

**Government of Pakistan**  
**Ministry of National Health Services, Regulation & Coordination**  
**Drug Regulatory Authority of Pakistan**  
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**DECISIONS OF 114<sup>th</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 24<sup>th</sup> DECEMBER-2025**

114<sup>th</sup> meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 24<sup>th</sup> December, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

<b>S.No.</b>	<b>Name and Designation/Department</b>	<b>Position in the MDB</b>
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr M Salik Zahid, Chief Drugs Inspector, Nominee of DGHS Baluchistan	Member
3.	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)
4.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
5.	Dr. Farid Khan, Senior Consultant Neuro Surgery/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.	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 Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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.	Mr. Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Ammar Ashraf Awan	Deputy Director
10.	Mr. Hanif Ullah	Deputy Director

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.

**Evaluator: Mr. Muhammad Amin (Deputy Director)**

**Item No. I: APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017**

**FRESH ESTABLISHMENT LICENSE TO MANUFACTURE (ELM) CASES:**

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Defence Science and Technology Organization Labs, Complex, Biological Research Centre, DESTO, 34-37 PNH, Lines, Karachi.	Dr. Shaukat Ali Bs Hons (Microbiology)  Experience as Deputy Chief Manager Desto from 01-09-2021 to 27-1-2023	Ms. Misbah Khadim  MSc Biosciences  Experience: Incharge QC Desto 15 Years	The board approved Molecular Diagnostic Section of the firm and endorsed issuance of Establishment License to Manufacture Medical Devices with addition of this section in addition to the sections approved in 108 meeting of Medical Devices Board.

**Item No. I(A): 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	Decision
1.	M/s Aoun Medical care SMC-PVT, limited Office: 194/C OPD society phase 1, Lahore  Godown: A-1, behind dyal singh mansion, the mall road Lahore.	Zafar Mahmood  Msc Microbiology	Rejected. The board rejected the application for establishment license to import medical devices based on the information that the applicant is no more interested to pursue this application.
2.	M/s Hayyat Life Sciences, Office: B-73-1, block 5 gulshan e Iqbal , Karachi  Godown: Warehouse # 5 , KDA, Appartment, block A, North Nizam abad, Karachi.	Amjad Javaid Lodhi  Phram D	Approved
3.	M/s Ramay Electromedix, 12-Alam Gheer flats, education town wahdat road iqblal town , Lahore.	Mishail fatma Ms microbiology	Approved
4.	M/s Talha brothers,  Office/godown : 6 jamal ud din afghani road, behind NBP main branch , Lahore.	Rauf Ahmed  Bs Medical Laboratory technology	Approved

**Item No. I (B): DEFERRED CASES IMPORT MEDICAL DEVICES LICENSE:**

of the panels are as mentioned against each is submitted for consideration of MDB please

S. #	Name of Establishment	Name of Qualified Technical	Name of Management	Decision
1.	M/s GR International Traders, House No.11, Street No.2, Mian Park, Badami Gagh, Lahore.	Niraj Liaqat Pharm D	Muhammad Shahid CEO	Approved

**Item No. I(C): APPLICATIONS FOR GRANT OF 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 A.j Mirza pharma Pvt Ltd,  Office/Godown: Plot No. 44, Sector 27, Korangi Industrial area, Karachi.  ELI-00321	Naseer Ahmed Zia  B-Pharmacy	Ali Abbas Adnan Hussain Syed Shahab balkhi	Approved
2.	M/s Audi Med Pakistan,  Office/godown: 63/3A, Block D-A, Gulberg III, Sir syed road, Opp, Hijaz Hospital, Lahore.  ELI-000596	Shahza Aslam  Pharm D	Nadeem Mukhtar  CEO	Approved The firm shall submit undertaking that the facility shall not be used for residential purposes and premises can be inspected any time without hindrance.
3.	M/s MED-EL Pakistan,  Office/Godown: 63/3A, Block D-1, Gulberg III, Sir Syed Road, Opp. Hijaz Hospital, Lahore  ELI-00597	Muhammad Usama  Pharm D	Nadeem Mukhtar	Approved
4.	M/s Siemens healthcare (Pvt) ltd,	Azfar Hussain  Biomedical engineer	Khurram Jameel Syed Imran Raza	Approved

	4 <sup>th</sup> floor state life building 15-A, Sir Agha khan (Davis road), Lahore.  ELI-00146			
5.	M/s Trowmedic international,  Office / godown: building no. 117, sagian T4, opposite sanda stop band road, Lahore.  ELI-00069	Nazia Kosar  Pharm D	Hassan Saleem  CEO	Approved
6.	M/s Muslim trading agencies,  Office / godown: Grond floor 3 syed Mok dary road Lahore.  Godown: 4 lake road , near jamia masjid qadsia, chouburji Lahore.  ELI-000359	Sami ullah Sheikh	Rafi ullah Sheikh Sami ullah Sheikh M sami ullah Sheikh	The board was informed that the applicant is no more inetested to renew establishment license to import medical devices. The board decided to provide oppurtunity of personal hearing to the firm to complete requirement of law before decision is made on license.

**Item No. I (D): RENEWAL DEFERRED CASES IMPORT MEDICAL DEVICES LICENSE:**

S.#	Name of Establishment	Name of Qualified Technical	Name of Management	Decision
1.	M/s Amir Enterprises, 1 <sup>st</sup> Floor, Plaza No. 55, Opposite Security Check Post Gate No. 1, Gulshan Abad, Adyalla Road, Rawalpindi  (ELI-00490)	Old Technical Person:  Furqan Aslam Chaudhry  New Technical Person: Tahzeen Fatima  Pharm D	Muhammad Asim Khan	Approved

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

**Evaluator: Dr. Hanif Ullah (Deputy Director)**

**I. APPLICATIONS SUBMITTED IN HARD DOSSIERS:**

S.No	Name of Importer	Manufacturers Detail	Name of Medical Device	Decision
1.	Medco, 19-Khyber Bazar Peshawar ELI-00686 R&I Date: 04.06.2025 3317-B-Punjab Fee: 31000/- Slip #777157401142	Legal Manufacturer: Bontech Co., Ltd., #D 1201, Digital Empire D-Building, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Korea LOA Type: Copy Notarization: No Validity: 27.05.2030 FSC (for BT-DA24-IA, BT-DB24-IA, BT-DA22W; BT-DB22W) Type: copy Issued by: National Institute of Medical Devices Safety Information, South Korea Legalization: no Issue date: 25.10.2024 ISO – Certificate: Type: Copy Notarization: No Validity: 27.09.2027 CE certificate Type: Copy Notarization: No Validity: 27.05.2024 Extended till 31.12.2028	Brand Name: Bontech Flat Panel Digital X-Ray Detector BSD Series Generic Name: Flat Panel Digital X-Ray Detector Applied as: Family Class: B Models/Code/sizes (as per FSC & application BT-DA24-IA, BT-DB24-IA, BT-DA22W; BT-DB22W; BT-DA22-IA; BT-DB22-IA Shelf Life: NIL	Deferred for: Apply with proper groping and class along with submission of requisite fee. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Conclusive stability study / shelf life verification report is required. Submit notarized copy of LOA. Variation of building number in the CE certificate, FSC and application shall be clarified. Submit DOC on the letterhead of the firm containing models, i.e., BT-DA22-IA; BT-DB22-IA of the applied device. You have not submitted FSC for the models, i.e., BT-DA22-IA; BT-DB22-IA of the applied device. Submit notarized copy of FSC covering all the applied models. Notarized copy of ISO – 13485 Certificate is required. Legalized FSC in reference country or notarized CE certificate is required.
2.	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 R&I Date:	Legal Manufacturer: Chengdu OCI Medical Devices Co., Ltd., No. 2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District,	Brand Name: Purifier Arteriovenous Fistula Needle Set Generic Name: Arteiovenous Fistula Needle Sets Applied as: single	Deferred for: Apply with proper groping along with submission of differential fee for grouping. Notarized declaration on Stamp paper issued in the name of the firm / signatory is

	07.07.2025 3056-B-Punjab Fee: 31000/- Slip #18728608	Chengdu, Sichuan Province, 610299, China LOA Type: Copy Notarization: No Validity: 06.01.2028 FSC Type: copy Issued by: NIL Legalization: no Issue date: 07.08.2026 ISO – Certificate: Type: Copy Notarization: No Validity: 02.04.2026 CE certificate Type: NIL Notarization: No Validity: NIL	Class: B Models/Code/sizes (as per FSC & application OCI-14G, OCI-15G, OCI- 16G, OCI-17G Shelf Life: 3 years	required. Submit notarized copy of FSC with English translation of the issuing authority Submit notarized copy of LOA. Notarized copy of ISO – 13485 Certificate is required. Legalized FSC in reference country or notarized CE certificate is required.
3.	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 R&I Date: 07.07.2025 3057-B-Punjab Fee: 31000/- Slip #317942639534	Legal Manufacturer: Chengdu OCI Medical Devices Co., Ltd., No. 2401, West Port Avenue, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, 610299, China LOA Type: Copy Notarization: No Validity: 06.01.2028 FSC Type: copy Issued by: NIL Legalization: no Issue date: 07.08.2026 ISO – Certificate: Type: Copy Notarization: No Validity: 02.04.2026 CE certificate Type: NIL Notarization: No Validity: NIL	Brand Name: Purifier Hemodialysis Blood Tubing Sets Generic Name: Hemodialysis Blood Tubing Sets Applied as: single Class: B Models/Code/sizes (as per FSC & application OCI-BD-D-A, OCI-BD- S-A, OCI-BD-S-AB Shelf Life: 3 years	Deferred for: Apply with proper grouping along with submission of differential fee for grouping, if any. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Submit notarized copy of FSC with English translation of the issuing authority Submit notarized copy of LOA. Notarized copy of ISO – 13485 Certificate is required. Legalized FSC in reference country or notarized CE certificate is required.
4.	Ideal Business Products, 40- Hurmaz Plaza, University Road,	Legal Manufacturer: Oricare Inc., A Delaware Corporation., 1900 AM Drive Quakertown, PA	Brand Name: Oricare Ventilator Generic Name: Ventilator Applied as: Single	Deferred for: Apply with proper grouping and class along with submission of properly filled

	<p>Peshawar ELI-00868 R&amp;I Date: 10.07.2025 3324-A-KPK Fee: 6000/- Slip #86318500947</p>	<p>18951 USA LOA Type: NIL Notarization: No Validity: NIL CFG Type: copy Issued by: USFDA Legalization: no validity: 25.06.2020 ISO – Certificate: Type: Copy Notarization: No Validity: 20.12.2022 CE certificate Type: NIL Notarization: No Validity: NIL</p>	<p>Class: B (registered as C) Models/Code/sizes (as per FSC &amp; application V8800 critical care ventilator Shelf Life: NIL</p>	<p>Form 7A and requisite fee. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Submit notarized complete and valid LOA. Notarized copy of valid ISO – 13485 Certificate is required. Valid and apostilled CFG is required. Essential principles of safety and performance shall be submitted. Service life verification report shall be submitted.</p>
5.	<p>Bio Indus, B-526, B Satellite Town, Rawalpindi. ELI-00979 R&amp;I Date: 15.07.2025 3202-A-Punjab Fee: 6000/- Slip #554547803049</p>	<p>Legal Manufacturer: Singuway Biotech Inc. B1302, Life Science Park, ShenchengTou Innovation factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, China LOA Type: copy Notarization: No Validity: NIL FSC Type: copy Issued by: Spain Legalization: no Issue date: 27.10.2021 ISO – Certificate: Type: Copy Notarization: No Validity: 11.02.2026</p>	<p>Brand Name: Nucleic Acid Extraction Reagents (Magnetic Bead) Generic Name: Nucleic Acid Extraction Reagents (Magnetic Bead) Applied as: Kit Class: A Models/Code/sizes (as per FSC &amp; application T-64(64 tests per box) Shelf Life: 12 months</p>	<p>Deferred for: Submit notarized and valid LOA. Notarized copy of valid ISO – 13485 Certificate is required. Valid and apostilled FSC (in Spain) is required.</p>
6.	<p>Reaction Scientific (Pvt) Ltd, 337, Street No. 17, Block-B, Sector B- 17, Islamabad. ELI-00228 R&amp;I Date: 11.07.2025 3158-A-ISB Fee: 6000/-</p>	<p>Legal Manufacturer: Human Gesellschaft fur Biochemica und Diagnostica mbH Max- Planck-Ring 21, 65205 Wiesbaden, Germany LOA Type: Original Notarization: Yes Validity: 31.12.2029</p>	<p>Brand Name: HumaLyzer 4000 Generic Name: Semi automated Photometer Applied as: Single Class: A Models/Code/sizes (as per FSC &amp; application 18250 Shelf Life: NA</p>	<p>Deferred for: Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Valid and apostilled FSC is required.</p>



	Slip #11208829501	FSC Type: copy Issued by: Germany Legalization: no Issue date: 18.02.2022 ISO – Certificate: Type: Copy Notarization: Yes Validity: 11.03.2028		
7.	Med Lab Services, Office Address: KT 34, Main Khayaban e Tanvir Road, Chaklala Scheme 3, Rawalpindi. Warehouse Address: Office No. 4, 2nd Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi. ELI-00056 R&I Date: 15.07.2025 3354-A-Punjab Fee: 6000/- Slip #271065586	Legal Manufacturer: GeneProof a.s, Videnska 101/119, Dolni Herspice 619 00 Brno Czech Republic LOA Type: Original Notarization: Yes Validity: 31.12.2028 FSC Type: copy Issued by: Czech Republic Legalization: no (just notarized) Issue date: 05.06.2025 ISO – Certificate: Type: Copy Notarization: No Validity: 26.11.2026	Brand Name: GeneProof Generic Name: croBee NA16 Nucleic Acid Extraction System Plus Applied as: Single Class: A Models/Code/sizes (as per FSC & application CBNA/16P Shelf Life: NA	Deferred for: Correction of the address of the applicant in application Form is required. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Notarized copy of valid ISO – 13485 Certificate is required. Valid and apostilled FSC is required.
8.	United Healthcare Plot No. 330/B, 2nd floor DMCH, Bahadurabad, Karachi ELI-00293 R&I Date: 08.07.2025 3027-B-Sindh Fee: 62000/- Slip #13143810	Legal Manufacturer: Xiamen Compower Medical Tech Co. Ltd., Unit 301, No. 16, Xianghong Road, Xiang'an Torch Industrial Zone, Xiamen China LOA Type: Copy Notarization: No Validity: 3 years from 27.06.2025 FSC Type: copy Issued by: China Chamber of Commerce Legalization: No Issue date: 16.05.2025 ISO – Certificate: Type: Copy Notarization: No Validity: 12.10.2026	Brand Name: Safety-Air CPR Mask Generic Name: CPR Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application CP4610 Shelf Life: 3 years	Deferred for: Submit notarized and valid LOA. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Notarized copy of valid ISO – 13485 Certificate is required. Valid and apostilled FSC in the country of origin is required. DOC shall be submitted on the letterhead of the manufacturer. Legalized FSC in reference country or notarized CE certificate is required.

9.	<p>Healer International, Off # 13, 7i/A 3<sup>rd</sup> Floor, Satellite Shopping Center A Block 6th Road, Rawalpindi, Pakistan ELI-01167 R&amp;I Date: 28.10.2024 Fee: 6000/- Slip # 682594462 This evaluation is based on the on-line data submitted through E-App. Tracking ID: 8BA- W22-TMTY</p>	<p>Legal Manufacturer: Torch Avenue, Fengcheng High-tech Park, Yichun City, Jiangxi Province, China LOA Type: Copy Notarization: Yes Validity: 01.10.2029 FSC Type: NIL Issued by: NIL Legalization: No Issue date: NIL ISO – Certificate: Type: Copy Notarization: Yes, CCPIT Validity: 28.12.2025 CE certificate: Type: Copy Notarization: Yes, CCPIT Validity: 30.04.2024 Extended till 31.12.2028</p>	<p>Brand Name: Hawkmed Generic Name: Disposable High-Pressure Angiographic Syringes Applied as: Family Class: B Models/Code/sizes (as per FSC &amp; application NIL Shelf Life: 3 years</p>	<p>Deferred for: Submit the requisite fee for the applied grouping and class. Complete name of the manufacturer shall be provided in the application Form. Details of the applied sizes as per FSC are required. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Conclusive stability study / shelf life verification report is required Valid and apostilled FSC in the country of origin is required.</p>
10.	<p>Amir Enterprises, 1st Floor Plaza # 55, Opposite Security Check Point, Gate No. 1 Gulshanabad, Adyala Road, Rawalpindi ELI-00410 R&amp;I Date: 17.07.2025 3343-B-Punjab Fee: 31000/- Slip #511535314570</p>	<p>Legal Manufacturer: Ophthalmic Experts Ltd., 50 Ripple Road, Barking, Essex, IG11 7PG, United Kingdom LOA Type: Copy Notarization: No Validity: 5 years from 09.12.2023 FSC Type: copy Issued by: MHRA, UK Legalization: No Issue date: 13.12.2023 ISO – Certificate: Type: Copy Notarization: No Validity: 17.11.2027</p>	<p>Brand Name: X-Ject Lens Delivery System Generic Name: Lens Delivery System Applied as: Single Class: B Models/Code/sizes (as per FSC &amp; application IA-S-B-RT3, IA-S-B-RT4 Shelf Life: NIL</p>	<p>Deferred for: The firm has applied two models and application is meant for single. Clarification is required. Submit notarized and valid LOA. Notarized declaration on Stamp paper issued in the name of the firm / signatory is required. Conclusive stability study / shelf life verification report is required. Notarized copy of valid ISO – 13485 Certificate is required. DOC depicts that the applied device is class C. Clarification is required. Legalized FSC in the country of origin having / highlighting the applied models / sizes is required.</p>

**CMS CASES:**

<b>Sr. No.</b>	<b>Name of Applicant(s)</b>	<b>Name of Manufacturer</b>	<b>Medical Device</b>	<b>Decision</b>
<b>1.</b>	<b>M/s Muslim Medical Services</b> <b>1st Floor of Sky Star Travels,3- Syed Moj Darya Road, Lahore</b>  <b>(ELI-00373)</b>  <b>R&amp;I Date:</b> 31-07-2024 <b>CMS tracking ID:</b> PPH-6GR-HQBS  <b>Fee: 25,000/-</b>	<b>Legal Manufacturer Name:</b> M/s Beurer Gmbh Germany. <b>Address:</b> Soeflinger Strasse 218, 89077 Ulm, Germany <b>Manufacturer:</b> GLOBAL CARE MEDICAL TECHNOLOGY CO., LTD <b>Address:</b> 7th Building, 39 Middle Industrial Main Road, European industrial Zone, Xiaolan Town, 528415 Zhongshan City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA <b>LOA</b> <b>Notarization:</b> Yes <b>Valid:</b> 31-12-2025  <b>• FSC</b> <b>Legalized:</b> Yes <b>Issued by:</b> German Authority <b>Issued:</b> 21-05-2024  <b>ISO – Certificate:</b> <b>Notarization:</b> No <b>Valid till:</b> 29-11-2026  <b>EC Certificate:</b> Valid till 26-05-2024	<b>Brand Name:</b> Beurer Nebulizer <b>Generic Name:</b> Nebulizer <b>Applied as:</b> Single <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application:</b> IH28 Pro <b>Shelf life</b> 7 years	<b>Approved. Firm shall submit ISO certificate of manufacturing site before issuance of enlistment certificate.</b>
<b>2.</b>	<b>M/s Muslim Medical Services</b> <b>1st Floor of Sky Star Travels,3- Syed Moj Darya Road, Lahore</b>  <b>(ELI-00373)</b>  <b>R&amp;I Date:</b> 31-07-2024 <b>CMS tracking ID:</b> QQE-19Z-97ZZ <b>Fee: 25,000/-</b>	<b>Legal Manufacturer Name:</b> M/s Beurer Gmbh Germany. <b>Address:</b> Soeflinger Strasse 218, 89077 Ulm, Germany <b>Manufacturer:</b> GLOBAL CARE MEDICAL TECHNOLOGY CO., LTD <b>Address:</b> 7th Building, 39 Middle Industrial Main Road, European industrial Zone, Xiaolan Town, 528415 Zhongshan City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA <b>LOA</b> <b>Notarization:</b> Yes <b>Valid:</b> 31-12-2025	<b>Brand Name:</b> Beurer Nebulizer <b>Generic Name:</b> Nebulizer <b>Applied as:</b> Single <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application:</b> IH24 Kids <b>Shelf life</b> 7 years	<b>Approved. Firm shall submit ISO certificate of manufacturing site before issuance of enlistment certificate.</b>

		<p>• <b>FSC</b>  <b>Legalized:</b> Yes  <b>Issued by:</b> German Authority  <b>Issued:</b> 21-05-2024</p> <p><b>ISO – Certificate:</b>  <b>Notarization:</b> No  <b>Valid till:</b> 29-11-2026</p> <p><b>EC Certificate:</b> Valid till 26-05-2024</p>		
3.	<p><b>M/s</b>  Varitron,  First Floor 60-D Zahoor  Elahi road, Gulberg IV,  Lahore, Pakistan.  <b>(ELI-00510)</b></p> <p><b>R&amp;I Date:</b>  04-07-2024  <b>CMS tracking ID:</b>  XJP-7RN-N6M5</p> <p><b>Fee:</b> 50,000/-</p>	<p><b>Legal Manufacturer:</b>  Varian Medical Systems, Inc  Address:  3100, Hansen Way Palo Alto  CA 94304 USA.  <b>CH REP:</b>  Siemens Healthineers Intl. AG.  Hinterbergstrasse 14,6312  Steinhausen, Switzerland  (CHRN-AR-2000721)  <b>Manufacturing Sites:</b>  Varian Medical Systems 2101  4th Avenue, Suite 100  SEATTLE, WA USA 98121  <b>Varian Medical Systems</b>  <b>China Co., Ltd.</b> No.8  Yuncheng Street BDA Beijing,  Beijing CHINA 100176 <b>Varian</b>  <b>Medical Systems Imaging</b>  <b>Laboratory GmbH</b>  Taefernstrasse 7 Daettwil,  Argovia, Aargau  SWITZERLAND CH-5405  <b>Varian Medical Systems, Inc</b>  3290 Northside Parkway NW  Suite 400 Atlanta, GA USA  30327  <b>Varian Medical Systems, Inc</b>  6212 Hellyer Ave San Jose, CA  USA 95138</p> <p><b>Varian Medical System Haan</b>  <b>GmbH</b>  Rheinische Strasse 2 Haan,  North RhineWestphalia  GERMANY 42781  <b>Varian Medical Systems, Inc</b>  Corredor TijuanaRosarito, No  21702 col. El Realito Tijuana,  Baja California MEXICO 22250  <b>Varian Medical Systems Haan</b></p>	<p><b>Brand Name:</b>  Halcyon  <b>Generic Name:</b>  Linear Accelerator  <b>Applied as:</b> Single  <b>Class:</b> C</p> <p><b>Models/Code/sizes (as</b>  <b>per FSC &amp;</b>  <b>application:</b>  BR10, BR60, BR90  <b>Shelf life</b>  N/A</p>	<p><b>Deferred for</b>  <b>verification of the</b>  <b>manufacturing site</b>  <b>for the applied</b>  <b>product along with</b>  <b>ISO certificate for</b>  <b>the relevant site</b></p>

		<b>GmbH</b> Manufacturing site Kemnath Building C10 Roentgenstrasse 19-21, Kemnath, Bavaria Germany 95478  <b>LOA</b> <b>Notarization:</b> Yes <b>Valid:</b> 30-06-2027  • <b>FSC</b> <b>Legalized:</b> Yes <b>Issued by:</b> USFDA <b>Valid:</b> 06-01-2027  <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 10-02-2027  <b>EC Certificate:</b> Valid till 15-07-2026		
4.	<b>Name</b> United Healthcare <b>Address</b> Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) <b>R&amp;I Date:</b> 08-07-2025 <b>CMS tracking ID:</b> RNZ-689-46UH  <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> M/s Xiamen Compower Medical Tech Co., Ltd. <b>Manufacturing Site:</b> Unit 301, No. 16, Xianghong Road, Xiang'an Torch Industrial Zone, Xiamen, China. . <b>LOA</b> <b>Notarization:</b> Yes <b>Valid:</b> 26-06-2028  • <b>FSC</b> <b>Legalized:</b> Apostille <b>Issued by:</b> China Chamber of Commerce <b>Valid:</b> 15-05-2027  <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 12-10-2026  <b>EC Certificate:</b> Valid till 12-10-2028	<b>Brand Name:</b> Safety-Air CPR Mask <b>Generic Name:</b> CPR Mask <b>Applied as:</b> Single <b>Class:</b> B  <b>Models/Code/sizes (as  per FSC &amp;  application:</b> CP6410 <b>Shelf life</b> 3 years	<b>Deferred for  following:</b> <i>Valid legalized FSC  issued by relevant  regulatory authority  of country of origin  shall be submitted.</i>
5.	<b>Name</b> United Healthcare <b>Address</b> Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) <b>R&amp;I Date:</b> 08-07-2025	<b>Manufacturer:</b> <b>Legal Manufacturer:</b> Intco Medical (HK) Co., Limited <b>Address:</b> Unit 04,7/F Bright Way Tower, No. 33 Mong Kok Road, KL Hongkong <b>Manufacturing Sites:</b> Shanghai Intco Electrode Manufacturing Co., Ltd. No.	<b>Brand Name:</b> SafetyElectrosurgical Disposable Grounding Pads <b>Generic Name:</b> Electrosurgical Disposable Grounding Pad <b>Applied as:</b> Family	<b>Deferred for  following:</b> <i>Valid legalized FSC  issued by relevant  regulatory authority  of country of origin  shall be submitted</i>  <i>Valid CE certificate</i>

	<b>CMS tracking ID:</b> RNZ-689-46UH  <b>Fee:</b> 62,000/-	1358, Hubin Road, Fengxian District, 201417  <b>Shanghai, P.R. China Jiangsu Intco Medical Products Co., Ltd.</b> No. 298 Yandunshan Road, Zhenjiang New District 212132 Jiangsu P.R. China  <b>LOA</b> <b>Notarization:</b> Yes <b>issued:</b> 25-06-2025  • <b>FSC</b> <b>Legalized:</b> Apostille <b>Issued by:</b> China Chamber of Commerce <b>Valid:</b> 07-05-2027  <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 15-12-2025  <b>EC Certificate:</b> Valid till 26-05-2024	<b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application:</b> GP01, GC01, GP02, GC02, GP03, GC03, GP04, GC04, GI01, GI02, GI03, GI04 <b>Shelf life</b> 3 years	<i>shall be submitted</i>
6.	<b>Name</b> United Healthcare <b>Address</b> Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) <b>R&amp;I Date:</b> 08-07-2025 <b>CMS tracking ID:</b> RNZ-689-46UH  <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> <b>Legal Manufacturer:</b> Intco Medical (HK) Co., Limited <b>Address:</b> Unit 04,7/F Bright Way Tower, No. 33 Mong Kok Road, KL Hongkong <b>Manufacturing Sites:</b> <b>Shanghai Intco Electrode Manufacturing Co., Ltd.</b> No. 1358, Hubin Road, Fengxian District, 201417  <b>Shanghai, P.R. China Jiangsu Intco Medical Products Co., Ltd.</b> No. 298 Yandunshan Road, Zhenjiang New District 212132 Jiangsu P.R. China  <b>LOA</b> <b>Notarization:</b> Yes <b>issued:</b> 25-06-2025  • <b>FSC</b> <b>Legalized:</b> Apostille <b>Issued by:</b> China Chamber of Commerce <b>Valid:</b> 07-05-2027	<b>Brand Name:</b> Safety Electrosurgical Disposable Grounding Pads <b>Generic Name:</b> Electrosurgical Disposable Grounding Pad <b>Applied as:</b> Family <b>Class:</b> C  <b>Models/Code/sizes (as per FSC &amp; application:</b> GP01, GC01, GP02, GC02, GP03, GC03, GP04, GC04, GI01, GI02, GI03, GI04 <b>Shelf life</b> 3 years	<b>Deferred for following:</b> <i>Valid legalized FSC issued by relevant regulatory authority of country of origin shall be submitted</i>  <i>Valid CE certificate shall be submitted</i> <i>Differential fee for grouping as family shall be submitted</i>

		<b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 15-12-2025  <b>EC Certificate:</b> Valid till 26-05-2024		
7.	<b>Name</b> United Healthcare <b>Address</b> Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) <b>R&amp;I Date:</b> 08-07-2025 <b>CMS tracking ID:</b> RNZ-689-46UH  <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> <b>Legal Manufacturer:</b> Intco Medical (HK) Co., Limited <b>Address:</b> Unit 04,7/F Bright Way Tower, No. 33 Mong Kok Road, KL Hongkong <b>Manufacturing Sites:</b> Shanghai Intco Electrode Manufacturing Co., Ltd. No. 1358, Hubin Road, Fengxian District, 201417  <b>LOA</b> <b>Notarization:</b> Yes <b>issued:</b> 25-06-2025  • <b>FSC</b> <b>Legalized:</b> Apostille <b>Issued by:</b> China Chamber of Commerce <b>Valid:</b> 07-05-2027  <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 15-12-2025  <b>EC Certificate:</b> Valid till 26-05-2024	<b>Brand Name:</b> Safety Electrosurgical Pencils <b>Generic Name:</b> Electrosurgical Pencils <b>Applied as:</b> Family <b>Class:</b> C  <b>Models/Code/sizes (as per FSC &amp; application:</b> EP01, EP01-T, EP02, EP03, EP04 <b>Shelf life</b> 3 years	<b>Deferred for following:</b> <i>Valid legalized FSC issued by relevant regulatory authority of country of origin shall be submitted</i>  <i>Valid CE certificate shall be submitted</i> <i>Differential fee for grouping as family shall be submitted</i>
8.	<b>Name</b> United Healthcare <b>Address</b> Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) <b>R&amp;I Date:</b> 08-07-2025 <b>CMS tracking ID:</b> DW6-HRB-58HS <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> Vivachek Biotech (Hangzhou) Co., Ltd. <b>Address:</b> Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, Zhejiang, 311100, P.R. China  <b>LOA</b> <b>Notarization:</b> Yes <b>valid:</b> 28-05-2027 • <b>FSC</b> Not submitted  <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 02-03-2027	<b>Brand Name:</b> Safety-Chek Blood Glucose Test Strips <b>Generic Name:</b> Blood Glucose Test Strips <b>Applied as:</b> Single <b>Class:</b> C  <b>Models/Code/sizes (as per FSC &amp; application:</b> VGS01 <b>Shelf life</b> 3 years	<b>Deferred for following:</b> <i>Valid legalized FSC issued by relevant regulatory authority of country of origin shall be submitted</i>

		<b>EC Certificate:</b> Valid till 31-12-2027		
<b>9.</b>	<b>Name</b> United Healthcare <b>Address</b> Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00293) <b>R&amp;I Date:</b> 08-07-2025 <b>CMS tracking ID:</b> DW6-HRB-58HS <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> Vivachek Biotech (Hangzhou) Co., Ltd. <b>Address:</b> Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, Zhejiang, 311100, P.R. China <b>LOA</b> <b>Notarization:</b> Yes <b>valid:</b> 28-05-2027 <b>• FSC</b> Not submitted <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 02-03-2027 <b>EC Certificate:</b> Valid till 31-12-2027	<b>Brand Name:</b> Safety-Chek Blood Glucose Meter <b>Generic Name:</b> Blood Glucose Meter <b>Applied as:</b> Single <b>Class:</b> C <b>Models/Code/sizes (as per FSC &amp; application):</b> VGM18 <b>Shelf life</b> 3 years	<b>Deferred for following:</b> <i>Valid legalized FSC issued by relevant regulatory authority of country of origin shall be submitted</i>
<b>10.</b>	<b>Name</b> Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) <b>R&amp;I Date:</b> 17-10-2024 <b>CMS tracking ID:</b> V18-QUW-HG7G <b>Fee:</b> 62,000/-	<b>Legal Manufacturer:</b> M/s KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI <b>Address:</b> Atakent Mah. 221 Sk. No: 3A Rota Office A Blok Kat:14 D:82-83, 34200 Küçükçekmece, Turkey. Telephone Number: +90 212 471 42 00 <b>Manufacturing Site:</b> KAF GRUP SAGLIK HIZ. INS. SAN. VE. TIC. LTD. STI Bardakci Mah. Teknokent Sok. No. 3. Tusba/Van/Turkey <b>LOA</b> <b>Notarization:</b> Yes <b>valid:</b> 31-12-2029 <b>• FSC</b> <b>Legalized:</b> No <b>Issued by:</b> MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE <b>Valid:</b> 26-03-2027 <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 04-03-2025	<b>Brand Name:</b> Wancare <b>Generic Name:</b> WANCARE ONESEPT GA 2% Glutaraldehyde <b>Applied as:</b> Single <b>Class:</b> C <b>Models/Code/sizes (as per FSC &amp; application):</b> KAF G23 <b>Pack Size:</b> 5L with Activator 100 ml <b>Accessory:</b> Test Strips <b>Shelf life</b> 2 years	<b>Deferred for submission of Valid legalized FSC</b>



		<b>EC Certificate:</b> Valid till 26-05-2024														
11.	<b>Name</b> Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) <b>R&amp;I Date:</b> 17-10-2024 <b>CMS tracking ID:</b> XE9-LWV-DRWW  <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> M/s NECM KİMYA AKARYAKIT ÜRÜNLERİ MEDİKAL MALZEMELER SAN.VE TİC.LTD.ŞTİ. Address : Battalgazi Mah. Sark Cad. Aytıp, I Blok No: 14 Sultanbeyli- Istanbul - Turkey <b>LOA</b> <b>Notarization:</b> Yes <b>valid:</b> 31-12-2029 • <b>FSC</b> <b>Legalized:</b> Apostille <b>Issued by:</b> MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE <b>Valid:</b> 26-03-2027  <b>ISO – Certificate:</b> <b>Notarization:</b> Yes <b>Valid till:</b> 09-02-2026  <b>EC Certificate:</b> Valid till 26-05-2024	<b>Brand Name:</b> Biorad Ready Flash <b>Generic Name:</b> High Level Medical instruments-devices and endoscopes disinfectant  <b>Applied as:</b> Family <b>Class:</b> C  <b>Models/Code/sizes (as per FSC &amp; application:</b> <table><tr><th>Descript ion</th><th>Pack Size</th></tr><tr><td>Biorad Ready Flash</td><td>100 ml</td></tr><tr><td>Biorad Ready Flash</td><td>250ml</td></tr><tr><td>Biorad Ready Flash Flash</td><td>1000 ml</td></tr><tr><td>Biorad Ready Flash Flash</td><td>5 L</td></tr><tr><td>Test Strips</td><td>Pack of 50 strips</td></tr></table> <b>Shelf life</b> 2 years	Descript ion	Pack Size	Biorad Ready Flash	100 ml	Biorad Ready Flash	250ml	Biorad Ready Flash Flash	1000 ml	Biorad Ready Flash Flash	5 L	Test Strips	Pack of 50 strips	<b>Approved</b>
Descript ion	Pack Size															
Biorad Ready Flash	100 ml															
Biorad Ready Flash	250ml															
Biorad Ready Flash Flash	1000 ml															
Biorad Ready Flash Flash	5 L															
Test Strips	Pack of 50 strips															
12.	<b>Name</b> Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) <b>R&amp;I Date:</b> 17-10-2024 <b>CMS tracking ID:</b> 121-ZJ3-84UQ  <b>Fee:</b> 62,000/-	<b>Manufacturer:</b> M/s NECM KİMYA AKARYAKIT ÜRÜNLERİ MEDİKAL MALZEMELER SAN.VE TİC.LTD.ŞTİ. Address : Battalgazi Mah. Sark Cad. Aytıp, I Blok No: 14 Sultanbeyli- Istanbul - Turkey <b>LOA</b> <b>Notarization:</b> Yes <b>valid:</b> 31-12-2029 • <b>FSC</b> <b>Legalized:</b> Apostille <b>Issued by:</b> MEDICINES AND	<b>Brand Name:</b> BIORAD POWDER PA <b>Generic Name:</b> High Level Medical instruments-devices and endoscopes disinfectant  <b>Applied as:</b> Family <b>Class:</b> C  <b>Models/Code/sizes (as per FSC &amp; application:</b> <b>Sizes :</b>	<b>Approved.</b>												

		<b>MEDICAL DEVICES</b> <b>AGENCY OF TÜRKİYE</b> <b>Valid: 26-03-2027</b>  <b>ISO – Certificate:</b> <b>Notarization: Yes</b> <b>Valid till: 09-02-2026</b>  <b>EC Certificate: Valid till 26-05-2024</b>	100 gm, 1kg, 2kg  <b>Shelf life</b> 3 years	
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**Evaluator: Saadat Ali Khan (Deputy Director)**

**LOCAL PRODUCTS AGENDA**

<b>Sr. No.</b>	<b>Name &amp; Address of Establishment</b>	<b>Name of Medical Devices With Size</b>	<b>Decision</b>
<b>1.</b>	Lasani Healthcare, Plot No. 29-A, Road R-1, Industrial Estate Gadoon Amazai, Swabi, KPK  (ELM-0036 Valid up to 01-02-2024 with receiving of Submission of Renewal  Original Application dated 30-12-2023. Reminder along with Form-7 R&I date 02-06-2025 [1058-L]	L-D Hypodermic needle (16G, 18G, 21G, 22G, 23G, 24G, 26G, 27G)  Class: B Shelf Life: 5 Years Fee: 20000 Fee Slip No. 282876039 plus Rs. 5000/- vide slip No. 7283479467.	The Board deferred the case for the submission of the followings: 1. Valid GMP Certificate 2. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed. 3. Complete documentation related to manufacturing & Quality Control processes 4. Submission of differential fee as per current fee SRO for Class-B family.
<b>2.</b>	Lasani Healthcare, Plot No. 29-A, Road R-1, Industrial Estate Gadoon Amazai, Swabi, KPK  (ELM-0036 Valid up to 01-02-2024 with receiving of Submission of Renewal  Original Application dated 30-12-2023. Reminder along with Form-7 R&I date 02-06-2025 [1059-L]	L-D Heparin Stopper  Injection Stopper for IV Cannula  Class: B Shelf Life: 5 Years Fee: Rs. 20000 Fee Slip No. 651172120177 plus Rs. 5000/- vide slip No. 1040597509.	The Board deferred the case for the submission of the followings: 1. Valid GMP Certificate 2. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed. 3. Complete documentation related to manufacturing & Quality Control processes 4. Code/Size of the applied product & if more than one size also Submit differential fee as per current fee SRO for Class-B family.
<b>3.</b>	Lasani Healthcare, Plot No. 29-A, Road R-1, Industrial Estate Gadoon Amazai, Swabi, KPK  (ELM-0036 Valid up to 01-02-2024 with receiving of Submission of Renewal	L-D Blood Transfusion Set  Class: B Shelf Life: 5 Years Fee: 20000 Fee Slip No. 8409101220 plus Rs. 5000/- vide slip No. 70842949125.	The Board deferred the case for the submission of the followings: 1. Evidence of required section for manufacturing of the applied product & if not having the approved

	R&I date 02-06-2025  [1061-L]		<p>manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</p> <ol style="list-style-type: none"> <li>Valid GMP Certificate</li> <li>Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>Complete documentation related to manufacturing &amp; Quality Control processes</li> <li>Code/Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-B family.</li> </ol>
4.	<p>Lasani Healthcare, Plot No. 29-A, Road R-1, Industrial Estate Gadoon Amazai, Swabi, KPK</p> <p>(ELM-0036 Valid up to 01-02-2024 with receiving of Submission of Renewal</p> <p>R&amp;I date 02-06-2025</p> <p>[1060-L]</p>	<p>Infucan Y-Port Infusion Set</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 44609941</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>Valid GMP Certificate</li> <li>Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>Complete documentation related to manufacturing &amp; Quality Control processes</li> <li>Code/Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-B family.</li> </ol>
5.	<p>Lasani Healthcare, Plot No. 29-A, Road R-1, Industrial Estate Gadoon Amazai, Swabi, KPK</p> <p>(ELM-0036 Valid up to 01-02-2024 with receiving of Submission of Renewal</p> <p>R&amp;I date 02-06-2025</p> <p>[1062-L]</p>	<p>Infucan IV Burette Set Metered Cylinder 50ml, 100ml, 150ml</p> <p>Class: B Shelf Life: 5 Years Fee: 20000 Fee Slip No. 3746685953 plus Rs. 5000/- vide slip No. 44922799112.</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>Valid GMP Certificate</li> <li>Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>Complete documentation related to manufacturing &amp; Quality Control processes</li> <li>Code/Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-B family.</li> </ol>
6.	Jassh Pharma, 20KM, Ferozpur Road, Lahore	Bacttol Multi Surface Cleaner / Disinfectant	The Board deferred the case for the submission of the

	<p>(ELM-0037 Valid up to 27-09-2021 with receiving of Submission of Renewal dated 01-09-2021.</p> <p>R&amp;I date 05-06-2025</p> <p>[1063-L]</p>	<p>Composition: Each 100ml: Banzalkonium chloride..0.2%w/v</p> <p>Class: A Shelf Life: 2 Years Fee: 25000 Fee Slip No. 6638257860</p> <p>Sizes/packing: Plastic Bottle</p>	<p>followings:</p> <ol style="list-style-type: none"> <li>1. Evidence is required that the applied product is classified as Medical Device as per MDR 2017 along with its Medical Device Class.</li> <li>2. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>3. Valid GMP Certificate</li> <li>4. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>5. Code/Pack Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-B family.</li> </ol>
7.	<p>Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM- 0084 valid till 27-10-2029)</p> <p>R&amp;I date 03-06-2025</p> <p>[1064-L]</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</li> <li>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter).</li> <li>9. Gauze swabs and sponges sterile and non-sterile Section.</li> <li>10. Gauze Roll Section (Non sterile).</li> <li>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.).</li> <li>12. Bandage Section (Cotton Bandages, Crepe Bandage,</li> </ol>	<p>Venus <b>Non Sterile</b> Disposable Examination Gloves</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 28734006</p> <p>Sizes: Xs, S, M, L,XL</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</li> <li>5. Submission of differential fee as per current fee SRO for Class-B family.</li> </ol>

	Eye pad, Non-Woven surgical tape). 13. Lap sponges with X-Ray Threads Section		
8.	<p>Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1065-L]</p> <p>R&amp;I date 03-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</li> <li>8. Assembling and Repacking Section (Three-way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter).</li> <li>9. Gauze swabs and sponges sterile and non-sterile Section.</li> <li>10. Gauze Roll Section (Non sterile).</li> <li>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.).</li> <li>12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</li> <li>13. Lap sponges with X-Ray Threads Section</li> </ol>	<p>Venus <b>Sterile</b> Light Powdered Examination Gloves</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 35990270</p> <p>Sizes: 6.5, 7.0, 7.5, 8, 8.5, 9 &amp; 9.5 Inches.</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</li> <li>5. Submission of differential fee as per current fee SRO for Class-B family.</li> </ol>
9.	<p>Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1066-L]</p> <p>R&amp;I date 03-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine,</li> </ol>	<p>Venus Transducer Kit Double Chamber</p> <p>Transducer Kit Double Chamber</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 46783894</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485</li> </ol>

	<p>hypodermic fistula, scalp vein, biopsy, tonsil needle).</p> <p>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section.</p> <p>10. Gauze Roll Section (Non sterile).</p> <p>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</p> <p>13. Lap sponges with X-Ray Threads Section</p>		<p>along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</p> <p>5. Code/Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-B family.</p>
10.	<p>Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1068-L] R&amp;I date 03-06-2025</p> <p><b>Approved Sections:</b></p> <p>1. Syringes (Auto-disable) Section.</p> <p>2. Syringes (Disposable) Section.</p> <p>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</p> <p>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</p> <p>5. IV Dialysis Set Section.</p> <p>6. Foley Catheter Section.</p> <p>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</p> <p>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section.</p> <p>10. Gauze Roll Section (Non sterile).</p> <p>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</p> <p>13. Lap sponges with X-Ray Threads Section</p>	<p>Venus Transducer Kit Single Chamber</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 84205617848</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</li> <li>5. Code/Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-B family.</li> </ol>
11.	<p>Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p>	<p>Venus Surgical Tape</p> <p>Class: A</p>	<p>The Board deferred the case for the submission of the followings:</p>

	<p>[1067-L] R&amp;I date 03-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</li> <li>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter).</li> <li>9. Gauze swabs and sponges sterile and non-sterile Section.</li> <li>10. Gauze Roll Section (Non sterile).</li> <li>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,).</li> <li>12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</li> <li>13. Lap sponges with X-Ray Threads Section</li> </ol>	<p>Shelf Life: 5 Years Fee: 6000</p> <p>Fee Slip No. 8069885302</p>	<ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</li> <li>5. Code/Size of the applied product &amp; if more than one size also Submit differential fee as per current fee SRO for Class-A family.</li> </ol>
12.	<p>Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1069-L] R&amp;I date 20-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</li> <li>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set,</li> </ol>	<p>Venus Multi Filament Sutures</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 1458891805</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local</li> </ol>

	<p>Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section.</p> <p>10. Gauze Roll Section (Non sterile).</p> <p>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</p> <p>13. Lap sponges with X-Ray Threads Section</p>		<p>manufacturer)</p> <p>5. The firm is advised to separate the application. The current application will be considered for one type of suture (like polyglactin 910 suture or any other of their choice) after submission differential fee as per current fee SRO for Class-C or Class-D (with justification of Class) family &amp; demanded codes.</p> <p>6. For the rest of the products (types) firm shall apply separately through online MDMC portal with prescribed Form, fee &amp; other required documents.</p>
13.	<p>Bioron Medics, 9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1070-L] R&amp;I date 20-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</li> <li>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter).</li> <li>9. Gauze swabs and sponges sterile and non-sterile Section.</li> <li>10. Gauze Roll Section (Non sterile).</li> <li>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,).</li> <li>12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</li> <li>13. Lap sponges with X-Ray Threads Section.</li> </ol>	<p>Venus MonoFilament Sutures</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 13257895435</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</li> <li>5. The firm is advised to separate the application. The current application will be considered for one type of suture (like Polydioxanone suture or any other of their choice) after submission differential fee as per current fee SRO for Class-C or Class-D (with justification of Class) family &amp; demanded codes.</li> <li>6. For the rest of the products (types) firm shall apply separately through online MDMC portal with prescribed</li> </ol>



			Form, fee & other required documents.
14.	<p>Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1071-L] R&amp;I date 20-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set).</li> <li>5. IV Dialysis Set Section.</li> <li>6. Foley Catheter Section.</li> <li>7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).</li> <li>8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter).</li> <li>9. Gauze swabs and sponges sterile and non-sterile Section.</li> <li>10. Gauze Roll Section (Non sterile).</li> <li>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.).</li> <li>12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</li> <li>13. Lap sponges with X-Ray Threads Section.</li> </ol>	<p>Venus Non-Absorbable Sutures</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 0226046112</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)</li> <li>5. The firm is advised to separate the application. The current application will be considered for one type of suture (like polyester suture or any other of their choice) after submission differential fee as per current fee SRO for Class-C or Class-D (with justification of Class) family &amp; demanded codes.</li> <li>6. For the rest of the products (types) firm shall apply separately through online MDMC portal with prescribed Form, fee &amp; other required documents.</li> </ol>
15.	<p>Bioron Medics,9F 2nd Floor Queens center, 33 Queens Road Lahore (ELM-00084)</p> <p>[1072-L] R&amp;I date 20-06-2025</p> <p><b>Approved Sections:</b></p> <ol style="list-style-type: none"> <li>1. Syringes (Auto-disable) Section.</li> <li>2. Syringes (Disposable) Section.</li> <li>3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube).</li> <li>4. IV Burette Set, Blood Transfusion Set</li> </ol>	<p>Venus Absorbable Sutures</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 700032499</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of the product</li> </ol>

	<p>(IV Set, IV Y-port set, Scalp Vein Set).  5. IV Dialysis Set Section.  6. Foley Catheter Section.  7. Needle assembly section (Dental, spine, hypodermic fistula, scalp vein, biopsy, tonsil needle).  8. Assembling and Repacking Section (Three way stopper, umbilical card clump, heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter). 9. Gauze swabs and sponges sterile and non-sterile Section.  10. Gauze Roll Section (Non sterile).  11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing.). 12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).  13. Lap sponges with X-Ray Threads Section.</p>		<p>on the basis of which the shelf life was claimed.  4. Bulk manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer)  5. The firm is advised to separate the application. The current application will be considered for one type of suture (like Polyglycolic Acid [PGA] suture or any other of their choice) after submission differential fee as per current fee SRO for Class-C or Class-D (with justification of Class) family &amp; demanded codes.  6. For the rest of the products (types) firm shall apply separately through online MDMC portal with prescribed Form, fee &amp; other required documents.</p>
16.	<p>Anax Associates Pvt Ltd.  Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071 Valid upto 21-08-2028)    R&amp;I date 17-06-2025    [1073-L]    Approved Sections as per ELI.  PPEs (Surgical &amp; Non-surgical Face mask section and Protective suits/ surgical gowns &amp; surgical drape)</p>	<p>Medpro Arthroscopy Drape Pack    Class: A  Shelf Life: 3 Years  Fee: 6000    Fee Slip No. 167607903    Reference Code: 8803 (with 3 gown)    <b>Set contain:</b>  Arthroscopy Drape 200cmx320cm--01  Foot Drape 150cmx220cm--01  Back Table cover 150cm x200cm--01  Coban Bandage 10cm--01  Skin Marker 0.3cm with flexible ruler..01  Medical Hand Towel 40cmx40cm..04  Reinforced Surgical Gown XXL..03  Camera cover..01  OP Tape 10cm x 50 cm...02  Sterilization Wrap 100 X 100cm..01</p>	<p>The Board deferred the case for the submission of the followings:  1. Evidence of required section for manufacturing of the rest of the products in the set (other than Drapes) will be manufactured in which of the section.  2. Valid GMP Certificate  3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed.  6. Complete documentation related to manufacturing &amp; Quality Control processes for the rest of the products in the set (other than Drapes).</p>
17.	<p>Anax Associates Pvt Ltd.  Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) Valid upto 21-08-2028)</p>	<p>Medpro Vertical Isolation Drape Pack    Class: A  Shelf Life: 3 Years</p>	<p>The Board deferred the case for the submission of the followings:  1. Evidence of required section for manufacturing of the rest</p>

	<p>[1074-L]</p> <p>R&amp;I date 17-06-2025</p> <p>Approved Sections as per ELI. PPEs (Surgical &amp; Non-surgical Face mask section and Protective suits/ surgical gowns &amp; surgical drape)</p>	<p>Fee: 6000 Fee Slip No. 1908282633 Reference Code: 7503 (with 3 gown)</p> <p><b>Set contain:</b> Vertical Isolation Drape 240 cm x 320 cm...01 Mayo Stand Cover 80 x 150cm...01 Medical Hand Towel 40cm x 40cm..06 Reinforced Surgical Gown XL...02 Back Table Cover 150cm x 200cm..01 Sterilization Wrap 100 cm X 100 cm..01</p>	<p>of the products in the set (other than Drapes) will be manufactured in which of the section.</p> <p>2. Valid GMP Certificate 3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed. 4. Complete documentation related to manufacturing &amp; Quality Control processes for the rest of the products in the set (other than Drapes).</p>
18.	<p>Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) Valid upto 21-08-2028)</p> <p>[1127-L]</p> <p>R&amp;I date 15-07-2025</p> <p>Approved Sections as per ELI. PPEs (Surgical &amp; Non-surgical Face mask section and Protective suits/ surgical gowns &amp; surgical drape)</p>	<p>Mdepro Caudal Block Pack</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 96182358999</p> <p>Reference Code: 6610</p> <p><b>Set contain:</b> Fenestrated Drape 75cmx90cm..01 Gallipot 120ml..02 Gauze Swab 10cmx 10cm..05 Plastic Towel Forceps...01 Drape sheet 75cmx90cm...01 Kidney Tray 700ml..01 Medical Hand Towel 40cmx40cm..02 Sterilization Wrap 90cm X 90cm...01</p>	<p>The Board deferred the case for the submission of the followings:</p> <p>1. Evidence of required section for manufacturing of the rest of the products in the set (other than Drapes) will be manufactured in which of the section. 2. Valid GMP Certificate 3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed. 4. Complete documentation related to manufacturing &amp; Quality Control processes for the rest of the products in the set (other than Drapes).</p>
19.	<p>Anax Associates Pvt Ltd. Plot # 15, HDR Industrial Estate Next to Zaamin City Gajjumatah Lahore (ELM-0071) Valid upto 21-08-2028)</p> <p>[1128-L]</p> <p>R&amp;I date 17-06-2025</p> <p>Approved Sections as per ELI. PPEs (Surgical &amp; Non-surgical Face mask section and Protective suits/ surgical gowns &amp; surgical drape)</p>	<p>Mdepro Spinal Epidural Pack</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 0482117105</p> <p>Reference Code: 6600</p> <p><b>Set contain:</b> Fenestrated Drape 75cmx90cm..01 Gallipot 120ml..02 Plastic Towel Tweezer..01 Gauze Swab 10cmx10cm...05 Plastic Towel Forceps...01 Drape sheet 75cmx90cm...01 Kidney Tray 700ml..01 Medical Hand Towel 40cmx40cm...02 Sterilization</p>	<p>The Board deferred the case for the submission of the followings:</p> <p>1. Evidence of required section for manufacturing of the rest of the products in the set (other than Drapes) will be manufactured in which of the section. 2. Valid GMP Certificate 3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed. 4. Complete documentation related to manufacturing &amp; Quality Control processes for the rest of the products in the set (other than Drapes).</p>

		Wrap 90cm X 90cm...01	
20.	<p>M/s. Medipak Limited. 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.</p> <p>[ELM No.0048] Valid upto 17-02-2027)</p> <p>[1126-L]</p> <p>R&amp;I date 10-07-2025</p> <p>Approved Sections as per Eli: Hemodialysis Section Disposable IV Set Section</p>	<p><b>MEDISOL CAPD 2 (LOW CALCIUM)</b> Peritoneal Dialysis Solution with Drainage Bag</p> <p>Class: C Shelf Life: 36 Months Fee: 25000 Fee Slip No. 79374584</p> <p><b>Packing: (500ml, 1000ml, 2000ml, 5000ml)</b></p> <p><b>Composition:</b> <b>Each 1000ml contains:</b> Sodium Chloride 5.380 g Sodium Lactate Solution 8.960 g (<math>\triangle</math> Sodium Lactate 4.48 g) Calcium Chloride 2H<sub>2</sub>O 0.184 g Magnesium Chloride 6H<sub>2</sub>O 0.0508 g Dextrose Anhydrous 15.00 g <b>(BP Specs)</b></p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. The product is Peritoneal Dialysis Solution therefore the firm is advised to submit evidence that the applied product is Medical Device &amp; MD Class as per Medical Device Rules 2017 along with the povission of meachism of action of the applied product &amp; its status in the Reference Regulatory Authorites.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed.</li> <li>4. Family fee of Class-C.</li> </ol>
21.	<p>M/s. Medipak Limited. 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.</p> <p>[ELM No.0048] Valid up to 17-02-2027)</p> <p>[1122-L]</p> <p>R&amp;I date 10-07-2025</p> <p>Approved Sections as per Eli: Hemodialysis Section Disposable IV Set Section</p>	<p><b>Brand Name:</b> <b>MEDISOL CAPD 3 (LOW CALCIUM)</b> Peritoneal Dialysis Solution with Drainage Bag</p> <p>Class: C Shelf Life: <b>36 Months</b> <b>(500ml, 1000ml, 2000ml, 5000ml)</b> <b>Fee Challan # 26600054977</b></p> <p><b>Each 1000ml contains:</b> Sodium Chloride 5.380 g Sodium Lactate Solution 8.960 g (<math>\triangle</math> Sodium Lactate 4.48 g) Calcium Chloride 2H<sub>2</sub>O 0.184 g Magnesium Chloride 6H<sub>2</sub>O 0.0508 g Dextrose Anhydrous 42.50 g <b>(BP Specs)</b></p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. The product is Peritoneal Dialysis Solution therefore the firm is advised to submit evidence that the applied product is Medical Device &amp; MD Class as per Medical Device Rules 2017 along with the povission of meachism of action of the applied product &amp; its status in the Reference Regulatory Authorites.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed.</li> <li>4. Family fee of Class-C.</li> </ol>
22.	<p>M/s. Medipak Limited. 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.</p> <p>[ELM No.0048] Valid up to 17-02-2027)</p> <p>[1123-L]</p> <p>R&amp;I date 10-07-2025</p>	<p><b>Brand Name:</b> <b>MEDISOL CAPD 4 (LOW CALCIUM)</b> Peritoneal Dialysis Solution with Drainage Bag</p> <p>Class: C Shelf Life: <b>36 Months</b> <b>(500ml, 1000ml, 2000ml, 5000ml)</b> <b>Fee Challan # 4279762566</b></p> <p><b>Each 1000ml contains:</b></p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. The product is Peritoneal Dialysis Solution therefore the firm is advised to submit evidence that the applied product is Medical Device &amp; MD Class as per Medical Device Rules 2017 along with the povission of</li> </ol>

	Approved Sections as per Eli: Hemodialysis Section Disposable IV Set Section	Sodium Chloride 5.380 g Sodium Lactate Solution 8.960 g (≅ Sodium Lactate 4.48 g) Calcium Chloride 2H <sub>2</sub> O 0.184 g Magnesium Chloride 6H <sub>2</sub> O 0.0508 g Dextrose Anhydrous 25.00 g (BP Specs)	meachism of action of the applied product & its status in the Reference Regulatory Authorities. 2. Valid GMP Certificate 3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed. 4. Family fee of Class-C.
23.	M/s. Medipak Limited. 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.  [ELM No.0048] Valid up to 17-02-2027)  [1121-L]  R&I date 10-07-2025  Approved Sections as per Eli: Hemodialysis Section Disposable IV Set Section	<b>Brand Name:</b> <b>MEDISOL CAPD 2 (LOW CALCIUM)</b> Peritoneal Dialysis Solution  Class: C Shelf Life: <b>36 Months</b> <b>(500ml, 1000ml, 2000ml, 5000ml)</b> <b>Fee Challan # 08149292029</b>  <b>Each 1000ml contains:</b> Sodium Chloride 5.380 g Sodium Lactate Solution 8.960 g (≅ Sodium Lactate 4.48 g) Calcium Chloride 2H <sub>2</sub> O 0.184 g Magnesium Chloride 6H <sub>2</sub> O 0.0508 g Dextrose Anhydrous 15.00 g (BP Specs)	The Board deferred the case for the submission of the followings: 1. The product is Peritoneal Dialysis Solution therefore the firm is advised to submit evidence that the applied product is Medical Device & MD Class as per Medical Device Rules 2017 along with the povission of meachism of action of the applied product & its status in the Reference Regulatory Authorities. 2. Valid GMP Certificate 3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed. 4. Family fee of Class-C.
24.	M/s. Medipak Limited. 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.  [ELM No.0048] Valid up to 17-02-2027)  [1125-L]  R&I date 10-07-2025  Approved Sections as per Eli: Hemodialysis Section Disposable IV Set Section	<b>Brand Name:</b> <b>MEDISOL CAPD 3 (LOW CALCIUM)</b> Peritoneal Dialysis Solution  Class: C Shelf Life: <b>36 Months</b> <b>(500ml, 1000ml, 2000ml, 5000ml)</b> <b>Fee Challan # 858673207568</b>  <b>Each 1000ml contains:</b> Sodium Chloride 5.380 g Sodium Lactate Solution 8.960 g (≅ Sodium Lactate 4.48 g) Calcium Chloride 2H <sub>2</sub> O 0.184 g Magnesium Chloride 6H <sub>2</sub> O 0.0508 g Dextrose Anhydrous 42.50 g (BP Specs)	The Board deferred the case for the submission of the followings: 1. The product is Peritoneal Dialysis Solution therefore the firm is advised to submit evidence that the applied product is Medical Device & MD Class as per Medical Device Rules 2017 along with the povission of meachism of action of the applied product & its status in the Reference Regulatory Authorities. 2. Valid GMP Certificate 3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed. 4. Family fee of Class-C.

25.	<p>M/s. Medipak Limited. 132/1 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.</p> <p>[ELM No.0048] Valid up to 17-02-2027)</p> <p>[1124-L]</p> <p>R&amp;I date 10-07-2025</p> <p>Approved Sections as per Eli: Hemodialysis Section Disposable IV Set Section</p>	<p><b>Brand Name:</b> <b>MEDISOL CAPD 4 (LOW CALCIUM)</b> Peritoneal Dialysis Solution</p> <p>Class: C Shelf Life: <b>36 Months</b> <b>(500ml, 1000ml, 2000ml, 5000ml)</b> <b>Fee Challan # 619080008</b></p> <p><b>Each 1000ml contains:</b> Sodium Chloride 5.380 g Sodium Lactate Solution 8.960 g (<math>\triangle</math> Sodium Lactate 4.48 g) Calcium Chloride 2H<sub>2</sub>O 0.184 g Magnesium Chloride 6H<sub>2</sub>O 0.0508 g Dextrose Anhydrous 25.00 g (BP Specs)</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. The product is Peritoneal Dialysis Solution therefore the firm is advised to submit evidence that the applied product is Medical Device &amp; MD Class as per Medical Device Rules 2017 along with the povission of meachism of action of the applied product &amp; its status in the Reference Regulatory Authorites.</li> <li>2. Valid GMP Certificate</li> <li>3. Stability Study Data or any other document of all the products included in the set/pack on the basis of which the shelf life was claimed.</li> <li>4. Family fee of Class-C.</li> </ol>
26.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1076-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Glim ECG Machine 3 Channel 12 Leads</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 45091494776</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Clarification of the class of the applied product &amp; submission of revised prescribed form &amp; fee as per the Class of the Medical Device.</li> <li>4. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>5. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>6. Princupal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal</li> </ol>

			<p>manufacturer as well as on finish product by local manufacturer).</p> <p>7. Code/model of the applied product</p>
27.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1098-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Glim ECG Machine Single Channel 12 Leads</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 10439233953</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Clarification of the class of the applied product &amp; submission of revised prescribed form &amp; fee as per the Class of the Medical Device.</li> <li>4. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>5. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>6. Principal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer).</li> <li>7. Code/model of the applied product</li> </ol>
28.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1078-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for</li> </ol>	<p>Glim Cervical Collar Foam</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 144017956716</p> <p>Sizes: S,M,L,XL</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> </ol>

	<p>Hemodialysis Concentrates)</p> <p>2. Hydrocolloid and Soft Silicone Foam Dressings</p> <p>3. Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>4. General IVDs cleaning solutions</p> <p>5. Disinfectant solutions for laboratory equipment</p> <p>6. Hematology diluent Solutions</p> <p>7. Semi-solid Section (for ostomy gel only)</p>		<p>2. Valid GMP Certificate</p> <p>3. The data/ information in the prescribed Form is incomplete, therefore data/ information along with required evidence against each applicable point of the prescribed application form.</p> <p>4. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</p> <p>5. Principal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer).</p> <p>6. Fee for family for Class-A.</p>
29.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1079-L]</p> <p>Approved Sections as per Eli:</p> <p>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</p> <p>2. Hydrocolloid and Soft Silicone Foam Dressings</p> <p>3. Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>4. General IVDs cleaning solutions</p> <p>5. Disinfectant solutions for laboratory equipment</p> <p>6. Hematology diluent Solutions</p> <p>7. Semi-solid Section (for ostomy gel only)</p>	<p>Glim Paraffin Wax</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 261197649</p> <p>Sizes/packing: 200gm, 500gm, 1000gm, 5000gm</p>	<p>The Board deferred the case for the submission of the followings:</p> <p>1. The firm is advised to submit evidence that the applied product is Medical Device as per Medical Device Rules 2017 along with the provision of mechanism of action of the applied product &amp; its status in the Reference Regulatory Authorities.</p> <p>2. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</p> <p>3. Valid GMP Certificate.</p> <p>4. The data/ information in the prescribed Form is incomplete, therefore data/ information along with required evidence against each applicable point of the prescribed application form.</p> <p>5. Stability Study Data or any other document on the basis of which the shelf life was claimed.</p> <p>6. Family fee.</p>
30.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial</p>	<p><b>Villa TTO Soap</b> Melaleuca Alternifolia (Australian</p>	<p>Rejected on the ground that the applied product is not Medical</p>



	<p>Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1083-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>tea Tree) Leaf Oil, Aloe Barbadensis (Aloe Vera) Leaf Extract, Laurus Nobilis Leaf Oil, Vitamin E, TIO2 (Titanium diOxide), GLYcerin</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 623855868</p> <p>Pack size:</p>	<p>Device as per Medical Device Rules 2017.</p>
31.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1085-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p><b>Villa Collagen Soap</b> Vegetable Collagen, Cocos nucifera (Coconut) Oil, Ricinus Communis (Castor) Oil, Prunus Amygdalus dulcis (Sweet almond) oil, Glycerin, Stearic Acid, Sodium Hydroxide, Distilled water, Mono propylene glycol, Sorbitol, Triethanoamine, Betaine, EDTA</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 64983239755</p> <p>Pack size: 5gm</p>	<p>Rejected on the ground that the applied product is not Medical Device as per Medical Device Rules 2017.</p>
32.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1087-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> </ol>	<p><b>Villa Hylluron Soap</b> Sodium Hyaluronate, Allantoin, Cocos, Nucifera Oil, Ricinus Communis seed oil, Glycerin, Stearic Acid, Sodium Hydroxide, Distilled Water, Mono Propylene Glycol, Sorbitol, Triethanolamine, Betaine, EDTA.</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3539372837</p>	<p>Rejected on the ground that the applied product is not Medical Device as per Medical Device Rules 2017.</p>

	6. Hematology diluent Solutions 7. Semi-solid Section (for ostomy gel only)		
<b>33.</b>	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1084-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Glim Spec Stool Specimen Collection Container PP/PS/PVC</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0903360583</p> <p>Sizes : 30ml, 40ml, 60ml, 100ml, 120ml</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>4. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>5. Clarification is required three different product manufactured from PP (Polypropylene), PS (Polystyrene) &amp; PVC (Polyvinyl Chloride), [three different materials] can be applied in single application.</li> <li>6. As multiple sizes are applied therefore family fee for class-A is needed.</li> </ol>
<b>34.</b>	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1086-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Perisafe Powder Hexamidine diisethinoate, Sodium Percarbonate, TAED (tetraacetylenediamine)</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 36056911</p> <p>Pack sizes: 15, 45, 75, 750gm</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>4. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> </ol>

			<p>5. Clarification is required for the Class of the applied medical device.</p> <p>6. As multiple sizes are applied therefore family fee for class-A is needed.</p>
35.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1088-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Clohex Cream Aqua, Cetearyl Alcohol, Paraffinum Liquidum, Ceteth-20, Chlorhexidine Digluconate</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4494684688</p> <p>Pack sizes: 30, 50, 100, 150gm</p>	<p>Rejected on the ground that the applied product is not Medical Device as per Medical Device Rules 2017.</p>
36.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1089-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Be Safe Insect Spray Diethyl meta tolu amide(DEET) 10%</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 9037793715</p> <p>Pack size: 100ml</p>	<p>Rejected on the ground that the applied product is not Medical Device as per Medical Device Rules 2017.</p>
37.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1090-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for</li> </ol>	<p>Clohex MouthWash 0.05% Chlorhexidine</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 990584488</p> <p>Pack size: 150ml, 300ml</p>	<p>Rejected on the ground that the applied product is not Medical Device as per Medical Device Rules 2017.</p>

	Hemodialysis Concentrates) 2. Hydrocolloid and Soft Silicone Foam Dressings 3. Liquid Section (Diluents and cleaning solutions for analyzers) 4. General IVDs cleaning solutions 5. Disinfectant solutions for laboratory equipment 6. Hematology diluent Solutions 7. Semi-solid Section (for ostomy gel only)		
38.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)  R&I date 24-06-2025  [1091-L]  Approved Sections as per Eli: 1. Sachet/Dry Powder Section (for Hemodialysis Concentrates) 2. Hydrocolloid and Soft Silicone Foam Dressings 3. Liquid Section (Diluents and cleaning solutions for analyzers) 4. General IVDs cleaning solutions 5. Disinfectant solutions for laboratory equipment 6. Hematology diluent Solutions 7. Semi-solid Section (for ostomy gel only)	Glim Centrifuge Tube PP with Pump Polypropylene  Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 5262291701  Pack size: 10ml, 15ml, 25ml, 50ml	The Board deferred the case for the submission of the followings: 1. The firm is advised to submit evidence that the applied product is Medical Device as per Medical Device Rules 2017 along with the povission of its intended purpose & its status in the Reference Regulatory Authorites. 2. Evidence of required section for manufacturing of the applied product & if not having the approved manufacturing & testing facility for the said product, the firm shall apply for the additional section. 3. Valid GMP Certificate. 4. The data/ information in the prescribed Form is incomplete, therefore data/ information along with required evidence against each applicable point of the prescribed application form. 5. Stability Study Data or any other document on the basis of which the shelf life was claimed. 6. Family fee.
39.	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)  R&I date 24-06-2025  [1092-L]  Approved Sections as per Eli: 1. Sachet/Dry Powder Section (for Hemodialysis Concentrates) 2. Hydrocolloid and Soft Silicone Foam Dressings 3. Liquid Section (Diluents and cleaning solutions for analyzers)	Fumigation Solution Quaternary Ammonium Compound (QAC), Silver Nitrate, Neem Extracts  Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 8335928527  Pack size: 500ml, 1000ml, 2500ml, 5000ml	Rejected on the ground that the applied product is not Medical Device as per Medical Device Rules 2017.

	4. General IVDs cleaning solutions 5. Disinfectant solutions for laboratory equipment 6. Hematology diluent Solutions 7. Semi-solid Section (for ostomy gel only)		
40.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1093-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Glim BP Set Dial Type</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4844477376</p> <p>Model: not mentioned.</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Clarification of the class of the applied product &amp; submission of revised prescribed form &amp; fee as per the Class of the Medical Device.</li> <li>4. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>5. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>6. Principal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer).</li> <li>7. Code/model of the applied product</li> </ol>
41.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1094-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> </ol>	<p>Glim BP Set Stand Model</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 5754256244</p> <p>Model: not mentioned.</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> </ol>

	<p>2. Hydrocolloid and Soft Silicone Foam Dressings</p> <p>3. Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>4. General IVDs cleaning solutions</p> <p>5. Disinfectant solutions for laboratory equipment</p> <p>6. Hematology diluent Solutions</p> <p>7. Semi-solid Section (for ostomy gel only)</p>		<p>3. Clarification of the class of the applied product &amp; submission of revised prescribed form &amp; fee as per the Class of the Medical Device.</p> <p>4. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</p> <p>5. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</p> <p>6. Principal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer).</p> <p>7. Code/model of the applied product</p>
42.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1095-L]</p> <p>Approved Sections as per Eli:</p> <p>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</p> <p>2. Hydrocolloid and Soft Silicone Foam Dressings</p> <p>3. Liquid Section (Diluents and cleaning solutions for analyzers)</p> <p>4. General IVDs cleaning solutions</p> <p>5. Disinfectant solutions for laboratory equipment</p> <p>6. Hematology diluent Solutions</p> <p>7. Semi-solid Section (for ostomy gel only)</p>	<p>Glim BP Set Mercurial Desk Type</p> <p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 9711696371</p> <p>Model: not mentioned.</p>	<p>The Board deferred the case for the submission of the followings:</p> <p>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</p> <p>2. Valid GMP Certificate</p> <p>3. Clarification of the class of the applied product &amp; submission of revised prescribed form &amp; fee as per the Class of the Medical Device.</p> <p>4. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</p> <p>5. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</p>

			<p>6. Principal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer).</p> <p>7. Code/model of the applied product</p>
43.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p> <p>R&amp;I date 24-06-2025</p> <p>[1096-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Zykone Syringe Pump</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 2309961766</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</li> <li>2. Valid GMP Certificate</li> <li>3. Clarification of the class of the applied product &amp; submission of revised prescribed form &amp; fee as per the Class of the Medical Device.</li> <li>4. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>5. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>6. Principal manufacturer &amp; their documents like ISO 13485 along with complete documentation related to manufacturing &amp; Quality Control processes (on the Bulk by principal manufacturer as well as on finish product by local manufacturer).</li> <li>7. Code/model of the applied product</li> </ol>
44.	<p>Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 Valid up to 08-04-2030)</p>	<p>Hysoprid Solution Quaternary Ammonium Compound (QAC)..0.1gm, Ethanol...20gm, 1-Propanol..28gm</p>	<p>The Board deferred the case for the submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Evidence of required section</li> </ol>

	<p>R&amp;I date 24-06-2025</p> <p>[1097-L]</p> <p>Approved Sections as per Eli:</p> <ol style="list-style-type: none"> <li>1. Sachet/Dry Powder Section (for Hemodialysis Concentrates)</li> <li>2. Hydrocolloid and Soft Silicone Foam Dressings</li> <li>3. Liquid Section (Diluents and cleaning solutions for analyzers)</li> <li>4. General IVDs cleaning solutions</li> <li>5. Disinfectant solutions for laboratory equipment</li> <li>6. Hematology diluent Solutions</li> <li>7. Semi-solid Section (for ostomy gel only)</li> </ol>	<p>Class: A</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 7943255308</p> <p>Pack Sizes: 500ml, 1000ml, 2500ml, 5000ml</p>	<p>for manufacturing of the applied product &amp; if not having the approved manufacturing &amp; testing facility for the said product, the firm shall apply for the additional section.</p> <ol style="list-style-type: none"> <li>2. Valid GMP Certificate</li> <li>3. The data/information in the prescribed Form is incomplete, therefore data/information along with required evidence against each applicable point of the prescribed application form.</li> <li>4. Stability Study Data or any other document of the product on the basis of which the shelf life was claimed.</li> <li>5. Clarification is required for the Class of the applied medical device.</li> <li>6. As multiple sizes are applied therefore family fee for class-A is needed.</li> </ol>
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## ADDITIONAL AGENDA

Evaluator: Rana Ahsan-Ul-Haq Athar: Deputy Director

### DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	HealthBee Projects Private Limited, E-02, Third floor, Jasim Arcade, Plaza 64-65, Lane 1, Square Commercial, Phase 7, Bahria Town, Islamabad. ELI: 00814	<b><u>Legal Manufacturer:</u></b> Maxigen biotech Inc. No. 88, Keji 1 <sup>st</sup> Road., Guishan dist., Taoyuan City 33383, Taiwan R.O.C.  FSC Taiwan issuance 14-06-2022	ArtiAid Intra-articulate Injection  Class-D  Shelf life: 3 years  Models: AA-20 AA-25 AA-27 AA-30 AA-35	Approved ArtiAid Intra-articulate Injection code AA-25 (2.5ml 1% Sodium Hyaluronate) subject submission of valid FQA and Design Examination Certificate.
2.	Kaumedex, E-144/2, New Super Town Link-2, Defence Road, Lahore.  ELI-00162 1582-P 6,000/-	<b><u>Legal Manufacturer:</u></b> Supermax Glove Manufacturing SDN. BHD, Lot 38 & 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia.  FSC: Malaysia. Date of Validity: 30-03-2025. LOA issuance 26-01-2024 ISO 13485 validity 21-07-2025	High-Max Non-Sterile Latex Examination Gloves, Powdered  Class-A  Shelf Life: 5 Years  Sizes: XS, S, M, L, XL	Approved subject to submission of differential fee.
3.	Kaumedex, E-144/2, New Super Town Link-2, Defence Road, Lahore.  ELI-00162 1582-P 6,000/-	<b><u>Legal Manufacturer:</u></b> Supermax Glove Manufacturing SDN. BHD, Lot 38 & 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia.  FSC: Malaysia. Date of Validity: 30-03-2025.	High-Max Non-Sterile Latex Examination Gloves, Powdered Free  Class-A  Shelf Life: 5 Years  Sizes: XS, S, M, L,	Approved subject to submission of differential fee.

		LOA issuance 26-01-2024 ISO 13485 validity 21-07-2025		
4.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  <b>(ELI- 00244)</b>  <b>R&amp;I detail</b> 16-06-2025 <b>Fee: 62,000/-</b> <b>Slip: 031845124</b>	<b>Name of Manufacturer:</b> M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.  • <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Notarize <b>Issue Date:</b> 23-04-2025 <b>Validity:</b> Not mentioned  • <b>FSC</b> Not aubmitted.  • <b>ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 15-10-2027  • <b>CE Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 27-05-2025	<b>Brand name:</b> Anti-A Monoclonal  <b>Generic Name:</b> Blood Grouping Reagent Kit  <b>Applied as:</b> Kit  <b>Class:</b> C  <b>Model/Codes/Sizes:</b> BG-A10 (as per DOC)  <b>Shelf life:</b> Not mentioned	Approved.
5.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  <b>(ELI- 00244)</b>  <b>R&amp;I detail</b> 16-06-2025 <b>Fee: 62,000/-</b> <b>Slip: 416173331</b>	<b>Name of Manufacturer:</b> M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.  • <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Notarize <b>Issue Date:</b> 23-04-2025 <b>Validity:</b> Not mentioned  • <b>FSC</b> Not aubmitted.  • <b>ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 15-10-2027	<b>Brand name:</b> Anti-D Monoclonal (IgG + IgM)  <b>Generic Name:</b> Blood Grouping Reagent Kit  <b>Applied as:</b> Kit  <b>Class:</b> C  <b>Model/Codes/Sizes:</b> BG-D10 (as per DOC)  <b>Shelf life:</b> Not mentioned	Approved.

		<ul style="list-style-type: none"> <li>• <b>CE Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 27-05-2025</li> </ul>		
6.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  <b>(ELI- 00244)</b>  <b>R&amp;I detail</b> 16-06-2025 <b>Fee: 62,000/-</b> <b>Slip: 70654835</b>	<b>Name of Manufacturer:</b> M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.  <ul style="list-style-type: none"> <li>• <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Notarize <b>Issue Date:</b> 23-04-2025 <b>Validity:</b> Not mentioned</li> <li>• <b>FSC</b> Not aubmitted.</li> <li>• <b>ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 15-10-2027</li> <li>• <b>CE Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 27-05-2025</li> </ul>	<b>Brand name:</b> ABOD Blood Grouping Kit  <b>Generic Name:</b> Blood Grouping Reagent Kit  <b>Applied as:</b> Kit  <b>Class:</b> C  <b>Model/Codes/Sizes:</b> BG-ABOD10 (as per DOC)  <b>Shelf life:</b> Not mentioned	Deferred (last opportunity) for followings: 1. clarification that product not mention in submitted FSC MHRA. 2. Shelf life data not submitted. 3. Clarification of classification of applied product.
7.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  <b>(ELI- 00244)</b>  <b>R&amp;I detail</b> 16-06-2025 <b>Fee: 62,000/-</b> <b>Slip: 3695108471</b>	<b>Name of Manufacturer:</b> M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.  <ul style="list-style-type: none"> <li>• <b>LOA</b> <b>Type:</b> Original <b>Notarization:</b> Notarize <b>Issue Date:</b> 23-04-2025 <b>Validity:</b> Not mentioned</li> <li>• <b>FSC</b> Not aubmitted.</li> <li>• <b>ISO Certificate</b> <b>Type:</b> Original</li> </ul>	<b>Brand name:</b> Anti-B Monoclonal  <b>Generic Name:</b> Blood Grouping Reagent Kit  <b>Applied as:</b> Kit  <b>Class:</b> C  <b>Model/Codes/Sizes:</b> BG-B10 (as per DOC)  <b>Shelf life:</b> Not mentioned	Approved.

		<b>Notarization:</b> Notarized <b>Validity:</b> 15-10-2027  <b>• CE Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 27-05-2025		
8.	M/s. Intra Health, 56/A, Unit No.1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi.  <b>(ELI- 00049)</b>  <b>R&amp;I detail</b> 07-05-2025 <b>Fee: 31,000/-</b> <b>Slip:</b> 759653253 <b>Dated:</b> 24-04-2025	<b>Name of Manufacturer:</b> M/s. Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, 528225 Guangdong Province, China.  <b>• LOA</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 31-12-2028  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Govt. Body <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 10-02-2027  <b>• ISO Certificate</b> <b>Type:</b> Copy of attested <b>Notarization:</b> By CCPIT <b>Validity:</b> 12-03-2026  <b>• EC Certificate</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 27-05-2024	<b>Brand name:</b> Ultimed Central Venous Catheter  <b>Generic Name:</b> Central Venous Catheter  <b>Class:</b> B  <b>Codes/Sizes:</b> Not mentioned in application  <b>Shelf life:</b> 5 Years  <b>Shelf life:</b> 3 Years	Deferred (last opportunity) for the following: 1. The firm need to apply requisite codes along with copy of the FSC. 2. Firm has not submitted FQA and Design Examination Certificate. 3. Clarification that product is of class D as per NB confirmation letter while firm has applied as class B. 4. Fee for the family required. 5. Clarification of grouping that firm has applied single, double, triple lumen catheters in single application.
9.	M/s. Intra Health, 56/A, Unit No.1, Justice Inamullah Road, Block 7/8, K.C.H.S., Karachi.  <b>(ELI- 00049)</b>  <b>R&amp;I detail</b> 07-05-2025 <b>Fee: 31,000/-</b> <b>Slip:</b> 09779761034	<b>Name of Manufacturer:</b> M/s. Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, 528225 Guangdong Province, China.  <b>• LOA</b>	<b>Brand name:</b> Ultimed Haemodialysis Catheter  <b>Generic Name:</b> Haemodialysis Catheter  <b>Class:</b> B  <b>Codes/Sizes:</b> Not mentioned in application	Deferred (last opportunity) for the following: 6. The firm need to apply requisite codes along with copy of the FSC. 7. Firm has not submitted FQA and Design Examination Certificate.

	<p><b>Dated:</b> 24-04-2025</p>	<p><b>Type:</b> Copy  <b>Notarization:</b> Not Notarized  <b>Validity:</b> 31-12-2028</p> <p>• <b>FSC</b>  <b>Type:</b> Copy  <b>Issued By:</b> Govt. Body  <b>Attested By:</b> CCPIT  <b>Legalization:</b> Not legalized  <b>Validity:</b> 10-02-2027</p> <p>• <b>ISO Certificate</b>  <b>Type:</b> Copy of attested  <b>Notarization:</b> By CCPIT  <b>Validity:</b> 12-03-2026</p> <p>• <b>EC Certificate</b>  <b>Type:</b> Copy  <b>Notarization:</b> Not Notarized  <b>Validity:</b> 27-05-2024</p>	<p><del><b>Shelf life:</b> 5 Years</del>  <b>Shelf life:</b> 3 Years</p>	<p>8. Clarification that product is of class D as per NB confirmation letter while firm has applied as class B.</p> <p>9. Fee for the family required.</p> <p>10. Clarification of grouping that firm has applied single, double, triple lumen catheters in single application.</p>
10.	<p>M/s <b>Johnson &amp; Johnson Pakistan (Pvt) Ltd.</b>, Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi (ELI-00154)</p> <p>Evaluator AD-II (2972-P)</p>	<p><b>Legal Manufacturer:</b>  M/s <b>DePuy Orthopaedics, Inc.</b>  <b>700 Orthopaedic Dr</b>  <b>Warsaw, IN 46582, USA</b></p> <p><b>Manufacturing Sites:</b>  M/s <b>DePuy Orthopaedics Inc.</b> 325 Paramount Drive Raynham, MA 02767 USA.</p> <p>M/s <b>DePuy Orthopaedics, Inc.</b> 700 Orthopaedic Drive Warsaw, IN 46582 USA.</p> <p>M/s <b>Johnson &amp; Johnson Medical (Depuy-Suzhou) Ltd.</b>, No. 299, Changyang street, Suzhou Industrial park, SUZHOU, Jiangsu, China 215126</p> <p>FSC: USA</p> <p>Valid till:</p>	<p><b>Knee Stems</b>  Class: C  Shelf life: 10 Years  Codes: As per FSC</p>	<p>Approved subject to submission of apostille/legalized FSC.</p>

		04.04.2021		
11.	<p>M/s <b>Johnson &amp; Johnson Pakistan (Pvt) Ltd.</b>, Office No.806, 8th Floor, Horizon Tower, Block 3, Scheme 5, Clifton, Karachi</p> <p>(ELI-00154)</p> <p>Evaluator AD-II</p> <p>(2977-P)</p>	<p><b>Legal Manufacturer:</b></p> <p>M/s <b>DePuy Orthopaedics, Inc.</b> 700 Orthopaedic Dr Warsaw, In 46582, USA</p> <p><b>Manufacturing Sites:</b></p> <p>M/s <b>DePuy Orthopaedics Inc.</b> 325 Paramount Drive Raynham, MA 02767 USA.</p> <p>M/s <b>DePuy Orthopaedics, Inc.</b> 700 Orthopaedic Drive Warsaw, IN 46582 USA.</p>	<p><b>Knee Accessories</b></p> <p>Class: C</p> <p>Shelf life: 10 Years</p> <p>Codes: As per FSC</p>	<p>Approved subject to submission of apostille/legalized FSC and fee verification. 960829-PFC SIGMA DI AUGMENTS. 960890-PFC SIGMA DI AUGMENTS 960870- PFC SIGMA DI AUGMENTS 960823- PFC SIGMA DI AUGMENTS</p> <p>Firm will apply separately for the followings; 129453225-UNI FEM SLEEVE. 12945110-MBT TRAY SLEEVE.</p>
12.	<p>M/s. BIOMADICS, Karachi Address: Gate #1, 211/B Sindhi Muslim, Block B Corporation Housing Society, Karachi</p> <p><b>ELI:00432</b></p> <p>Date of R&amp; I 17 April 2025</p> <p>Fee: 5000/ Slip: 2507409907 Dated 17.10.2023</p> <p>Differential Fee for family. 20,000 Challan No. 00586967936 Dated: 23-05-2025</p>	<p><b>Legal Manufacturer:</b> M/s Diagon Solutions Address: No.H-1047 Budapest, Baross u, Street 48-52, Hungary</p> <p><b>ISO 13485 Validity:</b> 17/01/2027 Copy &amp; Notarized</p> <p><b>FSC (Hungary):</b> Validity: 30/07/2026 Original &amp; Legalized</p> <p><b>LOA Validity:</b> 30/07/2026 Original &amp; Legalized</p>	<p><b>Brand Name:</b> Diagon Coagulation Analyzer</p> <p><b>Generic Name:</b> Coagulation Analyzer</p> <p><b>MD Group:</b> Family</p> <p><b>Class A</b></p> <p><b>Models:</b> <b>g-Coag S</b> (Coag S Coagulometer) <b>g-Coad 2D</b> (Coag 2D Coagulometer) <b>g-Coag 4D</b> (Coag 4D Coagulometer D-Dimer) <b>g-Coag M</b> (Coag M automated Coagulometer) <b>g-Coag L</b> (Coag L automated Coagulometer) <b>g-Coag LCP</b> (Coag L automated Coagulometer with cap piercing) <b>g-Coag XL</b> (Coag L automated</p>	<p>Approved <b>g-Coag M</b> (Coag M automated Coagulometer) Subject to submission of legalized FSC.</p>

			<b>Coagulometer)</b> <b>g-Coag XLCP</b> <i>((Coag XL automated Coagulometer with cap piercing)</i>  <b>Shelf Life:</b> Not applicable  <b>DOC:</b> 25 <sup>th</sup> May 2022	
13.	M/s. BIOMADICS, Karachi Address: Gate #1, 211/B Sindhi Muslim, Block B Corporation Housing Society, Karachi  ELI:00432  Date of R& I 17 April 2025  Fee: 25000/ Slip: 185059769006 Dated 17.10.2023	<b>Legal Manufacturer:</b> M/s Diagon Solutions Address: No.H-1047 Budapest, Baross u, Street 48-52, Hungary  ISO 13485 Validity: 17/01/2027  FSC (Hungary): Validity: 30/07/2026  LOA Validity: 30/07/2026  DOC: 24/ 08 / 2023	Diagon Coagulation Analyzer Reagents. Dia-TT Dia-AT III (FIIa) Dia-F II (Deficient Plasma) Dia-F V (Deficient Plasma) Dia-F VII (Deficient Plasma) Dia-F VIII (Deficient Plasma) Dia-F IX (Deficient Plasma) Dia-F X (Deficient Plasma) Dia-F XI (Deficient Plasma) Dia-F XII (Deficient Plasma) Dia-Protein C (Chromogenic)  Class B  Shelf Life: Not Specified	Deferred (last opportunity) for the followings: 1. apostille/legalized FSC of country of origin. 2. clarification that Dia-protein C not mentioned in FSC and LOA. 3. submission of FSC of RRA or CE marking certificate. 4. submission of stability studies. 5. submission of reagent compatible model of analyzer and catalogue.
14.	M/s. BIOMADICS, Karachi Address: Gate #1, 211/B Sindhi Muslim, Block B Corporation Housing Society, Karachi <b>ELI:00432</b>  Date of R& I 17 April 2025  Fee:107000/ Slip: 13475817647 (Rs. 50,000/-), 2953072816 (Rs. 12000/-) and 31576867202	M/s Diagon Solutions <b>Address:</b> No.H-1047 Budapest, Baross u, Street 48-52, Hungary  <b>FSC (Hungary):</b> Issued on 24-09-2019 (Copy) <i>The firm claimed that notarized attached with Coagulation Analyzer Dossier.</i>  <b>LOA Validity:</b> 30/07/2026 (Copy) <i>The firm claimed that notarized attached with Coagulation Analyzer Dossier.</i>  <b>DOC:</b> 24/ 08 / 2023 (Copy)	<b>Diagon</b> Coagulation Analyzer Reagents.  Applied as: Cluster  Class C  Dia-PT 5, Dia-PT 5 Dia-PT 10, Dia-PT LIQUID ( <b>18 months</b> )  Dia-PT R ( <b>24 months</b> ) , Dia-PT R Dia-PTT ( <b>24 months</b> ) Dia-PTT Dia-PTT LIQUID ( <b>18 months</b> ) Dia-FIB ( <b>24 months</b> ) , Dia-FIB 2	Deferred (last opportunity) for the followings: 1. apostille/legalized FSC of country of origin. 2. clarification that Dia-Cal II not mentioned in FSC and LOA. 3. submission of FSC of RRA or CE marking certificate. 4. submission of stability studies. 5. submission of reagent compatible model of analyzer and catalogue. 6. clarification regarding classification.

		<b>ISO 13485 Validity:</b> 17/01/2027 (Copy)	Dia-CONT I-II ( <b>24 months</b> )  Dia-CAL ( <b>24 months</b> ) Dia-D-DIMER ( <b>13 months</b> )  Dia-CONT DDI I-II ( <b>26 months</b> ) Dia-CAL II ( <b>24 months</b> )	
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#### DEFERRED CASES (LOCAL MANUFACTURING)

Name & Address of Establishment		Name of Medical Devices With Size	Decision
15.	Unisa Pvt. Ltd. Main GT Road\, Adamzai Akora Khattak, Nowshera KPK Pakistan (ELM-0002)  [758-6L]	UnibBag Single Blood Bag with CPDA-1 for whole Blood (human) with 16/17G for Single Use  Class: D Shelf Life: 2 Years Fee: 25000 Fee Slip No. 060033303283 Sizes: 100mL, 250mL, 350mL, 450mL,500mL	The board decided to re-constitute the panel comprising of Prof Dr. Brig (r) Nuzhat Mushahid, Pathologist, Riphah University, Dr. Abdul Aleem Awan, Member MDB and Mr. Adnan Shahidullah FID Peshawar, to evaluate the packaging, sterilization & testing facility of UNiBBAG Single Blood Bag which is a sterile, single-use system designed for the collection, storage, and transfusion of whole blood. It contains CPDA-1 (Citrate Phosphate Dextrose Adenine-1), an anticoagulant-preservative solution that extends the shelf life of collected blood. The bag is part of a closed system, minimizing contamination risk.

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