

**Government of Pakistan**  
**Ministry of National Health Services, Regulation & Coordination**  
**Drug Regulatory Authority of Pakistan**  
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**DECISIONS OF 121<sup>ST</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD**  
**ON 11-02-2026 (MANUAL APPLICATIONS PART-II)**

121<sup>st</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 11<sup>th</sup> February, 2026. 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. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	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.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
9.	Mrs. Tazeen Saeed Bukhari, 192 Cavetry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-expert (attended meeting through videolink)
10.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

<b>SR.NO.</b>	<b>NAME OF EVALUATOR</b>	<b>DESIGNATION</b>
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. CEO DRAP graced the occasion for a while with his presence to deliberate on some important issues. The following points were noted:

1. The CEO, DRAP, appreciated and thanked the Honorable Members of the Board for their active participation in the Board meetings, and acknowledged and appreciated the dedicated efforts of the officers of the Medical Devices and Medicated Cosmetics (MDMC) Division which has enabled the disposal of pending registration applications as well as the timely processing of new applications received on a daily basis.

3. The CEO informed the Board that the Medical Devices Rules are being updated to align them with international best practices. He further apprised the members that SIMAP Sialkot representatives have expressed their willingness to come under the regulatory framework. In this regard, it is necessary to formulate appropriate provisions within the Rules to accommodate such manufacturers, who are contributing significantly to Pakistan's exports by earning millions of dollars in foreign exchange. He emphasized that with focused regulatory facilitation, these exports could potentially increase to billions of dollars. The CEO requested the Board Members to actively contribute towards finalization of the updated Rules. He further proposed that, if required, an in-person meeting in Islamabad may be convened for detailed deliberations. The Members agreed to the proposal.

4. The Board Members expressed their gratitude to the CEO, DRAP, for sparing few moments from his busy schedule and appreciated his encouraging remarks and leadership.

Following the departure of the CEO, the Chair resumed the meeting and routine proceedings commenced as per the agenda. The Evaluators assisted the secretary in presenting the agenda of the meeting.

EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR)

## FRESH CASES-ELM:

S.No	Name and Address of Establishment	Name of Production In charge	Name of QC In charge	Inspection panel & date of inspection	Recommendations/ Conclusion
1	Al-Technique Corporation of Pakistan Limited,  Office/godown: 18 Km Multan road, Lahore Lahore.			Dr. Muhammad Farid Khan, Member MDB.  Ishtaiq Shafiq Deputy Director DRAP Lahore.	<p><b>Conclusion/Recommendation:</b></p> <p>Based on the inspection of the company's facilities and verification of its operations, including company profile, building, irradiation services, machinery/equipment, material management, personnel, and documentation, the panel recommended the grant of establishment license <b>for sterilization only</b> to M/s Al-Technique Corporation of Pakistan Limited at 18 KM Multan Road, Lahore of the following products:</p> <ol style="list-style-type: none"> <li>1. Nebulizers</li> <li>2. Ophthalmic Equipment</li> <li>3. Syringes and IV Sets</li> <li>4. Compression Bandages and Gauze</li> <li>5. Urine Containers</li> <li>6. Delivery Kits</li> <li>7. IV Kits</li> <li>8. Foot Kits</li> <li>9. Operation Tool Kits</li> <li>10. Ointments</li> <li>11. Vials</li> <li>12. Raw Talc</li> <li>13. Dental Kits</li> <li>14. Dressing Kits</li> <li>15. Healthcare Products</li> <li>16. Surgical Instruments and Implants</li> </ol>
<p><b>Decision:</b> The board considered inspection report of the firm and obtained comments of Dr Farid Khan Member MDB on inspection findings. He informed the board that the premises possess all facilities required for sterilization of medical devices mentioned in the inspection report through Gamma irradiation. Dr. Mahmood Member MDB opined that board should take such a decision that sterilization facility of the applicant becomes applicable to all relevant stake holders involved in the business under DRAP Act 2012 including pharmaceuticals.</p> <p>The board deliberated on the matter and endorsed the facility for sterilization of medical devices. However, there is no specific rule and certification form under medical devices rules 2017 that addresses certification/ licensure for only one process of manufacture i.e sterilization in the subject matter when the facility holder is not manufacturing the medical device in its finished form. Therefore, the board decided to refer this matter for consideration of Authority for making required changes in schedule if needed and to find a way out for certification/ licensure of all such applicants.</p>					

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

**(FRESH RENEWAL CASES-ELD):**

S. No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Diag. M (Pvt) Limited, Office/godwon: B-270, Sector 6-F, EBM Causeway, Mehran Town Korangi, Karachi.  ELI-00184	Muhammad Shoaib Shahab  Msc Microbiology	Arshad Aleem Muhammad Ziaullah Muhammad Shahabuddin M Nadeem Biswas Manzar Alam Faisal Warsi	Approved
2.	The Searle company limited,  Office: 2 <sup>nd</sup> floor, one IBL centre, plot no. 1, block 7/8, DMCHS, Tipu sultan road, off shhsrah e faisal , Karachi.  Godown: Plot no 56, sector 7/A, Korangi industrial area, Karachi.  ELI-00057	Sameer Ali  Pharm D	Zubair Razzak Palwala Mobeen Alam Muhammad Sajid Tahir Ahmed Moujood ul hasan Imtaiz Haider	Approved

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

S.NO.	Name of Firm	Renewal Due Date	Date of Renewal Application	Decision
1.	M/s Hospicare System,  Office/Godown: Mezzanine Floor, Rabbiya garden, Plot No. 3, MCHS Society, Shaheed e Millat road, Karachi.  ELI No. 00274	19-10-2023	<b>Not submitted.</b> In response to our letter Ref No. 2- 1/2024-MD dated 22 <sup>nd</sup> December, 2025, the firm failed to provide any evidence of submission of application for Renewal of Establishment License to import Medical Devices.	The board observed that the renewal application of the firm is now complete and division was able to retrieve/ verify old record of the applicant pertaining to renewal application submitted within time as defined under medical devices rules 2017. Therefore, the board overruled it earlier decision and decided to proceed with renewal application of the firm for renewal of establishment license to import medical devices. The board authorized additional director DRAP Karachi or his nominee to conduct renewal inspection and send report for consideration of medical devices board.

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

**(DEFERRED RENEWAL CASES-ELI):**

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Med impex  Office/Godown: 934-Shadman Colony-I, Lahore  ELI-00301	Babar Ali  Bio Medical Engineer	Muhammad Jamil  CEO	Approved
2.	M/s Zuis pharmland,  Office/Godown: 3 <sup>rd</sup> building doctor plaza near ghausia marriage hall , G- 13/4, & g-12, Main double road , Islamabad. ELI-00214	Safdar shah  Pharmacist	M Ibrahim  CEO	Approved

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

**Evaluator: Saadat Ali Khan (Deputy Director)**

**IMPORTED PRODUCT AGENDA (APPLICATIONS SUBMITTED IN CMS)**

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Siemens Healthcare (Pvt) Limited, 4th Floor State Life Building, 15-A, Sir Agha Khan Road, Lahore  (ELI- 00146)  Date of R&I 25-01-2021 Fee Details: Paid Fee: 50,000/- Challan No. 1924147 dated 22-09-2020	<b>Legal Manufacturer &amp; manufacturing site as per Form-7A:</b> Siemens Shanghai Medical Equipment Ltd. (SSME), 270 Zhou Zhu Road, Shanghai 201318, China  <b>Address of legal manufacturer &amp; manufacturing Site as per FSC:</b> Siemens Shanghai Medical Equipment Ltd XP Facility, 278 Zhou Zhu Road, Shanghai 201318, China. <b>Factory Site:</b> Siemens Shanghai Medical Equipment Ltd.(SSME), 278 Zhou Zhu Road, Shanghai 201318, China	<b>Multix Impact</b> (Stationary Basic Diagnostic X-ray machine)  <b>Applied as Single.</b>  <b>Class-C</b> <b>Service Life:</b> 10 years <b>Model:</b> 11020788	Deferred for submission of the following: 1. Valid legalized Free Sale Certificate (FSC) of country of origin plus valid notarized CE (FQA) or Valid Legalized Free Sale Certificate (FSC) of Germany or any reference country. 2. Verifiable evidence of submission of required fee.

		<p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity:</b> 24-05-2029</p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> Bavarian health and food safety authority, Germany  <b>Issuance Date:</b> 01-03-2019  <b>Validity:</b> not mentioned.</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 31-03-2028</p> <p>• <b>EU QMS (MDR):</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 05-11-2025</p>		
3.	<p>M/s Siemens Healthcare (Pvt) Limited, 4th Floor State Life Building, 15-A, Sir Agha Khan Road, Lahore</p> <p>(ELI- 00146)</p> <p>Date of R&amp;I 24-05-2021  Fee Details:  Paid Fee: 25,000/- Challan No. 1924141 dated 22-09-2020  Paid Fee: 25,000/- Challan No. 69095785 dated 30-09-2022</p>	<p><b>Legal Manufacturer:</b>  Siemens Healthcare GmbH  Henkestr.127, 91052 Erlangen, Germany</p> <p><b>Manufacturing Site:</b>  <b>Site 1:</b> Siemens Healthineers AG  Digital &amp; Automation (D&amp;A)  Siemensstr.1, 91301 Forchheim, Germany</p> <p><b>Site 2:</b> Siemens Medical Solutions USA, Inc. Digital &amp; Automation (D&amp;A) 400 W. Morgan Road Ann Arbor MI, 48108, USA.</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Issuance date:</b> 07-11-2022  <b>Validity:</b> Not mentioned</p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> Germany  <b>Issuance Date:</b> 12-06-2025  <b>Validity:</b> not mentioned.</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 14-05-2027</p>	<p><b>Syngo Family</b>  Software for viewing, manipulation, communication &amp; storage of medical images &amp; data</p> <p><b>Applied as Family.</b></p> <p><b>Class-C</b>  <b>Service Life:</b> N/A  <b>Model:</b>  <b>Syngo.via:</b> 11582847  <b>Syngo.MR Applications:</b> 11823214 + 11665248 + 11583169 + 11665595  <b>Syngo Carbon Space:</b> 11665527  <b>Syngo Carbon Clinicals:</b> 11824011 +11665568 + 11665330 + 11665628  <b>Syngo Carbon Enterprise Access:</b> 11666036  <b>SyngA via View&amp;Go:</b> 11665773 + 11665329 + 11582891  <b>Syngo Virtual Cockpit:</b> 11665703  <b>Syngo Dynamics:</b> 11707704</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Justification of the grouping with catalog or any other document. The grouping fee shall also be submitted.</li> <li>Verifiable evidence of submission of required fee.</li> </ol>

		<p>• <b>EU QMS (MDR):</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 29-09-2030</p>		
3.	<p>M/s. FAREED ARSHAD,  Ground Floor,  Zohra House,  Street No.1,  Beside Jinnah Masjid, Burns Road, Karachi.  E. Lic. No.:  ELI-01315</p> <p>Date of R&amp;I  30-05-2025  Fee Details:  Paid Fee: 6,000/-  Challan No.  79274200544</p>	<p>Zibo Blue Sail Innovation Co., Ltd.  No. 21 Qingtian Rd., Qilu Chemical Industrial Park Zibo City , Shangdong – P. R. China.</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity: 15-03-2030</b></p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> China  <b>Validity:</b> 18-06-2025.</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 31-07-2025</p>	<p><b>Disposable Nitrile Examination Gloves (Powdered &amp; Powdered Free)</b></p> <p><b>Applied as Single.</b></p> <p><b>Class-A</b>  <b>Service Life:</b> 5 years  <b>Model:</b>  XS/S/M/L/XL</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid legalized Free Sale Certificate (FSC) of country of origin issued by concerned regulatory authority or Valid Legalized Free Sale Certificate (FSC) of any reference country.</li> <li>Valid notarized ISO 13485</li> </ol>
4.	<p>M/s. FAREED ARSHAD,  Ground Floor,  Zohra House,  Street No.1,  Beside Jinnah Masjid, Burns Road, Karachi.  E. Lic. No.:  ELI-01315</p> <p>Date of R&amp;I  30-05-2025  Fee Details:  Paid Fee: 6,000/-  Challan No.  6812355208</p>	<p>Zibo Blue Sail Innovation Co., Ltd.  No. 21 Qingtian Rd., Qilu Chemical Industrial Park Zibo City , Shangdong – P. R. China.</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity: 15-03-2030</b></p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> China  <b>Validity:</b> 01-09-2026.</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 31-07-2025</p>	<p><b>Disposable Vinyl Examination Gloves (Powdered Free)</b></p> <p><b>Applied as Single.</b></p> <p><b>Class-A</b>  <b>Service Life:</b> 5 years  <b>Model:</b>  XS/S/M/L/XL</p>	<p>Approved.</p>
5.	<p>Noor International,  29-D, Block 6,  PECHS, Karachi  (ELI-00061)</p> <p>Date of R&amp;I</p>	<p><b>Legal Manufacturer</b>  Top Corporation  19-10 Senju Nakai-cho,  Adachi-ku, Tokyo 120-0035,  Japan.  <b>Manufacturing Site as per</b></p>	<p><b>TOP-S500</b>  Syringe Pump</p> <p><b>Applied as Single.</b></p> <p><b>Class-C</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid legalized Free Sale Certificate (FSC) of country of origin</li> <li>Valid notarized LOA</li> </ol>

	<p>28-02-2025  Fee Details:  Paid Fee: 62,000/-  Challan No.  2463026582</p>	<p><b>FSC:</b>  <b>1<sup>st</sup> Site:</b>  Meditop Corporation  (Malaysia)  SDN. BHD. Plant-2  N03, Persiaran Usahawan  Taman IKS,  Seksyen 9,43650 Bandar Baru  Bangi,  Selangor Darul Ehsan,  Malaysia.  <b>2<sup>nd</sup> Site:</b>  Top corporation Koshigaya  Factory,  40-34 Noborito-cho,  Koshigaya-shi, saitama,,  Japan.</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-  notarized copy.  <b>Validity: 31-12-2027</b></p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-  notarized copy  <b>Issued By:</b> Japan  <b>Issuance Date: 15-12-2020</b>  <b>Validity:</b> not mentioned.  • <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-  notarized copy  <b>Validity:</b> 31-03-2026  <b>&amp; ISO 13485 for Malaysia</b>  <b>site valid upto 31-08-2027</b></p> <p>• <b>EC (FQA)</b>  <b>Type:</b> Scan copy of non-  notarized copy  <b>Validity:</b> 26-05-2024</p>	<p><b>Service Life:</b> 6 years  <b>Model: S500</b></p>	<p>issued by the legal  manufacturer or any  authorized entity along  with evidence of its  authorization.</p>
6.	<p>M/s Sonotech, 938-C  Block, Faisal Town,  Lahore  ELI-00584</p> <p>Date of R&amp;I  11-03-2021  Fee Details:  Paid Fee: 25,000/-  Challan No.  2036877 dated 03-03-  2021</p>	<p>Shenzhen Emperor Electronic  Technology Co., Ltd. No.  1101, Tialiao Community,  Yutang Street, Guangming  District, 51810 Shenzhen,  China</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-  notarized copy.  <b>Validity: 30-12-2026</b></p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-  notarized copy  <b>Issued By:</b> China  <b>Validity:</b> 22-03-2026.</p>	<p><b>EMP</b>  Diagnostic Color Doppler  Ultrasound System</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b>  <b>Service Life:</b> 8 Yr  <b>Model:</b>  G20</p>	<p>Deferred for submission of the  following:  1. Valid notarized ISO 13485  2. Verifiable evidence of  submission of prescribed  fee.  3. Justification of class of the  product as per Medical  Device Rules 2017.</p>

		<ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 29-12-2025.</li> <li>• <b>EC (FQA)</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2024 <b>With extension letter</b></li> </ul>		
7.	<p>M/s Sonotech, 938-C Block, Faisal Town, Lahore ELI-00584</p> <p>Date of R&amp;I 11-03-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2036876 dated 03-03-2021</p>	<p>Shenzhen Emperor Electronic Technology Co., Ltd. No. 1101, Tialiao Community, Yutang Street, Guangming District, 51810 Shenzhen, China</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 30-12-2026</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> China <b>Validity:</b> 22-03-2026.</p> <ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 29-12-2025.</li> <li>• <b>EC (FQA)</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2024 <b>With extension letter</b></li> </ul>	<p><b>EMP</b> Diagnostic Color Doppler Ultrasound System</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life:</b> 8 Yr <b>Model:</b> G30</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Valid notarized ISO 13485</li> <li>2. Verifiable evidence of submission of prescribed fee.</li> <li>3. Justification of class of the product as per Medical Device Rules 2017.</li> </ol>
8.	<p>M/s Sonotech, 938-C Block, Faisal Town, Lahore ELI-00584</p> <p>Date of R&amp;I 11-03-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2036875 dated 03-03-2021</p>	<p>Shenzhen Emperor Electronic Technology Co., Ltd. No. 1101, Tialiao Community, Yutang Street, Guangming District, 51810 Shenzhen, China</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 30-12-2026</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> China <b>Validity:</b> 22-03-2026.</p> <ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 29-12-2025.</li> </ul>	<p><b>EMP</b> Full Digital Ultrasound Diagnostic Device</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life:</b> 8 Yr <b>Model:</b> N2</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Valid notarized ISO 13485</li> <li>2. Verifiable evidence of submission of prescribed fee.</li> <li>3. Justification of class of the product as per Medical Device Rules 2017.</li> </ol>

		<ul style="list-style-type: none"> <li>• <b>EC (FQA)</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2024 <b>With extension letter</b></li> </ul>		
9.	<p>M/s Sonotech, 938-C Block, Faisal Town, Lahore ELI-00584</p> <p>Date of R&amp;I 11-03-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2036874 dated 03-03-2021</p>	<p>Shenzhen Emperor Electronic Technology Co., Ltd. No. 1101, Tialiao Community, Yutang Street, Guangming District, 51810 Shenzhen, China</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 30-12-2026</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> China <b>Validity:</b> 22-03-2026.</p> <ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 29-12-2025.</li> <li>• <b>EC (FQA)</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2024 <b>With extension letter</b></li> </ul>	<p><b>EMP</b> Full Digital Ultrasound Diagnostic Device</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life:</b> 8 Yr <b>Model:</b> N5</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Valid notarized ISO 13485</li> <li>2. Verifiable evidence of submission of prescribed fee.</li> <li>3. Justification of class of the product as per Medical Device Rules 2017.</li> </ol>
10.	<p>M/s Combined Engineers ELI-00377</p> <p>Date of R&amp;I 03-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 44934423</p>	<p>M/s CEFLA s.c Via Selice Provinciale 23/A 40026 Imola (BO) Italy (Head office), and</p> <p>Via Bicocca, 14/C 40026 Imola (BO) Italy (Plant),</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 25-11-2027</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Italy <b>Issuance date:</b> 16-07-2022. <b>Validity:</b> Not mentioned</p> <ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 16-07-2027.</li> </ul>	<p><b>ANTHOS</b> Dental unit</p> <p><b>Applied as Family.</b></p> <p><b>Class-B</b> <b>Service Life:</b> 10 Yr <b>Model:</b> A3 PLUS CONTINENTAL A3 PLUS INTERNATIONAL A5 CART A5 CONTINENTAL A5 IDRICO SINGOLO A5 INTERNATIONAL A5 SINGLE CART A6 PLUS CONTINENTAL A6 PLUS INTERNATIONAL A7 PLUS CONTINENTAL A7 PLUS</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Justification of grouping of the products/codes/models as per Medical Device Rules 2017 with submission of catalog &amp; family/system fee.</li> </ol>

		<p>• <b>Eu QMS (MDR)</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 25-10-2026</p>	<p>INTERNATIONAL  AIRPOWER  DENTAL  TURBINES  VENUS PLUS  GOLD SPEED  EVO S1-L  GOLD SPEED  EVO D1  GOLD SPEED  EVO D1-L  GOLD SPEED  EVO E16  GOLD SPEED  EVO M5-L  GOLD SPEED  EVO S1  GOLD SPEED  EVO R20-L  i-MMr L  i-MMr  i-MMs  L6  CONTINENTAL  L6 SIDE  DELIVERY L9  CONTINENTAL  L9 SIDE  DELIVERY  R7 CART  R7 CONTINENTAL  R7  INTERNATIONAL  R7 ORTHO  R7 P  R7 M  CONTINENTAL  R7 M  INTERNATIONAL  SURGICAL  SINGLE CART  u-PZ6  u-PZ7  u-PZ8</p>	
11.	<p>M/s Combined Engineers  ELI-00377</p> <p>Date of R&amp;I  03-03-2023  Fee Details:  Paid Fee: 25,000/-  Challan No.  0090342993</p>	<p>M/s CRUXELL CORP.  Address:  405, Migun Techno World II, 187 Techno 2-ro, Yuseong-gu Daejeon, Republic of Korea</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity:</b> 24-11-2027</p> <p><b>FSC</b></p>	<p><b>Dental PSP</b>  Scanner  CRX-1000</p> <p><b>Software:</b>  <b>CRUXCAN twain driver</b></p> <p>Digital X-ray Imaging</p> <p><b>Applied as Family.</b></p> <p><b>Class-B</b>  <b>Service Life:</b> 5 Yr  <b>Model:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code.</li> <li>Valid Legalized FSC of any RRA or valid notarized CE Certificate.</li> <li>Justification of grouping of the product with the applied software with catalog if the product is</li> </ol>

		<p><b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> Korea  <b>Issuance date:</b> 20-06-2022.  <b>Validity:</b> 20-06-2027.</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 06-05-2028.</p>	CRX-1000	system or otherwise.
12.	<p>M/s. United Brothers.,  Office # 301,  Mehrab Market,  Medicine Street No. 1,  Marriot Road,  Karachi.  ELI: 00451</p> <p>Date of R&amp;I  19-11-2021  Fee Details:  Paid Fee: 5,000/-  Challan No.  945852228</p>	<p>Shandong Dermcosy Medical Co., Ltd,  <b>Address as per Form-6A:</b>  No.17 Nanzhi First Road,  Zibo Science &amp;Technology Industrial Park,  Zhangdian District,  Zibo City,  Shandong, China.  <b>Address as per FSc:</b>  No.17 South Branch Road,  Science &amp;Technology Industrial Park,  Zhangdian District,  Zibo City,  Shandong, China.</p> <p><b>Agency Agreement</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity: 01-01-2026</b></p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> China  <b>Validity:</b> 20-06-2023.</p> <p>• <b>ISO 13485</b> not opened/not attached.</p>	<p><b>UB-POREs</b>  Non-Woven Dressing Pad (Non-woven Adhesive Wound Dressing)</p> <p><b>Applied as Single.</b></p> <p><b>Class-A</b>  <b>Service Life:</b> 5 years  <b>Model/codes/sizes:</b>  6x7cm,  9x10cm,9x15cm,  9x20cm, 9x25cm,  9x30cm, 9x35cm,  10x10cm,10x15cm,  10x20cm,  10x25cm,  10x30cm, 10x35cm</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid notarized LOA</li> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>The product is of Class-B as per submitted DOC, so revised Form-7A &amp; fee is required.</li> <li>Valid Legalized FSC of any RRA or valid notarized CE Certificate.</li> <li>Valid notarized ISO13485</li> <li>Justification of grouping of the product with family fee.</li> <li>Shelf life evidence or data</li> </ol>
13.	<p>MH Pharma Lahore (ELI-00720)</p> <p>Date of R&amp;I:  24/01/2024  Fee details:  PKR 25000/-  Slip# 2458037794</p>	<p><b>Manufacturer as per Fsc:</b>  Winner Guilin Latex Co., Ltd.  No. 6 Wushan Road  Guilin  541001 Guangxi  P.R. China</p> <p><b>Agency Agreement/LOA not attached</b></p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> China  <b>Validity:</b> 19-05-2027.</p>	<p><b>Gobon</b>  Single-Use Sterile Rubber Surgical Gloves (Powdered).</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b>  <b>Service Life:</b>  <b>Model/codes/sizes:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid notarized LOA</li> <li>Valid Legalized FSC of any RRA or valid notarized CE Certificate.</li> <li>Valid notarized ISO13485</li> <li>Shelf life evidence or data.</li> <li>Copy of R&amp;I receiving</li> <li>Copy of Form-7A duly signed along with all information &amp; relevant annexures.</li> </ol>

		<ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 01-07-2027.</li> <li>• <b>EC (FQA)</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2024 With extension letter but powdered Gloves not mentioned in the scope only powdered free is mentioned.</li> </ul>		
14.	<p>Innovate Medical Technologies (Pvt) Ltd, House No. A-7, Baloch Goth Block No 13-D-3 Gulshan-e-Iqbal, Karachi. (ELI- 00352)</p> <p>Date of R&amp;I 23-11-2022 Fee Details: Paid Fee: 5,000/- Challan No. 425242909</p>	<p>Manufacturer as per Fsc: Amoena Medizin-Orthopadia-Technik GmbH Kapellenweg 36 83064 Raubling Deutschland Germany.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 15-12-2025</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Germany <b>Issuance Date: 08-12-2022</b> <b>Validity:</b> not mentioned.</p> <ul style="list-style-type: none"> <li>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 20-01-2028</li> </ul>	<p><b>Amoena Brassieres</b></p> <p><b>Applied as Single.</b></p> <p><b>Class-Service Life: Model:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Valid notarized LOA</li> <li>2. Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>3. Copy of R&amp;I receiving</li> <li>4. Copy of prescribed Form duly signed along with all information &amp; relevant annexures including description of the product &amp; DOC for confirmation class. Also valid notarized CE Certificate if in class-B or higher.</li> <li>5. Justification of grouping of the product with family fee if multiple codes.</li> <li>6. Shelf life evidence or data</li> </ol>
15.	<p>Innovate Medical Technologies (Pvt) Ltd, House No. A-7, Baloch Goth Block No 13-D-3 Gulshan-e-Iqbal, Karachi. (ELI- 00352)</p> <p>Date of R&amp;I 23-11-2022 Fee Details: Paid Fee: 5,000/- Challan No. 08894966412</p>	<p>Manufacturer as per Fsc: Yasemin Medikal Malzemeleri Ticaret Sanayi Anonim Sirketi, Istanbul, Turkey</p> <p><b>Distribution Agreement</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Issuance Date: 18-09-2022</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Turkey <b>Issuance Date: 17-08-2022</b> <b>Validity:</b> 16-08-2025</p> <ul style="list-style-type: none"> <li>• <b>ISO 13485:</b></li> </ul>	<p><b>Hexatulle</b> Paraffin Gauze Dressing with chlorhexidine Acetate 0.5%</p> <p><b>Applied as Single.</b></p> <p><b>Class-Service Life: Model/Sizes (cm)</b> 10x10 30x10</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Valid notarized LOA</li> <li>2. Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>3. Copy of R&amp;I receiving</li> <li>4. Copy of prescribed Form duly signed along with all information &amp; relevant annexures including description of the product.</li> <li>5. The product is of class-D. revised fee, valid notarized CE Certificate (FQA) &amp; Design Examination</li> </ol>

		<p><b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 09-03-2026</p> <p>CE (FQA)  Valid upto 27-05-2024</p>		<p>Certificate.</p> <p>6. Justification of grouping of the product with family fee.</p> <p>7. Shelf life evidence or data</p>
16.	<p>Innovate Medical Technologies (Pvt) Ltd, House No. A-7, Baloch Goth Block No 13-D-3 Gulshan-e-Iqbal, Karachi. (ELI- 00352)</p> <p>Date of R&amp;I  07-01-2021  Fee Details:  Paid Fee: 5,000/-  Challan No.  2057806 dated 07-01-2021</p>	<p>Manufacturer as per Fsc: Zhejiang Kanglidi Medical Articles CO., LTD., Dongshan Industrial Zone, Shangwuzhai, Liushi, Yueqing 325604 Zhejiang, P.R. China.</p> <p><b>Authority Letter</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Issuance Date:</b> 11-02-2025  <b>Validity:</b> 10-02-2025</p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> China  <b>Validity:</b> 23-05-2026</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 22-12-2025</p>	<p><b>IMT Kalgistat Dressing</b>  Calcium Alginate Wound Dressing</p> <p><b>Applied as Single.</b></p> <p><b>Class-</b>  <b>Service Life:</b>  <b>Model/Sizes (cm)</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid notarized LOA</li> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>Copy of R&amp;I receiving</li> <li>Copy of prescribed Form duly signed along with all information &amp; relevant annexures including description of the product.</li> <li>The product is of Class-C. revised fee, valid notarized CE Certificate (FQA) &amp; Design Examination Certificate (if applicable).</li> <li>Justification of grouping of the product with family fee.</li> <li>Shelf life evidence or data.</li> <li>Valid notarized ISO13485</li> </ol>
17.	<p>Innovate Medical Technologies (Pvt) Ltd, House No. A-7, Baloch Goth Block No 13-D-3 Gulshan-e-Iqbal, Karachi. (ELI- 00352)</p> <p>Date of R&amp;I  07-01-2021  Fee Details:  Paid Fee: 5,000/-  Challan No.  7220724970</p>	<p>Manufacturer as per Fsc: Fortune Medical Instrument Corp., No. 256, Changchun 2<sup>nd</sup> Rd., Jhongli Dist., Taoyuan City, Taiwan</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Issuance Date:</b> 11-02-2025  <b>Validity:</b> 21-08-2027</p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> Taiwan  <b>Validity:</b> 08-04-2025.</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 08-08-2025</p>	<p><b>Name as per FSC:</b></p> <p><b>Rystora Scar Gel</b>  Silicon Scar Gel (Non Sterile)</p> <p><b>Applied as Single.</b></p> <p><b>Class-</b>  <b>Service Life:</b>  <b>Model/Sizes</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>Copy of R&amp;I receiving</li> <li>Copy of prescribed Form duly signed along with all information &amp; relevant annexures including description of the product &amp; DOC for confirmation class. Also valid notarized CE Certificate if in class-B or higher.</li> <li>Justification of grouping of the product with family fee if multiple codes.</li> <li>Shelf life evidence or data.</li> <li>Valid notarized ISO13485</li> </ol>

18.	<p>Innovate Medical Technologies (Pvt) Ltd, House No. A-7, Baloch Goth Block No 13-D-3 Gulshan-e-Iqbal, Karachi. (ELI- 00352)</p> <p>Date of R&amp;I 07-01-2021 Fee Details: Paid Fee: 5,000/- Challan No. 416059282892</p>	<p><b>Manufacturer as per Fsc:</b> Fortune Medical Instrument Corp., No. 256, Changchun 2<sup>nd</sup> Rd., Jhongli Dist., Taoyuan City, Taiwan</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Issuance Date: 11-02-2025</b> <b>Validity: 21-08-2027</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Taiwan <b>Issuance date:</b> 02-11-2022 Validity : Not mentioned.</p> <p>• <b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 08-08-2025</p>	<p><b>Name as per FSC:</b> <b>Rystora Silicon Scar Sheet (Non-Sterile)</b></p> <p><b>Applied as Single.</b></p> <p><b>Class- Service Life: Model/Sizes</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>Copy of R&amp;I receiving</li> <li>Copy of prescribed Form duly signed along with all information &amp; relevant annexures including description of the product &amp; DOC for confirmation class. Also valid notarized CE Certificate if in class-B or higher.</li> <li>Justification of grouping of the product with family fee if multiple codes.</li> <li>Shelf life evidence or data.</li> <li>Valid notarized ISO13485</li> </ol>
19.	<p>Fuzion Healthcare, 15-HBFC, Opp. Emergency gate of Jinnah Hospital, Faisal Town, Lahore. (ELI- 00916)</p> <p>Date of R&amp;I 19-01-2024 Fee Details: Paid Fee: 25,000/- Challan No. 6241716243</p>	<p><b>Manufacturer as per Fsc:</b> Canyon Medical Inc., Building 3, Phase 2 Accelerator, No. 11, Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, China</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Issuance Date: 01-05-2023</b> <b>Validity: 01-05-2026</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> China <b>Validity:</b> 11-05-2024.</p> <p>• <b>ISO 13485: Not attached</b></p>	<p><b>Name as per FSC:</b> <b>Coaxial Biopsy Needle</b></p> <p><b>Applied as Single.</b></p> <p><b>Class- Service Life: Model/Sizes</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>Copy of prescribed Form duly signed along with all information &amp; relevant annexures including description of the product &amp; DOC for confirmation class. Also valid notarized CE Certificate if in class-B or higher.</li> <li>Justification of grouping of the product with family fee if multiple codes.</li> <li>Shelf life evidence or data.</li> <li>Valid notarized ISO13485</li> </ol>
20.	<p>Fuzion Healthcare, 15-HBFC, Opp. Emergency gate of Jinnah Hospital, Faisal Town, Lahore. (ELI- 00916)</p> <p>Date of R&amp;I 19-01-2024 Fee Details: Paid Fee: 25,000/-</p>	<p><b>Manufacturer as per Fsc:</b> Canyon Medical Inc., Building 3, Phase 2 Accelerator, No. 11, Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, China</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy.</p>	<p><b>Disposable Biopsy Needle Manual, Semi-automatic &amp; Automatic</b></p> <p><b>Applied as Single.</b></p> <p><b>Class-B Service Life: Model/Sizes</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin or any reference country wherein the applied product shall be on free sale with the applied code/size.</li> <li>Copy of prescribed Form duly signed along with all information &amp; relevant</li> </ol>

	Challan No. 3411137286	<b>Issuance Date: 01-05-2023</b> <b>Validity: 01-05-2026</b>  <b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> China <b>Validity:</b> 11-05-2024.  <b>• ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 02-08-2026		annexures including description of the product & DOC for confirmation class. Also valid notarized CE Certificate if in class-B or higher. 3. Justification of grouping of the product with family fee if multiple codes. 4. Shelf life evidence or data. 5. Valid notarized ISO13485
21.	M/s Ferozsons Laboratories Limited (ELI-00120)  Date of R&I 10-01-2025 Fee Details: Paid Fee: 62,000/- Challan No. 2090751249	<b>Legal Manufacturer:</b> Boston Scientific Neuro Modulation Corporation 25155 Rye Canyon Loop Valencia, CA 91355, USA.  <b>Manufacturing Site:</b> <b>Site I:</b> Boston Scientific Corporation-Coyol Boston Scientific de Costa Rica, S.R.L. 2546 2546 First Street, ProPark El Coyol, Alajuela COSTA RICA 20904  <b>Site II:</b> Boston Scientific Corporation - St. Paul 4100 Hamline Avenue North, St. Paul, MN 55112, USA  <b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 31-12-2025</b>  <b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> HPRA Ireland <b>Issuance Date: 26-10-2021</b> <b>Validity:</b> not mentioned. <b>• ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 30-11-2026  <b>• EC:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2024	<b>RF Ablation Electrodes for Central Nervous System (CNS)</b> Radio-Frequency Ablation System  <b>Applied as Family.</b>  <b>Class-D</b> <b>Service Life: 4 Yr</b> <b>Model/Codes/Size:</b> LCED LCED-P TC-11-2-250-D TC-11-4-250-D TC-16-2-250-D TC-16-4-250-D TC-16-10-250-D CB112-TC CB114-TC CB116 CB135-TC CB114-ADP TCN-10 TCN-10-3M TCN-15 TCN-15-3M TCN-20 TCN-20-3M TCN-5 TCN-5-3M TCN-CASE CSK-TC5 CSK-TC10 CSK-TC15 CSK-TC20 CSK-TC5-3M CSK-TC10-3M CSK-TC15-3M CSK-CASE TCD-5-P TCD-10-P TCD-15-P TCD-20-P TCD-5-3M-P	Deferred for submission of the following: 1. Valid notarized LOA issued by legal manufacturer or any authorized entity along with evidence its authorization. 2. Valid Legalized FSC of country of origin wherein the applied product shall be on free sale with the applied code/size with all sites. 3. Justification of grouping of the product with family fee & catalog. 4. Shelf life evidence or data.

			TCD-10-3M-P TCD-15-3M-P DS-11-D-P DS-16-D-P FLEX-K151320-5P RCE-E401519-P RCE-E661519-P	
22.	M/s Ferozsons Laboratories Limited (ELI-00120)  Date of R&I 14-07-2025 Fee Details: Paid Fee: 62,000/- Challan No. 20136488	<b>Legal Manufacturer:</b> Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA USA 01752 <b>Manufacturing Site:</b> Boston Scientific, Ltd. Ballybrit Business Park Galway Ireland. <b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 31-12-2025</b>  <b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> HPRA Ireland <b>Issuance Date: 20-11-2024</b> <b>Validity:</b> not mentioned. <b>• ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 23-03-2027  <b>• EU QMS (MDR):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 28-10-2027	<b>Wallflex Esophageal Partially Covered Stent System.</b> Polymer-metal Esophageal Stent  <b>Applied as Single.</b>  <b>Class-C</b> <b>Service Life: 25 months</b> <b>Model/Codes/Size:</b> M00516900 M00516910 M00516920 M00516930 M00516940 M00516950	Deferred for submission of the following: 1. Valid notarized LOA issued by legal manufacturer or any authorized entity along with evidence its authorization. 2. Justification of grouping of the product with family fee & catalog.
23.	M/s Ferozsons Laboratories Limited (ELI-00120)  Date of R&I 14-02-2025 Fee Details: Paid Fee: 62,000/- Challan No. 9550075802	<b>Legal Manufacturer:</b> Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA.  <b>Manufacturing Site:</b> Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, MN 55112 USA.  <b>Contract Manufacturing Site:</b> Dedicated Computing LLC, N26 W23880 Commerce Circle Waukesha, Wisconsin 53188 USA. <b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 31-12-20254</b>  <b>FSC</b>	<b>Labsystem Pro EP Recording System,</b> LABSYSTEM PRO EP Recording System, LS10K Win 10 Computer, V4.0 SW <b>Applied as Single.</b>  <b>Class-C</b> <b>Service Life: N/A</b> <b>Model/Codes/Size:</b>	Deferred for submission of the following: 1. Valid notarized LOA issued by legal manufacturer or any authorized entity along with evidence its authorization. 2. Valid Legalized FSC of country of origin wherein the applied product shall be on free sale with the applied code/size with all sites. 3. Codes as per FSC & Justification of grouping of the product with family fee & catalog.

		<p><b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> HPRA Ireland  <b>Validity:</b> 27-05-2025</p> <p><b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 01-09-2026</p> <p>• <b>EC (FQA):</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 26-05-2024</p>		
24.	<p>M/s Aesthetic Life, 4th Floor, Plot 16-C, Ittehad Commercial Area, Khyaban-e-Nishat, DHA Phase-VI, Karachi ELI-01029.</p> <p>R&amp;I evidence not attached.</p> <p>Fee Details:  Paid Fee: 50,000/-  Challan No. 48877842163</p>	<p>APTOS LLC, Givi Amilakhvari Street 15, 0109 Tbilisi, Georgia</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity:</b> 31-12-2026</p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> Germany  <b>Validity:</b> 05-04-2026</p> <p><b>ISO 13485:</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 01-10-2026</p> <p>• <b>EC (FQA):</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 24-05-2026</p> <p>• <b>EC (Design Examination):</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Validity:</b> 24-05-2026</p>	<p><b>Visage Excellence Method</b>  Aptos– Sterile Absorbable (Poly(L-lactide-co-caprolactone) copolymer (P(LA/CL)) Threads with needle or cannula suture)</p> <p><b>Applied as Single.</b></p> <p><b>Class-D</b>  <b>Service Life: 3 Yr</b>  <b>Model/Codes/Size:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Copy of R&amp;I receiving of the applied product.</li> <li>2. Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</li> </ol>
25.	<p>M/s Aesthetic Life, 4th Floor, Plot 16-C, Ittehad Commercial Area, Khyaban-e-Nishat, DHA Phase-VI, Karachi ELI-01029.</p> <p>R&amp;I evidence not attached</p> <p>Fee Details:  Paid Fee: 50,000/-  Challan No.</p>	<p>APTOS LLC, Givi Amilakhvari Street 15, 0109 Tbilisi, Georgia</p> <p><b>LOA</b>  <b>Type:</b> Scan copy of non-notarized copy.  <b>Validity:</b> 31-12-2026</p> <p><b>FSC</b>  <b>Type:</b> Scan copy of non-notarized copy  <b>Issued By:</b> Germany  <b>Validity:</b> 05-04-2026</p>	<p><b>Light Lift Needle Method S</b>  Aptos– Sterile Absorbable (Poly(L-lactide-co-caprolactone) copolymer (P(LA/CL)) Threads with needle or cannula suture)</p> <p><b>Applied as Single.</b></p> <p><b>Class-D</b>  <b>Service Life: 3 Yr</b>  <b>Model/Codes/Size:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Copy of R&amp;I receiving of the applied product.</li> <li>2. Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</li> </ol>

	3260051882	<p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 01-10-2026</p> <p>• <b>EC (FQA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 24-05-2026</p> <p>• <b>EC (Design Examination):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 24-05-2026</p>		
26.	<p>M/s Aesthetic Life, 4th Floor, Plot 16-C, Ittehad Commercial Area, Khyaban-e-Nishat, DHA Phase-VI, Karachi ELI-01029.</p> <p>R&amp;I evidence not attached</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 33668120350</p>	<p>APTOS LLC, Givi Amilakhvari Street 15, 0109 Tbilisi, Georgia</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 31-12-2026</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Germany <b>Validity: 05-04-2026</b></p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 01-10-2026</p> <p>• <b>EC (FQA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 24-05-2026</p> <p>• <b>EC (Design Examination):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 24-05-2026</p>	<p><b>Light Lift Needle Method B</b> Aptos– Sterile Absorbable (Poly(L-lactide-co-caprolactone) copolymer (P(LA/CL)) Threads with needle or cannula suture)</p> <p><b>Applied as Single.</b></p> <p><b>Class-D</b> <b>Service Life: 3 Yr</b> <b>Model/Codes/Size:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Copy of R&amp;I receiving of the applied product.</li> <li>2. Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</li> </ol>
27.	<p>M/s Aesthetic Life, 4th Floor, Plot 16-C, Ittehad Commercial Area, Khyaban-e-Nishat, DHA Phase-VI, Karachi ELI-01029.</p> <p>R&amp;I evidence not attached</p> <p>Fee Details:</p>	<p>APTOS LLC, Givi Amilakhvari Street 15, 0109 Tbilisi, Georgia</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity: 31-12-2026</b></p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy</p>	<p><b>Visage Excellence Method HA</b> Aptos– Sterile Absorbable (Poly(L-lactide-co-caprolactone) copolymer (P(LA/CL)) Threads with needle or cannula suture)</p> <p><b>Applied as Single.</b></p> <p><b>Class-D</b> <b>Service Life: 3 Yr</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>1. Copy of R&amp;I receiving of the applied product.</li> <li>2. Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</li> </ol>

	<p>Paid Fee: 50,000/- Challan No. 9836297565</p>	<p><b>Issued By:</b> Germany <b>Validity:</b> 05-04-2026</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 01-10-2026</p> <p>• <b>EC (FQA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 24-05-2026</p> <p>• <b>EC (Design Examination):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 24-05-2026</p>	<p><b>Model/Codes/Size:</b></p>	
28.	<p>M/s S.A. Corporation, Office No: 3, First Floor, Almerag Arcade, Bahawal Shair Road, Choburgi, Lahore ELI-00915</p> <p>Date of R&amp;I 26-08-2022 Fee Details: Paid Fee: 25,000/- Challan No. 106053222</p>	<p>Jiangsu Province Huaxing Medical Apparatus Industry Co, Ltd., Building No. 328, Tongda Road, Tauqlao Town, Yangzhou City, Jiangsu Province, China.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. Issuance Date: 31-07-2025 Without expiry date.</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Germany <b>Validity:</b> 30-05-2026</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 14-04-2027</p> <p>• <b>EC (Production QA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2027</p>	<p><b>CORE II</b> Semi-Automatic Biopsy Needle</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life: 5-Yr</b> <b>Model/Codes/Size:</b> 16G x 150mm, 18G x 150mm, 18G x 2000mm, 18G x 100mm, 14G x 150mm</p>	Approved
29.	<p>M/s S.A. Corporation, Office No: 3, First Floor, Almerag Arcade, Bahawal Shair Road, Choburgi, Lahore ELI-00915</p> <p>Date of R&amp;I 26-08-2022</p>	<p>Jiangsu Province Huaxing Medical Apparatus Industry Co, Ltd., Building No. 328, Tongda Road, Tauqlao Town, Yangzhou City, Jiangsu Province, China.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-</p>	<p><b>Traplock</b> Bone Marrow Biopsy Needle</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life: 5-Yr</b> <b>Model/Codes/Size:</b> 11G x 100mm,</p>	Approved

	<p>Fee Details: Paid Fee: 25,000/- Challan No. 0025646235</p>	<p>notarized copy. Issuance Date: 31-07-2025 Without expiry date.</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Germany <b>Validity:</b> 30-05-2026</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 14-04-2027</p> <p>• <b>EC (Production QA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2027</p>	<p>13G x 100mm, 11G x 150mm</p>	
30.	<p>M/s S.A. Corporation, Office No: 3, First Floor, Almerag Arcade, Bahawal Shair Road, Choburgi, Lahore ELI-00915</p> <p>Date of R&amp;I 26-08-2022 Fee Details: Paid Fee: 25,000/- Challan No. 6172226954</p>	<p>Jiangsu Province Huaxing Medical Apparatus Industry Co, Ltd., Building No. 328, Tongda Road, Tauqlao Town, Yangzhou City, Jiangsu Province, China.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. Issuance Date: 31-07-2025 Without expiry date.</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Germany <b>Validity:</b> 30-05-2026</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 14-04-2027</p> <p>• <b>EC (Production QA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 26-05-2027</p>	<p><b>Core One</b> Automatic Biopsy Gun,</p> <p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life: 5-Yr</b> <b>Model/Codes/Size:</b> 16G x 150mm, 18G x 150mm, 18G x 200mm</p>	Approved
31.	<p>Lab Medikal Solutions Pvt Ltd, Rawalpindi</p> <p>ELI-00694</p> <p>Date of R&amp;I for product MQ- 3000/MQ-8000</p>	<p>DIALAB Produktion und Vertrieb von chemisch- technischen Produkten und Laborinstrumenten Gesellschaft m.b.H. IZ-NOE Sued, Hondastrasse, Objekt M55 A-2351 Wr. Neudorf, Austria.</p>	<p><b>Chemistry Kits Dossier</b></p> <p><b>Applied as Single.</b></p> <p><b>Class-</b> <b>Service Life:</b> <b>Model/Codes/Size:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin wherein the applied product shall be on free sale with the applied code/size with all sites.</li> <li>Valid legalized FSC of</li> </ol>

	<p>Glycated Hemoglobin Analyzer:</p> <p>21-11-2024</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 4446693269 for MQ-3000/MQ-8000 Glycated Hemoglobin Analyzer.</p> <p><b>Tracking ID</b> TT3-79L-QLRN</p>	<p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity:</b> 31-12-2028</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Austria. <b>Validity:</b> 09-09-2026</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 15-04-2027</p>		<p>RRA or valid notarized CE certificate.</p> <p>3. Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</p> <p>4. Copy of prescribed Form-7A duly signed along with all information &amp; relevant annexures including description of the product &amp; its codes.</p>
32.	<p>Safeway Systems Pakistan Rawalpindi</p> <p>ELI-00308</p> <p>Date of R&amp;I: 18-02-2025</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 8204420417</p> <p><b>Tracking ID</b> XXY-H7J-BJ73</p>	<p>Disopet Tibbi Ürünler Sanayi ve Ticaret. A.Ş. <b>Site Address as per FSc:</b> Bati Sitesi Mah. Gersan Sanayi Sitesi Cd. 2307 Sok. No,92/. YENİMAHALLE ANKARA.</p> <p><b>Site Address as per Form-7A:</b> Alcı Osb Mah. 2000 Cad. No:20 Sincan/Ankara, Turkey <b>Site Address as per CE:</b> Susuz Maho!lesi 3795, Codde Dempa Sanoyi Sitesi No:6 Yenimahoile Ar-IKA.RA / TURKEY.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non-notarized copy. <b>Validity:</b> 31-12-2026</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non-notarized copy <b>Issued By:</b> Turkey. <b>Validity:</b> 13-11-2027</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 28-02-2025 &amp; 13-05-2028</p> <p><b>CE (Production QA):</b> <b>Type:</b> Scan copy of non-notarized copy <b>Validity:</b> 27-05-2024</p>	<p><b>Disopet Vascular Tourniquet Set</b> Vascular Tourniquet sets <b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life: 3 Yrs</b> <b>Model/Codes/Size:</b> 959 300 001- Adult Vascular Tourniquet Set, Single 959 300 101- Pediatric Vascular Tourniquet Set, Single 959 300 002- Adult Vascular Tourniquet Set, Double 959 300 102- Pediatric Vascular Tourniquet Set, Double 959 300 003- Adult Vascular Tourniquet Set, Triple 959 300 103- Pediatric Vascular Tourniquet Set, Triple 959 300 005- Adult Vascular Tourniquet Set, Five 959 300 105- Pediatric Vascular Tourniquet Set, Five 959 300 011- Adult Vascular Tourniquet Set, Single 959 300 111- Pediatric Vascular Tourniquet Set, Single 959 300 012- Adult Vascular Tourniquet Set, Double 959 300 112- Pediatric Vascular Tourniquet Set,</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSC of country of origin wherein the applied product shall be on free sale with the applied code/size with all sites.</li> <li>Valid legalized FSC of RRA or valid notarized CE certificate with all manufacturing sites.</li> <li>Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</li> <li>Copy of prescribed Form-7A duly signed along with all information &amp; relevant annexures including description of the product &amp; its codes.</li> <li>Shelf life evidence/study</li> <li>Justification of Class.</li> </ol>

			<p>Double 959 300 013- Adult Vascular Tourniquet Set, Triple 959 300 113- Pediatric Vascular Tourniquet Set, Triple 959 300 015- Adult Vascular Tourniquet Set, Five 959 300 115- Pediatric Vascular Tourniquet Set, Five 959 300 016- Vascular Tourniquet Set, 2 Snare, 4 Red, 2 Blue, 2 Transparent 959 300 017- Vascular Tourniquet Set, 2 Snare, 1 Red, 2 Blue, 5 Transparent 959 300 018- Vascular Tourniquet Set, 1 Snare, 5 Red 959 300 019- Vascular Tourniquet Set, 2 Snare, 2 Red, 2 Blue, 4 Transparent 959 300 020- Vascular Tourniquet Set, 1 Snare, 3 Transparent 959 300 021- Vascular Tourniquet Set, 1 Snare, 3 Transparent 959 300 022- Vascular Tourniquet Set, 1 Snare, 5 Tubes 959 300 023- Vascular Tourniquet Set, 1 Snare, 4 Tubes 959 300 024- Vascular Tourniquet Set, 2 Snare, 8 Tubes 959 300 025- Vascular Tourniquet Set, 1 Snare, 6 Tubes (stainless steel snare) 959 300 026- Vascular Tourniquet Set, 5 Tubes, 2 Red, 2 Blue, 1 Transparent 959 300 027- Vascular Tourniquet Set, 2- Piece Dacron/Polyester Band</p>	
33.	Safeway Systems Pakistan Rawalpindi	M/s Shunmei Medical Co. Ltd, located at Address as per FSC & Form-	<b>Shun Route</b> Disposable Pressure Transducers	Deferred for submission of the following: 1. Valid Legalized FSC of country of origin wherein

	<p>ELI-00308</p> <p>Date of R&amp;I: 13-12-2024</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 1844797531 for Shunmei Shun Route Disposable Pressure Transducer (DPT) kit</p> <p><b>Tracking ID</b> YYS-BTS-ST5Q</p>	<p>7A: R301 and R401, Building B, Shenchanggang Investment Co., Ltd., No. 8, Jinlong First Road, Baolong Community, Baolong, Street, Longgang District, Shenzhen, 518116 Guangdong, P.R. China.</p> <p><b>Site No.2:</b> Huizhou Branch, Shunmei Medical Co., Ltd Address: Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non- notarized copy. <b>Validity:</b> 23-09-2027</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non- notarized copy <b>Issued By:</b> China. <b>Validity:</b> 27-02-2025</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non- notarized copy <b>Validity:</b> 14-02-2025 <b>CE :</b> <b>Type:</b> Scan copy of non- notarized copy <b>Validity:</b> 26-05-2024</p>	<p><b>Applied as Single.</b></p> <p><b>Class-B</b> <b>Service Life: 3 Yrs</b> <b>Model/Codes/Size:</b></p> <p><b>DPT-C</b> <b>DPT-01</b> <b>DPT-02</b></p>	<p>the applied product shall be on free sale with the applied code/size with all sites.</p> <ol style="list-style-type: none"> <li>Valid legalized FSC of RRA or valid notarized CE certificate with all manufacturing sites.</li> <li>Codes as per FSC &amp; Justification of grouping of the product with family fee &amp; catalog.</li> <li>Copy of prescribed Form- 7A duly signed along with all information &amp; relevant annexures including description of the product &amp; its codes.</li> <li>Shelf life evidence/study</li> </ol>
34.	<p>M/s Future D Pakistan, House No: 482, G3, Johar Town, Lahore ELI-00568</p> <p>Date of R&amp;I: 23-09-2024</p> <p>Fee Details: Paid Fee: 6,000/- Challan No. 533906382 for i-LiNQ Dental Components</p> <p><b>Tracking ID</b> YYS-BTS-ST5Q</p>	<p>NOVODENT SA Y-PARC Technopole, Avenue des Sciences 11, CH-1400 Yverdon-les-Bains, Switzerland.</p> <p><b>LOA</b> <b>Type:</b> Scan copy of non- notarized copy. <b>Validity:</b> 15-08-2026</p> <p><b>FSC</b> <b>Type:</b> Scan copy of non- notarized copy <b>Issued By:</b> Swissmedics. <b>Validity:</b> 21-08-2026</p> <p><b>ISO 13485:</b> <b>Type:</b> Scan copy of non- notarized copy <b>Validity:</b> 21-05-2026 <b>CE :</b> <b>Type:</b> Scan copy of non-</p>	<p><b>i-LiNQ Dental Components</b></p> <p><b>Applied as Set.</b></p> <p><b>Class-A</b> <b>Service Life: N/A</b> <b>Model/Codes/Size:</b></p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> <li>Required Codes as per FSC with description &amp; Justification of grouping of the product with family fee &amp; catalog.</li> <li>Justification Class of the product as per MDR 2017 &amp; fee is in higher class.</li> </ol>

		notarized copy <b>Validity:</b> 27-05-2024		
35.	M/s Future D Pakistan, House No: 482, G3, Johar Town, Lahore ELI-00568  Date of R&I: 23-09-2024 Fee Details: Paid Fee: 6,000/- Challan No. 636997472310 for i- LiNQ Surgical Kit  <b>Tracking ID</b> YYS-BTS-ST5Q	NOVODENT SA Y-PARC Technopole, Avenue des Sciences 11, CH-1400 Yverdon-les-Bains, Switzerland.  <b>LOA</b> <b>Type:</b> Scan copy of non- notarized copy. <b>Validity:</b> 15-08-2026  <b>FSC</b> <b>Type:</b> Scan copy of non- notarized copy <b>Issued By:</b> Swissmedics. <b>Validity:</b> 21-08-2026  <b>ISO 13485:</b> <b>Type:</b> Scan copy of non- notarized copy <b>Validity:</b> 21-05-2026 <b>CE :</b> <b>Type:</b> Scan copy of non- notarized copy <b>Validity:</b> 27-05-2024	<b>i-LiNQ Surgical Kit</b>  <b>Applied as Set.</b>  <b>Class-A</b> <b>Service Life: N/A</b> <b>Model/Codes/Size:</b> Surgical Kit Accessories Drills i-Reamer <input type="checkbox"/> Drills L- Reamer <input type="checkbox"/> Pins <input type="checkbox"/> Extensions	Deferred for submission of the following: 1. Required Codes as per FSC with description & Justification of grouping of the product with family fee & catalog. 2. Justification Class of the product as per MDR 2017 & fee is in higher class.

#### ADDITIONAL AGENDA CASES

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

**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.	Applicant Name: M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.  <b>(ELI-00153)</b>  Date of R& I 13-06-2025  <b>Fee:</b> PKR 6,000/- <b>Slip #</b> 944244503524	<b>Name of Manufacturer:</b> G-Flex Europe SPRL 20, Rue de l' Industries 1400-Nivelles- Belgium.  <b>LOA</b> <b>Type:</b> Copy of notarized <b>Notarization:</b> Notarized <b>Issue Date:</b> 15-10-2018 <b>Validity:</b> Not mentioned  • <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> Federal Agency of Medicines <b>Legalization:</b> Legalized <b>Issue Date:</b> 30-06-2021 <b>Validity:</b> Not mentioned.	Brand Name: Performance  Generic Name: Biopsy Forceps  Applied as: Single  Class: A  <b>Models/Code/sizes:</b> Models mentioned in application are not for forceps  <b>Service Life:</b> Not mentioned	Board deferred the case (final opportunity) for the followings: 1. clarification for the change of application from Biopsy Forceps to Foreign Body Retrievers. 2. Submission of legalized/notarized documents or link/barcode from where online attestation can be verified. 3. submission of stability/shelf life studies. 4. submission of fee for the family as per SRO 1399(I)/2025 dated 1 <sup>st</sup> August 2025.

		<ul style="list-style-type: none"> <li>• <b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 03-06-2027</li> </ul>		5. submission of brochure/catalogue.
2.	<p>Applicant Name: M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.</p> <p><b>(ELI-00153)</b></p> <p>Date of R&amp; I 13-06-2025</p> <p><b>Fee:</b> PKR 6,000/- <b>Slip #</b> 0322351243</p>	<p><b>Name of Manufacturer:</b> G-Flex Europe SPRL 20, Rue de l' Industries 1400-Nivelles-Belgium.</p> <p><b>LOA</b> <b>Type:</b> Copy of notarized <b>Notarization:</b> Notarized <b>Issue Date:</b> 15-10-2018 <b>Validity:</b> Not mentioned</p> <ul style="list-style-type: none"> <li>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> Federal Agency of Medicines <b>Legalization:</b> Legalized <b>Issue Date:</b> 30-06-2021 <b>Validity:</b> Not mentioned.</li> <li>• <b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 03-06-2027</li> </ul>	<p>Brand Name: Inflation Device</p> <p>Generic Name: Inflation Device</p> <p>Applied as: Single</p> <p>Class: A</p> <p><b>Models/Code/sizes (as per tech documents and application)</b> INFL20 INFL40</p> <p><b>Shelf Life:</b> 3 Years</p>	<p>Board deferred the case (final opportunity) for the followings:</p> <ol style="list-style-type: none"> <li>1. Submission of legalized/notarized documents or link/barcode from where online attestation can be verified.</li> <li>2. submission of fee for the family as per SRO 1399(I)/2025 dated 1<sup>st</sup> August 2025.</li> <li>3. submission of brochure/catalogue.</li> </ol>
3.	<p>Applicant Name: M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.</p> <p><b>(ELI-00153)</b></p> <p>Date of R&amp; I 12-06-2025</p> <p><b>Fee:</b> PKR 31,000/- <b>Slip #</b> 0413561883</p>	<p><b>Name of Manufacturer:</b> G-Flex Europe SPRL 20, Rue de l' Industries 1400-Nivelles-Belgium.</p> <p><b>LOA</b> <b>Type:</b> Copy of notarized <b>Notarization:</b> Notarized <b>Issue Date:</b> 15-10-2018 <b>Validity:</b> Not mentioned</p> <ul style="list-style-type: none"> <li>• <b>FSC</b> <b>Type:</b> Copy of Legalized <b>Issued By:</b> Federal Agency of Medicines <b>Legalization:</b> Legalized <b>Issue Date:</b> 25-06-2021 <b>Validity:</b> Not mentioned.</li> <li>• <b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 03-06-2027</li> </ul>	<p>Brand Name: Disposable Endoscopic Forceps Retrievers</p> <p>Generic Name: Disposable Endoscopic Forceps &amp; Retrievers</p> <p>Applied as: Single</p> <p>Class: B</p> <p><b>Models/Code/sizes (as per tech documents and application)</b></p> <p><b>i. Sharp Prongs:</b></p> <ul style="list-style-type: none"> <li>• GF1222</li> </ul> <p><b>ii. Rotatable Net-system for Polyp retrieval:</b></p> <ul style="list-style-type: none"> <li>• GF4500 (Oval)</li> <li>• GF4500-120 (Oval)</li> <li>• GF4501 (Oval)</li> <li>• GF4502 (Hexagonal)</li> </ul> <p><b>iii. Forceps</b></p> <ul style="list-style-type: none"> <li>• U860-230 (Alligator With Rat Tooth)</li> <li>• U870-180 (Pelican Shape)</li> <li>• U870-230 (Pelican Shape)</li> <li>• U622-165 (Alligator)</li> <li>• U822-165 (Rat Toot)</li> </ul> <p><b>Shelf Life:</b> 3 Years</p>	<p>Board deferred the case (final opportunity) for the followings:</p> <ol style="list-style-type: none"> <li>1. Submission of legalized/notarized documents or link/barcode from where online attestation can be verified.</li> <li>2. submission of fee for the family as per SRO 1399(I)/2025 dated 1<sup>st</sup> August 2025.</li> <li>3. submission of brochure/catalogue.</li> </ol>

4.	<p>Applicant Name: M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot.</p> <p><b>(ELI-00153)</b></p> <p>Date of R&amp; I 12-06-2025</p> <p><b>Fee:</b> PKR 62,000/- <b>Slip #</b> 34770194250</p>	<p><b>Name of Manufacturer:</b> G-Flex Europe SPRL 20, Rue de l' Industries 1400-Nivelles-Belgium.</p> <p><b>LOA</b> <b>Type:</b> Copy of notarized <b>Notarization:</b> Notarized <b>Issue Date:</b> 15-10-2018 <b>Validity:</b> Not mentioned</p> <p>• <b>FSC</b> <b>Type:</b> Copy of Legalized <b>Issued By:</b> Federal Agency of Medicines <b>Legalization:</b> Legalized <b>Issue Date:</b> 25-06-2021 <b>Validity:</b> Not mentioned.</p> <p>• <b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized <b>Validity:</b> 03-06-2027</p>	<p>Brand Name: Sensor</p> <p>Generic Name: Disposable Polypectomy Snares</p> <p>Applied as: Single</p> <p>Class: C</p> <p><b>Models/Code/sizes (as per tech documents and application):</b></p> <ol style="list-style-type: none"> <li>i. GF4532R (Asymmetrical, Rotatable, Multibraided with lateral connection)</li> <li>ii. GF4564R (Oval, Rotatable, Multibraided, with lateral connection)</li> <li>iii. GF4580R (Oval, Rotatable, Multibraided, with lateral connection)</li> <li>iv. GF4300 (Hexagonal, Multibraided)</li> <li>v. GF4301 (Hexagonal, Multibraided)</li> <li>vi. GF4406 (Oval, Multibraided, No HF Connection)</li> <li>vii. GF4410 (Oval, Multibraided, No HF Connection)</li> <li>viii. GF4606R (Oval, Multibraided, Rotatable)</li> <li>ix. GF4610R (Oval, Multibraided, Rotatable)</li> <li>x. GF4615R (Oval, Multibraided, Rotatable)</li> <li>xi. GF4625R (Oval, Multibraided, Rotatable)</li> <li>xii. GF4635R (Oval, Multibraided, Rotatable)</li> <li>xiii. GF4710R (Round, Multibraided, Rotatable)</li> <li>xiv. GF4606 (Oval, Multibraided)</li> <li>xv. GF4610 (Oval, Multibraided)</li> <li>xvi. GF4615 (Oval, Multibraided)</li> <li>xvii. GF4625 (Oval, Multibraided)</li> <li>xviii. GF4635 (Oval, Multibraided)</li> <li>xix. GF4815R (Oval, Monofilament, Rotatable)</li> <li>xx. GF4825R (Oval, Monofilament, Rotatable)</li> <li>xxi. GF481525CR (Oval-Combi, Monofilament, Rotatable)</li> <li>xxii. GF461525CR (Oval-Combi, Multibraided, Rotatable)</li> </ol> <p><b>Shelf Life:</b> 3 Years</p>	<p>Board deferred the case (final opportunity) for the followings:</p> <ol style="list-style-type: none"> <li>1. Submission of legalized/notarized documents or link/barcode from where online attestation can be verified.</li> <li>2. submission of fee for the family as per SRO 1399(I)/2025 dated 1<sup>st</sup> August 2025.</li> <li>3. submission of brochure/catalogue.</li> </ol>
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5.	<p>Medco, 19-Khyber Bazar Peshawar</p> <p>ELI-00105  <b>R&amp;I Date:</b> 21-07-2025  <b>Fee:</b> Rs. 50,000 vide deposit slip no. 649929409800</p>	<p><b>Name of Manufacturer:</b> Ecotron Co., Ltd.,  <b>Address:</b> 505Ho, Hanshin IT Tower II, 47, Digital-ro 9-gil Geumcheon-Gu, Seoul, 08511, Korea  <b>LOA</b>  <b>Type:</b> Copy  <b>Notarization:</b> Notarized  <b>Validity date:</b> 14-05-2029  <b>• FSC:</b>  <b>Type:</b> Copy  <b>Issued by:</b> National Institute of Medical Device Safety Information  <b>Notarization:</b> Apostille  <b>Issue date:</b> 22-05-2025  <b>ISO – Certificate:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Notarized  <b>Validity:</b> 18-02-2028</p> <p>Notarized copy of EU QMS certificate submitted.</p>	<p><b>Brand Name:</b> Ecotron Stationary/Conventional X-Ray System ESX Series EXS-32-R, EXS-40R, EXS-52R, EXS-68R  <b>Generic Name:</b> Conventional X-Ray system  <b>Applied as:</b> Family  <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application)</b> EXS-32R, EXS-40R, EXS-52R, EXS-68R  <b>Shelf Life:</b> 2 years</p>	<p>Deferred with final opportunity for the followings:  1. Form 7 A with undertakings on stamp paper.  2. apostille/legalized FSC in which model EXS is mentioned.  3. Fee for class C for both devices.  4. CE marking certificate issued by the Notified Body or FSC of RRA.</p>
6.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p><b>ELI-01330</b></p> <p><b>R&amp;I Date:</b> 04-07-2025  <b>Fee:</b> Rs. 31,000/- vide deposit slip no. 7555347581</p> <p><b>R&amp;I Date</b> 11-11-2025.</p>	<p><b>Name of Manufacturer:</b> Jiangsu Webest Medical Product Co., Ltd.  <b>Address:</b> No. 5 Yingchun Rd. Industrial Park 211700 Xuyi, Jiangsu China  <b>LOA:</b>  <b>Type:</b> Original  <b>Notarization:</b> Apostille  <b>Valid date:</b> 15-12-2029  <b>FSC:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Apostille  <b>Issued by:</b> China Chamber of Commerce for Import &amp; Export of Medicines and Health Products  <b>Validity Date:</b> 10-12-2026</p> <p><b>ISO – Certificate:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Apostille  <b>Validity:</b> 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p><b>Brand Name:</b> Surgi + Pulse Infusion Set with Burette  <b>Generic Name:</b> Infusion Set with Burette  <b>Applied as:</b> Set  <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application)</b> Infusion set with Burette-100ml, 120ml, 150ml Y-port type, Burette type all infusion types  <b>Shelf Life:-</b> 5 years</p>	<p>Approved. Generic name as per FSC i.e. Infusion Set with Burette for single use - size 100ml.</p>

7.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p><b>ELI-01330</b></p> <p><b>R&amp;I Date:</b> 26-06-2025</p> <p><b>Fee:</b> Rs. 31,000/- vide deposit slip no. 42344534574</p> <p><b>R&amp;I Date</b> 11-11-2025.</p>	<p><b>Name of Manufacturer:</b> Tianchang City Anrui Medical Equipment Co., Ltd.,</p> <p><b>Address:</b> Renhe Industrial District, TianChang City, Anhui Province China</p> <p><b>LOA:</b> <b>Type:</b> Original <b>Notarization:</b> Apostille <b>Valid date:</b> 14-03-2030</p> <p><b>FSC:</b> <b>Type:</b> Original <b>Notarization:</b> Apostille <b>Issued by:</b> China Chamber of Commerce for Import &amp; Export of Medicines and Health Products <b>Validity Date:</b> 27-03-2027</p> <p><b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Validity:</b> 19-07-2027</p> <p>Copy of EC Certificate also submitted</p>	<p><b>Brand Name:</b> Surgi+ Pulse Surgical Gloves Powder Free</p> <p><b>Generic Name:</b> Surgical Gloves Powder Free</p> <p><b>Applied as:</b> Family</p> <p><b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application)</b> Scalp vein set 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5</p> <p><b>Shelf Life:</b> 5 years</p>	<p>Approved Sterile Surgical Gloves with sizes as per FSC.</p>
8.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p><b>ELI-01330</b></p> <p><b>R&amp;I Date:</b> 04-07-2025</p> <p><b>Fee:</b> Rs. 31,000/- vide deposit slip no. 5007838901</p> <p><b>R&amp;I Date</b> 11-11-2025.</p>	<p><b>Name of Manufacturer:</b> Tianchang City Anrui Medical Equipment Co., Ltd.,</p> <p><b>Address:</b> Renhe Industrial District, TianChang City, Anhui Province China</p> <p><b>LOA:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Valid date:</b> 14-03-2030</p> <p><b>FSC:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Issued by:</b> China Chamber of Commerce for Import &amp; Export of Medicines and Health Products <b>Validity Date:</b> 27-03-2027</p> <p><b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Validity:</b> 19-07-2027</p> <p>Copy of EC Certificate also submitted</p>	<p><b>Brand Name:</b> Surgi+ Pulse Surgical Gloves Powdered</p> <p><b>Generic Name:</b> Surgical Gloves Powdered</p> <p><b>Applied as:</b> Family</p> <p><b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application)</b> Scalp vein set 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5</p> <p><b>Shelf Life:</b> 5 years</p>	<p>Rejected as Surgical Gloves Powdered not mentioned in FSC or NB extension certificate.</p>

9.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p><b>ELI-01330</b></p> <p><b>R&amp;I Date:</b> 04-07-2025</p> <p><b>Fee:</b> Rs. 31,000/- vide deposit slip no. 1196376801</p> <p><b>R&amp;I Date</b> 11-11-2025.</p>	<p><b>Name of Manufacturer:</b> Jiangsu Webest Medical Prouduct Co., Ltd.</p> <p><b>Address:</b> No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China</p> <p><b>LOA:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Valid date:</b> 15-12-2029</p> <p><b>FSC:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Issued by:</b> China Chamber of Commerce for Import &amp; Export of Medicines and Health Products <b>Validity Date:</b> 10-12-2026</p> <p><b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Validity:</b> 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p><b>Brand Name:</b> Surgi + Pulse Blood Transfusion Set</p> <p><b>Generic Name:</b> Blood Transfusion Set</p> <p><b>Applied as:</b> Set</p> <p><b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application)</b></p> <p><b>Shelf Life:-</b> 5 years</p>	<p>Approved with codes SXQ1 &amp; SXQ2.</p>
10.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p><b>ELI-01330</b></p> <p><b>R&amp;I Date:</b> 04-07-2025</p> <p><b>Fee:</b> Rs. 31,000/- vide deposit slip no. 7892247671</p> <p><b>R&amp;I Date</b> 11-11-2025.</p>	<p><b>Name of Manufacturer:</b> Jiangsu Webest Medical Prouduct Co., Ltd.</p> <p><b>Address:</b> No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China</p> <p><b>LOA:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Valid date:</b> 15-12-2029</p> <p><b>FSC:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Issued by:</b> China Chamber of Commerce for Import &amp; Export of Medicines and Health Products <b>Validity Date:</b> 06-12-2026</p> <p><b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Validity:</b> 31-05-2026</p> <p>Copy of EC Certificate also submitted.</p>	<p><b>Brand Name:</b> Surgi + Pulse Scalp Vein Set</p> <p><b>Generic Name:</b> Scalp Vein Set</p> <p><b>Applied as:</b> Set</p> <p><b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application)</b> Scalp vein set 16G, 17G,18G,19G,20G,21G,22G,23G,24 G,25G,26G,27G</p> <p><b>Shelf Life:-</b> 5 years</p>	<p>Rejected as Scalp Vein Set not mentioned in the FSC.</p>

11.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p><b>ELI-01330</b></p> <p><b>R&amp;I Date:</b> 04-07-2025</p> <p><b>Fee:</b> Rs. 31,000/- vide deposit slip no. 7892247671</p> <p><b>R&amp;I Date</b> 11-11-2025.</p>	<p><b>Name of Manufacturer:</b> Jiangsu Webest Medical Prouduct Co., Lts.</p> <p><b>Address:</b> No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China</p> <p><b>LOA:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Valid date:</b> 15-12-2029</p> <p><b>FSC:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Issued by:</b> China Chamber of Commerce for Import &amp; Export of Medicines and Health Products <b>Validity Date:</b> 06-12-2026</p> <p><b>ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Apostille <b>Validity:</b> 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p><b>Brand Name:</b> Surgi + Pulse Scalp Vein Set</p> <p><b>Generic Name:</b> Scalp Vein Set</p> <p><b>Applied as:</b> Set</p> <p><b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application)</b> Scalp vein set 16G, 17G,18G,19G,20G,21G,22G,23G,24 G,25G,26G,27G</p> <p><b>Shelf Life:-</b> 5 years</p>	<p>Approved. The MDB after through deliberation decided to approve the device, “Surgi + Plus Three way stopcocks” with following codes: 3SC-P-1 and 3SC- P-2 Shelf life 5 years.</p>
12.	<p>M/s. Alam and Sons, 2<sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.</p> <p><b>(ELI- 01147)</b></p> <p><b>R&amp;I detail</b> 14-05-2025</p> <p><b>Fee: 6,000/-</b> <b>Slip:</b> 065731143238</p>	<p><b>Name of Manufacturer:</b> M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <p>• <b>LOA</b> <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> March-2030</p> <p>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> CCCIEMHP <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 06-04-2025</p> <p>• <b>ISO Certificate</b> <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> 29-06-2026</p>	<p><b>Brand name:</b> KMN Gussted Reel</p> <p><b>Generic Name:</b> Sterilization Gussted Reel</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned</p> <p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> Not mentioned</p>	<p>Approved.</p>
13.	<p>M/s. Alam and Sons, 2<sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.</p> <p><b>(ELI- 01147)</b></p>	<p><b>Name of Manufacturer:</b> M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <p>• <b>LOA</b> <b>Type:</b> Original</p>	<p><b>Brand name:</b> KMN Sterilization Pouches</p> <p><b>Generic Name:</b> Sterilization Pouches</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned</p>	<p>Approved.</p>

	<p><b>R&amp;I detail</b> 14-05-2025 <b>Fee: 6,000/-</b> <b>Slip: 28496777</b></p>	<p><b>Attested By:</b> CCPIT <b>Validity:</b> March-2030</p> <ul style="list-style-type: none"> <li>• FSC <b>Type:</b> Original <b>Issued By:</b> CCCIEMHP <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 06-04-2025</li> <li>• ISO Certificate <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> 29-06-2026</li> </ul>	<p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> Not mentioned</p>	
14.	<p>M/s. Alam and Sons, 2<sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.</p> <p><b>(ELI- 01147)</b></p> <p><b>R&amp;I detail</b> 14-05-2025 <b>Fee: 6,000/-</b> <b>Slip: 401295349</b></p>	<p><b>Name of Manufacturer:</b> M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <ul style="list-style-type: none"> <li>• LOA <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> March-2030</li> <li>• FSC <b>Type:</b> Original <b>Issued By:</b> CCCIEMHP <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 06-04-2025</li> <li>• ISO Certificate <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> 29-06-2026</li> </ul>	<p><b>Brand name:</b> KMN Flat Reel</p> <p><b>Generic Name:</b> Sterilization Flat Reel</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned</p> <p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> Not mentioned</p>	Approved.
15.	<p>M/s. Alam and Sons, 2<sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.</p> <p><b>(ELI- 01147)</b></p> <p><b>R&amp;I detail</b> 14-05-2025 <b>Fee: 6,000/-</b> <b>Slip: 13361428962</b></p>	<p><b>Name of Manufacturer:</b> M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <ul style="list-style-type: none"> <li>• LOA <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> March-2030</li> <li>• FSC <b>Type:</b> Original <b>Issued By:</b> CCCIEMHP <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 06-04-2025</li> <li>• ISO Certificate <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> 29-06-2026</li> </ul>	<p><b>Brand name:</b> KMN Steam Indicator Strips</p> <p><b>Generic Name:</b> Steam Indicator Strips</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned</p> <p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> Not mentioned</p>	Approved.

16.	<p>M/s. Alam and Sons, 2<sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.</p> <p><b>(ELI- 01147)</b></p> <p><b>R&amp;I detail</b> 14-05-2025 <b>Fee: 6,000/-</b> <b>Slip: 24181713696</b></p>	<p><b>Name of Manufacturer:</b> M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <ul style="list-style-type: none"> <li>• <b>LOA</b> <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> March-2030</li> <li>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> CCCIEMHP <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 06-04-2025</li> <li>• <b>ISO Certificate</b> <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> 29-06-2026</li> </ul>	<p><b>Brand name:</b> KMN Sterilization Crepe Paper</p> <p><b>Generic Name:</b> Sterilization Crepe Paper</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned</p> <p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> Not mentioned</p>	Approved.
17.	<p>M/s. Alam and Sons, 2<sup>nd</sup> Floor, Asmat Chamber, 68-Mozang Road, Lahore.</p> <p><b>(ELI- 01147)</b></p> <p><b>R&amp;I detail</b> 14-05-2025 <b>Fee: 6,000/-</b> <b>Slip: 1435001130</b></p>	<p><b>Name of Manufacturer:</b> M/s. Anqing Kangmingna Packaging Co., Ltd., No. 8, Wuxiang Road, Daqiao Street, Yixiu District, 246000 Anqing City, China.</p> <ul style="list-style-type: none"> <li>• <b>LOA</b> <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> March-2030</li> <li>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> CCCIEMHP <b>Attested By:</b> CCPIT <b>Legalization:</b> Not legalized <b>Validity:</b> 06-04-2025</li> <li>• <b>ISO Certificate</b> <b>Type:</b> Original <b>Attested By:</b> CCPIT <b>Validity:</b> 29-06-2026</li> </ul>	<p><b>Brand name:</b> KMN Tyvek Reel</p> <p><b>Generic Name:</b> Tyvek Sterilization Reel</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned</p> <p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> Not mentioned</p>	Approved.
18.	<p>Cardiac Care 848-C Shadman -1, Lahore ELI-00070</p> <p>R&amp;I 14-11-22 Fee Challan No 2376701207 dated 08-11-22</p>	<p>Company: Ningbo Greetmed Medical Instruments Co., Ltd. Add.: 16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA Tel: +86-574-87722370 Fax: +86-574-87722360 Website: www.chinagreetmed.com</p>	<p>Brand Name Connecting tube with Yankauer handle (Oropharyngeal secretions suction) Class: B</p> <p>Shelf Life: 05 years</p>	Rejected as FSC has not been issued by the relevant regulatory authority.

		FSC VALID: 06-07-2026 LOA VALID: 09-10-2026 ISO 13485 VALID: 31-03-24		
19.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  <b>Date of R&amp; I</b> 29.04.2025  <b>Fee:</b> Rs.62000/through slip no. 9182038880	M/s Karex Industries Sdn. Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia.  <b>LOA:</b> Valid till: 21-04-2030 (Copy)  <b>FSC:</b> Not provided  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)	Pulse-Strawberry  Natural Rubber Latex Male Condoms Pulse – <b>Strawberry</b>  <b>(Identifier: P53S-N1-180-Red)</b>  Applied as: Family  Class C  Shelf Life: 5 Years  Code/sizes:	Rejected due to the following reasons: Form-7A without undertaking on stamp paper; Required documents as per form 7A not submitted; Clarification for submission of wrong address not provided.
20.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  ELI-00073  <b>Date of R&amp; I</b> 29.04.2025  <b>Fee:</b> Rs.62000/through slip no. 6379675693	M/s Karex Industries Sdn. Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia.  <b>LOA:</b> Valid till: 21-04-2030 (Copy)  <b>FSC:</b> Not provided  ISO 13485 - Validity Date: 02-07-2025 (Copy)  EC Certificate (FQA) Valid till: 26-05-2024 (Copy)	<b>Pulse-Extra Sensitive</b>  Natural Rubber Latex Male Condoms Pulse – Extra Sensitive  Applied as: Family  Class C  Shelf Life: 5 Years  Code/sizes:	Rejected due to the following reasons: Form-7A without undertaking on stamp paper; Required documents as per form 7A not submitted; Clarification for submission of wrong address not provided.
21.	M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.  ELI-01011  Date of R& I 14-05-2025  Fee: PKR 31,000/- Slip # 66380455847	<b>Name of Manufacturer (As per FSC):</b> GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.  <b>• LOA:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2025  <b>• FSC</b> <b>Type:</b> Original <b>Issued By:</b> Danish Medicine Agency <b>Legalization:</b> Legalized <b>Validity:</b> 30-09-2026  <b>• ISO – Certificate:</b>	<b>Brand Name:</b> Interton <b>Family Name:</b> Move <b>Hearing Aid Type:</b> BTE  <b>Generic Name:</b> Hearing Aid  <b>Applied as:</b> Single  <b>Class: B</b>  <b>Models/Sizes:</b> MV665-DW, MV465-DW, MV365-DW, MV265-DW, MV670-DW, MV470-DW, MV370-DW, MV270DW, MV170-MV680-DWH, MV480-DWH, MV380DWH, MV280-DWH, MV180-DWH, MV690-DW, MV490-DW, MV390-	Rejected for the following: 1. LOA is valid till 31 December 2025. 2. the code MW390-DW not mentioned in the LOA. 3 The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S.. 4. In manufacturer credential Interton A/s not mentioned.

		<b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2026  <b>• EU QMS/EC Certificate:</b> Not Submitted	DW, MV290-DW  <b>Shelf Life:</b> 5 Years	
22.	M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.  ELI-01011  Date of R& I 14-05-2025  Fee: PKR 31,000/- Slip # 30684205	<b>Legal Manufacturer (as per FSC):</b> GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.  <b>Manufacturing Site1 (as per FSC):</b> GN ReSound (Malaysia) Sdn Bhd , No. 5, Jalan i-Park 1/1, Kawasan Perindustrian i- Park, 81000 Bandar Indahpura, Kulai, Johor, Malaysia.  <b>Manufacturing Site2 (as per FSC):</b> GN Resound China Ltd., No. 15, Chuang Xin Road, CTP Area 361006 Xiamen, China.  <b>• LOA:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2025  <b>• FSC</b> <b>Type:</b> Original <b>Issued By:</b> Danish Medicine Agency <b>Legalization:</b> Legalized <b>Validity:</b> 19-09-2026  <b>• ISO – Certificate:</b> Not submitted.  <b>• EU QMS/EC Certificate:</b> Not Submitted	<b>Brand Name:</b> Interton <b>Family Name:</b> Move <b>Hearing Aid Type:</b> ITC  <b>Generic Name:</b> Hearing Aid  <b>Applied as:</b> Single  <b>Class: B</b>  <b>Models/Sizes:</b> MV6CIC-MP,                    MV6CIC-LP, MV6CIC-HP,                    MV4CIC-MP, MV4CIC-LP,                    MV4CIC-HP, MV3CIC-MP,                    MV3CIC-LP, MV3CIC-HP  <b>Shelf Life:</b> 5 Years	Approved as a family.
23.	M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.  ELI-01011  Date of R& I 14-05-2025  Fee: PKR 31,000/- Slip # 624458423523	<b>Name of Manufacturer (As per FSC):</b> GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.  <b>• LOA:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2025  <b>• FSC</b> <b>Type:</b> Original <b>Issued By:</b> Danish Medicine	<b>Brand Name:</b> Interton <b>Family Name:</b> Move <b>Hearing Aid Type:</b> BTE  <b>Generic Name:</b> Hearing Aid  <b>Applied as:</b> Single  <b>Class: B</b>  <b>Models/Sizes:</b> MV661-DRW,                    MV461-DRW,	Rejected for the following: 1. LOA is valid till 31 December 2025. 2. the code MW390-DW not mentioned in the LOA. 3 The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S.. 4. In manufacturer credential Interton A/s not mentioned.

		<p>Agency <b>Legalization:</b> Legalized <b>Validity:</b> 30-09-2026</p> <ul style="list-style-type: none"> <li>• <b>ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2026</li> <li>• <b>EU QMS/EC Certificate:</b> Not Submitted</li> </ul>	<p>MV361-DRW, MV261-DRW, MV662-DRW, MV462-DRW, MV362-DRW, MV262-DRW, MV661-DRWC, MV461-DRWC, MV361-DRWC</p> <p><b>Shelf Life:</b> 5 Years</p>	
24.	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p> <p>Date of R&amp; I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 599641119</p>	<p><b>Name of Manufacturer (As per FSC):</b> GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <ul style="list-style-type: none"> <li>• <b>LOA:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2025</li> <li>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> Danish Medicine Agency <b>Legalization:</b> Legalized <b>Validity:</b> 30-09-2026</li> <li>• <b>ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2026</li> <li>• <b>EU QMS/EC Certificate:</b> Not Submitted</li> </ul>	<p><b>Brand Name:</b> Interton <b>Family Name:</b> Move <b>Hearing Aid Type:</b> ITE</p> <p><b>Generic Name:</b> Hearing Aid</p> <p><b>Applied as:</b> Single</p> <p><b>Class:</b> B</p> <p><b>Models/Sizes:</b> MV6ITC-DW-UP, MV6ITC-DW- MP, MV6ITC-DW-HP, MV4ITC- DW-UP, MV4ITC-DW-MP, MV4ITC-DW-HP, MV3ITC-DW- UP, MV3ITC-DW-MP, MV3ITC- DW-HP, MV6CIC-W-MP, MV6CIC-W-HP, MV6CIC-W-LP, MV4CIC-W-MP, MV4CIC-W-LP, MV4CIC-W-HP, MV3CIC-W-MP, MV3CIC-W-LP, MV3CIC-W-HP</p> <p><b>Shelf Life:</b> 5 Years</p>	<p>Rejected for the following:</p> <ol style="list-style-type: none"> <li>1. LOA is valid till 31 December 2025.</li> <li>2. the code MW390-DW not mentioned in the LOA.</li> <li>3 The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S..</li> <li>4. In manufacturer credential Interton A/s not mentioned.</li> </ol>
25.	<p>M/s Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p> <p>Date of R&amp; I 14-05-2025</p> <p>Fee: PKR 31,000/- Slip # 94218291673</p>	<p><b>Name of Manufacturer (As per FSC):</b> GN Hearing A/S, Lautrupbjerg 7, DK-2750 Ballerup, Denmark.</p> <ul style="list-style-type: none"> <li>• <b>LOA:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2025</li> <li>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> Danish Medicine Agency <b>Legalization:</b> Legalized <b>Validity:</b> 30-09-2026</li> <li>• <b>ISO – Certificate:</b> <b>Type:</b> Original <b>Notarization:</b> Notarized</li> </ul>	<p><b>Brand Name:</b> Interton <b>Family Name:</b> Move <b>Hearing Aid Type:</b> ITE</p> <p><b>Generic Name:</b> Hearing Aid</p> <p><b>Applied as:</b> Single</p> <p><b>Class:</b> B</p> <p><b>Models/Sizes:</b> MV6ITE-DW-UP, MV6ITE-DW- MP, MV6ITE-DW-HP, MV4ITE- DW-UP, MV4ITE-DW-MP, MV4ITE-DW-HP, MV3ITE-DW-UP, MV3ITE-DW-MP, MV3ITE-DW-HP</p> <p><b>Shelf Life:</b> 5 Years</p>	<p>Rejected for the following:</p> <ol style="list-style-type: none"> <li>1. LOA is valid till 31 December 2025.</li> <li>2. the code MW390-DW not mentioned in the LOA.</li> <li>3 The name of manufacturer mentioned on FSC is Interton A/S while LOA has been issued by GN Hearing A/S..</li> <li>4. In manufacturer credential Interton A/s not mentioned.</li> </ol>

		<b>Validity:</b> 31-12-2026  • <b>EU QMS/EC Certificate:</b> Not Submitted		
26.	MSB Medical, F2 1 <sup>st</sup> Floor 51-1/C, PECHS Block 6 75400, Karachi  ELI-00035  Date of R&I 22-04-2025  Fee Details: Paid Fee: 31000/- Fee Challan No: 60047640	<b>Legal Manufacturer:</b> Super Health Medical (Qingdao) No. 236, Heyuan Road, High-Tech Zone, Qingdao, 266510 Shandong P.R. China LOA Validity: 08-02-2030  FSC: China Validity: 27-04-2025  FSC: UK Issue date: 31-12-2029  ISO Validity: 29-03-2029  CE Certificate with extension notification letter.	Flow One I.V Cannula Pen Type  Class-B  Shelf life: 3 years  Models/ Specification; 16, 18G, 20G, 22G, 24G	Approved

**Case No.01: Change of Name and Address of Manufacturer of Already Registered Medical Devices for Import.**

S.#	Name Of Importer	Enlistment/ Regn. No	Detail Of Medical Device	Existing Name and Address of Manufacturer	Proposed Name and Address of Manufacturer	Decision
1.	M/s Hashir Surgical Services, Office No 16, Street 1, F-2, Phase 6, Hayatabad, Peshawar.  ELI-00075.	MDIR-0000075	Flow Cath IV Cannula with Injection Port  Sizes: 14G, 16G, 18G, 20G, 22G, 24G & 26G  Class-B Shelf Life: 05 years.	M/s Jiangxi Fenglin Medical Technology Co. Ltd, FengCheng Industrial Park, FengCheng City, Jiangxi Province, China	M/s Jiangxi Fenglin Medical Appliances Co. Ltd, Fulin Road, Fuzhou City, Jiangxi 344100 Province, China.	The Board rejected the case due to following reason: • FSC not issued by relevant Health Regulatory Authority. • Firm has not submitted the approval of change of manufacturer from relevant Health Regulatory Authority as per MDB decision taken in its 93 <sup>rd</sup> meeting.