangi Industrial Area, Karachi (ELI-00039) Evaluator: Ms. Unum Zia Shamsi	Manufacturer: M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8 th Street, Hangzhou Econ. &Tech. Development Zone, China Manufacturing site: No. 866, Moganshan Road (No. 700, Shixiang Road), Hangzhou, China (FSC China Valid Till 17-09-2020)	Bonisa® Bone Repairing Material (0.5 mg rhBMP-2/vial) Class D Shelf Life: 02 Years Fee Submitted: Rs 50,000/-	Approved subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.
2	-do-	-do-	Bonisa® Bone Repairing Material (2.0 mg rhBMP-2/vial) Class D Shelf Life: 02 Years Fee Submitted: Rs 50,000/-	-do-
3	-do-	-do-	Bonisa® Bone Repairing Material (1.0 mg rhBMP-2/vial) Class D Shelf Life: 02 Years Fee Submitted: Rs 50,000/-	-do-

After that the firm has applied for change of manufacturing site address of above mentioned medical devices for import as per detail given below:-

Existing Approved Address of Manufacturer and Manufacturing site	Proposed Address of Manufacturer and Manufacturing site
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Manufacturer: M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8 th Street, Hangzhou Econ. &Tech. Development Zone, China. Manufacturing site: No. 866, Moganshan Road (No. 700, Shixiang Road), Hangzhou, China.	Manufacturer: M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8 th Street, Hangzhou Econ. & Tech. Development Zone, China. Manufacturing site: 1 st Floor, 4 th Building, HEDA Medicine Valley Center, No.291, Fucheng Road, Xiasha District, Hangzhou Economic and Technology Development Zone, China.
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Decision: MDB has approved the following products:

- Bonisa
- 0.5 mg rhBMP-2/Vial
- 1.0 mg rhBMP-2/Vial
- 2.0 mg rhBMP-2/Vial

Case No.2

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Health Solutions 28B, Second Floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) Challan No. 72443626 Dated: 02-07-2025 Fee: /-104,500 R&I Date: 18-09-2024	Manufacturer Name: M/s. Shandong Haidike Medical Products Co., Ltd Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. LOA Notarization: Yes Valid: 28-04-2029. • FSC Legalized: Not Legalized Issued by: MPA. Valid: 14-12-2026. ISO – Certificate: Notarization: Yes Valid till: 19-11-2026. EC Certificate: Notarization: Yes Valid till 09-11-2027. Design Examination Certificate: Not Submitted	Brand Name: Suicare Surgical Sutures Generic Name: Chromic Catgut Surgical Absorbable Suture with Needle Applied as: Family Class: D Models/Code/sizes (as per FSC & application: USP Suture Size: 12-0#, 11-0#, 10-0#, 9-0#, 8-0#, 7-0#, 6-0#, 5-0#, 4-0#, 3-0#, 2-0#, 0#, 1#, 2#, 3#, 4#, 5#. Needle Shape: Round Bodied, Straight, Curve Cutting & Reverse Cutting Needle Curvature: ½ circle, 3/8 circle, Straight. Shelf life 5 Years	Approved

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