

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

DECISIONS OF 122ND MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
18-02-2026 (MANUAL APPLICATIONS PART-II)

122nd 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 18th February, 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S. No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	Member (attended meeting through videolink)
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.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
5.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
6.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
7.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
10.	Mrs. Tazeen Saeed Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director
2.	Mr. Waqar Ahmad	Deputy Director
3.	Mst. Sadaf Ahmad	Deputy Director
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director
5.	Mr. Muhammad Ashfaq	Deputy Director
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director
8.	Mr. Muhammad Amin	Deputy Director
9.	Mr. Ammar Ashraf Awan	Deputy Director
10.	Mr. Hanif Ullah	Deputy Director

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

EVALUATOR: Mr. MUHAMMAD AMIN (DEPUTY DIRECTOR)

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

FRESH CASES FOR RENEWAL OF ELI:

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s M/s Aswad Medical Co, Office: C-2, 3rd Floor, Rahat Jo Daro, P.E.C.H.S, Block-2, Tariq Road, Karachi Godown: D-5, 4th Floor, Rahat Jo Daro, P.E.C.H.S, Block-2, Tariq Road, Karachi ELI-00523	Mr. Muhammad Zahid Siddiqui Biomedical Engineer	Ms. Muneza Saleem CEO	Approved
2.	M/s Bench Mark Corporation, Office: A-706, 7th Floor, Saima Trade Tower, I.I Chundrigar Road, Karachi Godown: M-12, Mezzanine Floor, Saima Trade Tower, I.I.Chundrigar Road, Karachi ELI-00420	Sikandar Faizan Pharm D	Faraz Ahmad	Approved
3.	M/s M/s Medichem Enterprises, Office / godown; 331/C, Block No 3, DMCH Society, Alamgir Road Karachi. ELI-00252	Shahzeena komal Pharm D	Khalid Sultan Saba Sultan	Approved
4.	M/s M/s Elate CC Pvt Ltd., Office / godown: Bungalow No. D-17/1, first floor , Block No. 7, KDA Scheme 24, gulshan e Iqbal , Karachi. ELI-00294	Kanwal Jahan Arslan Pharm D	Syed ashar alam	Approved

5.	M/s Shahco Medical (pvt) ltd, Office / godown: 729-C, Faisal town, Lahore. ELI-00230	Amna bibi Bs biomedical engineer	Arfat Javeed Javed ul Hassan	Deferred for submission of fee and documents regarding change of technical staff and godown.
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**Item No. I(B): APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES
UNDERMEDICAL DEVICES RULES, 2017.**

(DEFERRED CASES FOR RENEWAL OF -ELI):

1.	M/s shahbaz scientific corporation, Office/Godown: shahbaz plaza No. 1, street no. 32, mini market , G-15/1, Islamabad. ELI-00234	Maheen shahbaz Bs biomedical engineering	Muhammad shahbaz CEO	Decision: Approved
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Item No. I(C): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017

The following firms have applied for grant of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The recommendations of the panels are as mentioned against each is submitted for consideration of MDB please;

FRESH CASES-ELM:

S. No	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Recommendations/ Conclusion	Decision
1	M/s Tecno instrument (Pvt) Ltd, 316- Industrial Estate Sialkot.	Asad Ali Mechanical Engineer 4 years experience	Muhammad Awais Biomedical engineer	Conclusion: Based on documents reviewed, technical discussion with the technical staff and physical inspection of the unit panel is of the view that currently some up-gradations required as mentioned above in the report. Upon respective up-gradations firm may inform the MDMC Division for re-inspection of the unit. Furthermore, panel is of the view that as the medical device manufacturing has diversification in manufacturing processes based on their type and usage therefore a comprehensive category wise checklist may be devised so that only relevant part of checklist be followed uniformly across the country for respective category of medical device unit being inspected.	The board considered the inspection report of the firm and deliberated on the matter in detail. It was discussed that the Sialkot surgical instruments industry is playing a pivotal role in national economy by exporting surgical instruments across the globe. The board need to support this industry especially those who want to come under regulatory framework of DRAP Act 2012. However, it was emphasized that the firm need to address the shortcomings highlighted during inspection and following panel will re-inspect the firm to conduct a detailed inspection for consideration of medical devices board. 1. Dr Mahmood Ahamd, Member MDB 2. Mr. Abdul Rasheed Shaikh, Deputy Director DRAP Lahore.
2	M/s Technodent Industries, 23-Temple rad,	Mr Usman	Shahbaz Ali	Conclusion: Firm was situated in the residential area and established in a	Rejected. The board considered inspection report of the firm and noticed major

	Lahore.			<p>residential building. In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, personnel and documentation etc. the panel is of the opinion to not recommend the firm M/s. Technodent Industries, 23 Temple Road, Lahore, for grant of Establishment License to manufacture medical devices</p>	<p>shortcomings especially with the location of unit in a residential building in a residential area. The other observation including production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, personnel and documentation etc. were also taken into account and it was decided to reject application of the firm for establishment license to manufacture medical devices. The existing operations of the firm at present site stands ceased off and applicant is not allowed to manufacture any medical device at this location. However, the firm may apply a fresh for grant of license at a new site preferably in an industrial area which shall considered after going through required regulatory steps.</p>
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Item No. II: REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT / LOCAL PRODUCTS.

Evaluator: Ammar Ashraf Awan (Deputy Director)

IMPORTED PRODUCT AGENDA:

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision																						
1.	M/s. Hoor Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037) R&I Date: 06-07-2022 CMS tracking ID: UM7-PVD-6V9Q Fee: 25,000/-	Manufacturing site: Name: Guangzhou Improve Medical Instruments Co. Ltd. Address: 102, Kaiyuan Avenue Science City, Guangzhou Economical & Technological Development District, 510530 Guangzhou, China LOA Notarization: Yes Valid: 31-12-2026 • FSC Legalized: Apostille Issued by: Guangzhou Association of Medical Device Valid: 16-05-2027 ISO – Certificate: Notarization: yes Valid till: 30-06-2027 EC Certificate: Valid till 06-02-2027	Brand Name: IMPROSAFE BLOOD COLLECTION SET Generic Name: Blood collection set Applied as: Set Class: B Models/Code/sizes (as per FSC & application: <table border="1"> <thead> <tr> <th>Ref/ Catalog No</th> <th>Specification/ Model</th> </tr> </thead> <tbody> <tr> <td>596121190</td> <td>21G x 3/4" x 7" (0.8x19mmx180mm)</td> </tr> <tr> <td>596121300</td> <td>21G x 3/4"x12"(0.8 x19mmx305mm)</td> </tr> <tr> <td>596122190</td> <td>22G x 3/4" x 7" (0.7 x 19 mm x 180 mm)</td> </tr> <tr> <td>596122300</td> <td>22G x 3/4" x 12" (0.7 x 19mm x 305mm)</td> </tr> <tr> <td>596123190</td> <td>23G x 3/4" x 7" (0.6 x 19mm x 180mm)</td> </tr> <tr> <td>596123300</td> <td>23G x 3/4" x 12" (0.6 x 19mmx 305mm)</td> </tr> <tr> <td>596124190</td> <td>24G x 3/4" x 7" (0.55 x 19mm x 180mm)</td> </tr> <tr> <td>596124300</td> <td>24G x 3/4" x 12" (0.55 x19m x305mm)</td> </tr> <tr> <td>596125190</td> <td>25G x 3/4" x 7" (0.5 x 19mm x 180 mm)</td> </tr> <tr> <td>596125300</td> <td>25G x 3/4" x12" (0.5 x 19 mmx305mm)</td> </tr> </tbody> </table> Shelf life: 36 months	Ref/ Catalog No	Specification/ Model	596121190	21G x 3/4" x 7" (0.8x19mmx180mm)	596121300	21G x 3/4"x12"(0.8 x19mmx305mm)	596122190	22G x 3/4" x 7" (0.7 x 19 mm x 180 mm)	596122300	22G x 3/4" x 12" (0.7 x 19mm x 305mm)	596123190	23G x 3/4" x 7" (0.6 x 19mm x 180mm)	596123300	23G x 3/4" x 12" (0.6 x 19mmx 305mm)	596124190	24G x 3/4" x 7" (0.55 x 19mm x 180mm)	596124300	24G x 3/4" x 12" (0.55 x19m x305mm)	596125190	25G x 3/4" x 7" (0.5 x 19mm x 180 mm)	596125300	25G x 3/4" x12" (0.5 x 19 mmx305mm)	Deferred for submission of differential fee against the different sizes applied.
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5.	<p>M/s. Hooraa Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037)</p> <p>R&I Date: 06-07-2022 CMS tracking ID: 7RJ-EP1-13AM</p> <p>Fee: 25,000/-</p>	<p>Manufacturing site: Name: Guangzhou Improve Medical Instruments Co. Ltd. Address: 102, Kaiyuan Avenue Science City, Guangzhou Economical & Technological Development District, 510530 Guangzhou, China LOA</p> <p>Notarization: Yes Valid: 31-12-2026</p> <p>• FSC Legalized: Apostille Issued by: Guangzhou Association of Medical Device Valid: 16-05-2027 ISO – Certificate: Notarization: yes Valid till: 30-06-2027</p> <p>EC Certificate: Valid till 06-02-2027</p>	<p>Brand Name: IMPROVACUTER MULTI SAMPLE NEEDLE Generic Name: MULTI SAMPLE NEEDLE Applied as: Single Class: B</p> <p>Models/Code/sizes (as per FSC & application):</p> <table border="1"> <thead> <tr> <th>Ref/ Catalog No</th> <th>Specification /Model</th> </tr> </thead> <tbody> <tr><td>592118250</td><td>18G x 1" (1.2 x 38 mm)</td></tr> <tr><td>592118380</td><td>18G x 1 1/2" (1.2 x 38 mm)</td></tr> <tr><td>592120250</td><td>20G x 1" (0.9 x 25 mm)</td></tr> <tr><td>592120380</td><td>20G x 1 1/2"(0.9 x 38 mm)</td></tr> <tr><td>592121250</td><td>21G x 1"(0.8 x 25 mm)</td></tr> <tr><td>592121380</td><td>21G x 1 1/2" (0.8 x 38 mm)</td></tr> <tr><td>592121320</td><td>21G x 1 1/4" (0.8 x 32 mm)</td></tr> <tr><td>592122250</td><td>22G x 1" (0.7 x 25 mm)</td></tr> <tr><td>592122320</td><td>22G x 1 1/4" (0.7 x 32 mm)</td></tr> <tr><td>592122380</td><td>22G x 1 1/2" (0.7 x 38 mm)</td></tr> <tr><td>592123250</td><td>23G x 1" (0.6 x 25 mm)</td></tr> <tr><td>592123380</td><td>23G x 1 1/2" (0.6 x 38 mm)</td></tr> </tbody> </table> <p>Shelf life: 36 months</p>	Ref/ Catalog No	Specification /Model	592118250	18G x 1" (1.2 x 38 mm)	592118380	18G x 1 1/2" (1.2 x 38 mm)	592120250	20G x 1" (0.9 x 25 mm)	592120380	20G x 1 1/2"(0.9 x 38 mm)	592121250	21G x 1"(0.8 x 25 mm)	592121380	21G x 1 1/2" (0.8 x 38 mm)	592121320	21G x 1 1/4" (0.8 x 32 mm)	592122250	22G x 1" (0.7 x 25 mm)	592122320	22G x 1 1/4" (0.7 x 32 mm)	592122380	22G x 1 1/2" (0.7 x 38 mm)	592123250	23G x 1" (0.6 x 25 mm)	592123380	23G x 1 1/2" (0.6 x 38 mm)	<p>Deferred for submission of differential fee against the different sizes applied.</p>
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6.	<p>M/s. Hooraa Pharma (Pvt.) Ltd. Korangi Creek Industrial Park. Korangi, Karachi (ELI-00037)</p>	<p>Manufacturing site: Name: Guangzhou Improve Medical Instruments Co. Ltd. Address: 102, Kaiyuan Avenue Science City, Guangzhou Economical & Technological Development</p>	<p>Brand Name: IMPROVACUTER MULTI SAMPLE NEEDLE (FLASHBACK) Generic Name: MULTI SAMPLE</p>	<p>Deferred for submission of differential fee against the different sizes applied.</p>																										

	<p>R&I Date: 06-07-2022</p> <p>CMS tracking ID:</p> <p>NM5-3XL-WDXA</p> <p>Fee: 25,000/-</p>	<p>District, 510530 Guangzhou, China LOA</p> <p>Notarization: Yes</p> <p>Valid: 31-12-2026</p> <p>• FSC</p> <p>Legalized: Apostille</p> <p>Issued by: Guangzhou Association of Medical Device</p> <p>Valid: 16-05-2027</p> <p>ISO – Certificate:</p> <p>Notarization: yes</p> <p>Valid till: 30-06-2027</p> <p>EC Certificate: Valid till 06-02-2027</p>	<p>NEEDLE (FLASHBACK)</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC & application):</p> <table border="1"> <thead> <tr> <th>REF/ CATALOG NUMBER</th> <th>SPECIFICATION /MODEL</th> </tr> </thead> <tbody> <tr> <td>595121380</td> <td>21 G x 1 1/2" (0.8 x 38mm)</td> </tr> <tr> <td>595121320</td> <td>21G x 1 1/4" (0.8x32mm)</td> </tr> <tr> <td>595121250</td> <td>21G x 1" (0.8 x25mm)</td> </tr> <tr> <td>595122380</td> <td>22G x 1 1/2"(0.7 x 38 mm)</td> </tr> <tr> <td>595122320</td> <td>22G x 1 1/4" (0.8 x 32 mm)</td> </tr> <tr> <td>595122250</td> <td>22G x 1"(0.7 x 25mm)</td> </tr> </tbody> </table> <p>Shelf life: 36 months</p>	REF/ CATALOG NUMBER	SPECIFICATION /MODEL	595121380	21 G x 1 1/2" (0.8 x 38mm)	595121320	21G x 1 1/4" (0.8x32mm)	595121250	21G x 1" (0.8 x25mm)	595122380	22G x 1 1/2"(0.7 x 38 mm)	595122320	22G x 1 1/4" (0.8 x 32 mm)	595122250	22G x 1"(0.7 x 25mm)	
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7.	<p>M/s HAM International First Floor Portion of House Bearing No. B-49, Block No. 16, K.D.A, Scheme-36 Gulistan-e-Jouhar, Karachi 75350 (ELI-00008)</p> <p>R&I Date: 02-06-2025</p> <p>Fee: 62,000/-</p> <p>Slip # 589647901</p>	<p>Name of Manufacturer: M/s Shunmei Medical Co., Ltd.</p> <p>Address: R401 of Building B, No. 8 of 1st Jinlong Road, Baolong Industrial Zone, LongGang District, 518116 Shenzhen, Guandong, China</p> <p>LOA</p> <p>Notarization: Apostille</p> <p>Validity: 19-01-2028</p> <p>FSC</p> <p>Issued By: MHRA, UK</p> <p>Legalization: Yes</p> <p>Validity: 15-05-2029</p> <p>ISO – Certificate:</p> <p>Notarization: Yes</p> <p>Validity: 12-06-2026</p> <p>CE certificate: Valid upto 15-05-2029</p>	<p>Brand Name: ShockFast</p> <p>Generic Name: Intravascular Lithotripsy Generator and Connector Cable</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Models/Code/sizes (as per FSC & application) IVLG-I</p> <p>Shelf Life: 36 months</p>	<p>Deferred for submission of catalogue of the applied product along with details of intended product with which the applied product will be used.</p>														
8.	<p>M/s HAM International First Floor Portion of House Bearing No. B-49, Block No. 16, K.D.A, Scheme-36 Gulistan-e-Jouhar, Karachi 75350 (ELI-00008)</p> <p>R&I Date: 02-06-2025</p> <p>Fee: 100,000/-</p> <p>Slip # 1036344206</p>	<p>Name of Manufacturer: M/s Shunmei Medical Co., Ltd.</p> <p>Address: R401 of Building B, No. 8 of 1st Jinlong Road, Baolong Industrial Zone, LongGang District, 518116 Shenzhen, Guandong, China</p> <p>LOA</p> <p>Notarization: Apostille</p> <p>Validity: 19-01-2028</p> <p>FSC</p> <p>Issued By: MHRA, UK</p> <p>Legalization: Yes</p>	<p>Brand Name: ShockFast</p> <p>Generic Name: Peripheral Intravascular Lithotripsy Catheter</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Models/Code/sizes (as per FSC & application)</p> <p>PIVL18-40600</p> <p>PIVL18-40400</p> <p>PIVL18-35800</p> <p>PIVL18-35600</p> <p>PIVL18-35400</p> <p>PIVL18-30600</p>	<p>Deferred for submission of catalogue of the applied product along with details of intended product with which the applied product will be used.</p> <p>Also differential fee shall be submitted for the several models applied.</p>														

		Validity: 15-05-2029 ISO – Certificate: Notarization: Yes Validity: 12-06-2026	PIVL18-30400 PIVL18-25600 PIVL18-25400 PIVL14-80800 PIVL14-80600 PIVL14-70800 PIVL14-70600 PIVL18-40800 PIVL18-45600 PIVL18-80800 PIVL18-80600 PIVL18-70800 PIVL18-70600 PIVL18-65800 PIVL18-65600 PIVL18-60800 PIVL18-60600 PIVL18-55800 PIVL18-55600 PIVL18-50800 PIVL18-50600 PIVL18-45800 PIVL14-65800 PIVL14-65600 PIVL14-60800 PIVL14-25600 PIVL14-25400 PIVL14-30400 PIVL14-30600 PIVL14-60600 PIVL14-55800 PIVL14-55600 PIVL14-50800 PIVL14-50600 PIVL14-45800 PIVL14-45600 PIVL14-40800 PIVL14-40600 PIVL14-40400 PIVL14-35800 PIVL14-35600 PIVL14-35400 Shelf Life: 36 months	
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IMPORTED PRODUCT AGENDA:

Imported products Agenda

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
9.	<p>M/s Ferozsons Laboratories Limited (ELI-00120)</p> <p>Date of R&I 27-03-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Challan No. 870319456412 for Balloon Catheters</p>	<p>Legal Manufacturer: Cardiac Pacemakers Inc., (CPI) A wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline A venue North St. Paul, MN 55112 USA</p> <p>Manufacturing Site: (Contract Manufacturer) Arrow International, LLC (subsidiary of Teleflex, Incorporated) 16 Elizabeth Dr Chelmsford, MA USA 01824.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC (CFG) Type: Scan copy of non-notarized copy Issued By: USFDA Validity: 05-11-2025</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 22-08-2027</p> <p>• EC (FQA): Type: Scan copy of non-notarized copy- Validity: 26-05-2024 =-0987654321\</p>	<p>Balloon Catheter Coronary Sinus Venogram Catheter</p> <p>Applied as Single.</p> <p>Class-D</p> <p>Service Life: 2 Yrs Model/Codes/Size: Balloon Catheter (90cm): 6714 Balloon Catheter (110cm): 6747</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid notarized LOA issued by the legal manufacturer. Valid legalized FSC of country of origin. Justification of multiple codes with catalog & family fee.
2.	<p>M/s Ferozsons Laboratories Limited</p>	<p>Legal Manufacturer & manufacturing site as per FSC: Micropace Pty Ltd</p>	<p>Micropace Cardiac Stimulator System Stimulator, electrical, cardiac, diagnostic</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid notarized LOA

	<p>(ELI-00120)</p> <p>Date of R&I 05-05-2025</p> <p>Fee Details: Paid Fee: 170,000/- Challan No. 47225178</p>	<p>41/159 Arthur Street Homebush West NSW 2140, Australia</p> <p>Additional Manufacturing Site as per Form-7A: MICROPACE EP, Inc., 3205 West Warner Ave., Santa Ana, CA 92704, USA</p> <p>LOA Type: Scan copy of non- notarized copy. Validity: 31-12-2025</p> <p>FSC Type: Scan copy of non- notarized copy Issued By: Australia Issuance Date: 19-03-2025 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non- notarized copy Validity: 23-03-2027</p> <p>• EC (FQA): Type: Scan copy of non- notarized copy Validity: 26-05-2024</p>	<p>Applied as System.</p> <p>Class-C</p> <p>Service Life: N/A</p> <p>Model/Codes/Size:</p>	<p>issued by the legal manufacturer.</p> <p>2. Justification of multiple codes with catalog & codes as FSc shall be specified.</p> <p>3. Sites shall be issued as per FSC.</p>
3.	<p>M/s Ferozsans Laboratories Limited (ELI-00120)</p> <p>Date of R&I 04-03-2025</p> <p>Fee Details: Paid Fee: 6,000/- Challan No. 83854215775 for CPR Assist 1100</p>	<p>Nihon Kohden Corporation 1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan</p> <p>Manufacturing Site as per FSC: Nihon Kohden Tomioka Corporation Tomioka Production Center 1-1 Tajino, Tomioka-shi, Gunma, Japan</p> <p>LOA Type: Scan copy of non- notarized copy. Validity: 31-03-2026</p> <p>FSC Type: Scan copy of non-</p>	<p>CPR Assist 1100 Cardiopulmonary Resuscitation (CPR) Assist Device (Defibrillator)</p> <p>Applied as Single.</p> <p>Class-A</p> <p>Service Life: N/A</p> <p>Model/Codes/Size: CPR Assist 1100</p>	Approved.

		<p>notarized copy Issued By: Japan Issuance Date: 26-01-2023 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 05-04-2027</p> <p>• EC (FQA): Type: Scan copy of non-notarized copy Validity: 12-04-2027</p>		
4.	<p>Rech International 247-B, Block-6, PECHS,, Karachi</p> <p>ELI-00257</p> <p>Date of R&I 18-01-2024</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 50177253674</p>	<p>Beijing Libeier Bio-engineering Institute Co., Ltd. Add.: 12 Chuangxin Road, Changping Science and Technology Park, Changping Area, Beijing, P.R. China.</p> <p>LOA not attached</p> <p>FSC not attached</p> <p>ISO 13485: not attached</p> <p>• EC (FQA): not attached</p>	<p>Soprano Spinal Fixation System</p> <p>Applied as System.</p> <p>Class-C</p> <p>Service Life: Not mentioned</p> <p>Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer. 2. Valid legalized FSC of country of origin. 3. Valid legalized FSC any RRA or notarized CE (FQA). 4. Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall also be specified. 5. Form-7A properly filled with annexures & information.
5.	<p>Rech International 247-B, Block-6, PECHS,, Karachi</p> <p>ELI-00257</p> <p>Date of R&I 20-06-2024</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 5891899818</p>	<p>Shandong Weigao Orthopedics Devices Company Limited Address: NO.26 Xiangjiyang Road, tourist resort, Weihei city Shandong Province, China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 15-11-2027</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Validity: 20-08-2025</p> <p>ISO 13485:</p>	<p>Bone Plates</p> <p>Applied as Family.</p> <p>Class-C</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA for applied product issued by the legal manufacturer. 2. Valid legalized FSC of country of origin wherein applied products with codes shall be mentioned. 3. Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall also be specified. 4. Form-7A properly filled with annexures & information.

		<p>Type: Scan copy of non-notarized copy Validity: 30-04-2027</p> <p>• EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024 With extension letter</p>		
6.	<p>Rech International 247-B, Block-6, PECHS,, Karachi</p> <p>ELI-00257</p> <p>Date of R&I 03-09-2024</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 5772555614</p>	<p>Arthrex, Inc. 1370 Creekside Boulevard Naples 34108-1945 USA</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 30-06-2027</p> <p>FSC (CFG) Type: Scan copy of non-notarized copy Issued By: USFDA Validity: 14-09-2025</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 21-11-2025</p> <p>• EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024 With extension letter</p>	<p>Bio absorbable Anchor</p> <p>Applied as Family.</p> <p>Class-C</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA for applied product issued by the legal manufacturer. 2. Valid legalized FSC of country of origin wherein applied products with codes shall be mentioned. 3. The product is of Class-D while applied in Class-C, clarification is required with additional fee as per SRO. 4. Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall also be specified. 5. Form-7A properly filled with annexures & information. 6. Valid notarized ISO 13485
7.	<p>Rech International 247-B, Block-6, PECHS,, Karachi</p> <p>ELI-00257</p> <p>Date of R&I 03-09-2024</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 3407969169</p>	<p>Arthrex, Inc. 1370 Creekside Boulevard Naples 34108-1945 USA</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 30-06-2027</p> <p>FSC (CFG) Type: Scan copy of non-notarized copy Issued By: USFDA Validity: 19-08-2026</p> <p>ISO 13485: Type: Scan copy of non-</p>	<p>Bio absorbable Screw</p> <p>Applied as Family.</p> <p>Class-C</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA for applied product issued by the legal manufacturer. 2. Valid legalized FSC of country of origin wherein applied products with codes shall be mentioned. 3. The product is of Class-D while applied in Class-C, clarification is required with additional fee as per SRO. 4. Justification of multiple codes as system or family with catalog & family

		<p>notarized copy Validity: 21-11-2025</p> <p>• EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024 With extension letter</p>		<p>fee. Codes as FSc shall also be specified.</p> <p>5. Form-7A properly filled with annexures & information.</p> <p>6. Valid notarized ISO 13485</p>
8.	<p>Zymotic Diagnostic International Faisalabad Address: 4th floor business center regency road new civil lines Faisalabad ELI-00880</p> <p>Date of R&I: 28-01-2025 Fee Details: Paid Fee: 6,000/- Challan No. 387592195</p>	<p>Legal Manufacturer & Site as per Form-7A: Goldsite Diagnostics Inc.</p> <p>Goldsite Mansion, No. 9 Rongtian Road, Kengzi, Pingshan District, Shenzhen, China, 518122</p> <p>Address as per FSC (China & Spain):</p> <p>No. 1001, Building No.1, GOLDSITE Mansion, No. 9 Rongtian Road, Kengzi, Pingshan District, Shenzhen, 518122 China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 18-07-2029</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Validity: 02-01-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Spain Issuance Date: 06-03-2025 Validity: not mentioned</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 15-10-2027</p>	<p>Goldsite Nephstar Protein Analyzer</p> <p>Applied as Single.</p> <p>Class-A</p> <p>Service Life: 10 yrs</p> <p>Model/Codes/Size: Nephstar</p>	<p>Approved with manufacturing site as per FSC. (No. 1001, Building No.1, GOLDSITE Mansion, No. 9 Rongtian Road, Kengzi, Pingshan District, Shenzhen, 518122 China.)</p>
9.	<p>Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS,</p>	<p>Argon Medical Devices, Inc. 1445 Flat Creek road, Athens, Texas 75751 USA</p> <p>LOA</p>	<p>Argon Retrieval kits : Single loop share and triple loop share</p> <p>Applied as Family.</p>	<p>Approved</p>

	<p>Karachi, (ELI-00578)</p> <p>Date of R&I 21-01-2025</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 6708440750</p>	<p>Type: Scan copy of non-notarized copy. Validity: 21-03-2029</p> <p>FSC (CFG) Type: Scan copy of non-notarized copy Issued By: USFDA Validity: 15-05-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-04-2025</p>	<p>Class-B</p> <p>Service Life: 3 Yrs</p> <p>Model/Codes/Size: Single loop share 380911120 Triple loop share 380911330</p>	
10.	<p>Pulse Surgicals Address: Suite No. 113, First floor, Almas height, 190/1, Block 2 PECHS, Karachi, (ELI-00578)</p> <p>Date of R&I 03-06-2024</p> <p>Fee Details: Paid Fee: 50,000/- Challan No. 6672001951</p>	<p>Argon Medical Devices, Inc. 1445 Flat Creek road, Athens, Texas 75751 USA</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 21-03-2029</p> <p>FSC (CFG) Type: Scan copy of non-notarized copy Issued By: USFDA Validity: 15-05-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-04-2025</p>	<p>SKATER Nephrostomy Kit (Locking and non-Locking Pigtail) Drainage Catheter Kits</p> <p>Applied as Family.</p> <p>Class-C</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size: 757306600 757306700 757307000 757308000 757308600 757308700 757308700 757310000 757312000 757314700</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Justification of multiple codes as family with catalog & family fee. Codes as per FSc shall also be specified. 2. Valid notarized ISO 13485
11.	<p>Absolute Health Care Systems (SMC) Pvt Ltd., Islamabad. (ELI-01457)</p> <p>Date of R&I 10-06-2025</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 5317822353</p>	<p>Name & Address of Legal manufacturer & manufacturing site (as per FSC & EC): Ultra for medical products Co. (Ultramed) (U.M.I.C) S.A.E. Part No. (304:310) & Part No. (312) – Industrial Area, Arab El Awamer- Abnoub- Assiut- Egypt.</p> <p>Address as per Form-7A: HEAD OFFICE 64 Nakhla El Motaiy St,</p>	<p>Ultramed Silicone Coated Latex Foley Catheter (2-Way & 3 Way)</p> <p>Applied as Family.</p> <p>Class-C</p> <p>Service Life:</p> <p>Model/Codes/Size: 3006-6/2 Silicone Coated Latex Foley Balloon Catheter Size 6 FG/ 2-Way 3006-8/2 Silicone Coated</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of country of origin wherein applied products with codes shall be mentioned. 2. The product is of Class-C while applied in Class-B, clarification is required with additional fee as per SRO. 3. Justification of multiple codes family with catalog & family fee. Codes as FSc shall also be

		<p>Triumph Square, Cairo, Egypt FACTORY Arab El Awamer, Industrial zone, Abnoub, Assiut, Egypt.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Egypt Validity: 09-01-2027</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 20-05-2026.</p> <p>EC Production QA: Type: Scan copy of non-notarized copy Validity: 26-05-2024</p>	<p>Latex Foley Balloon Catheter Size 8 FG/ 2-Way 3006-10/2 Silicone Coated Latex Foley Balloon Catheter Size 10 FG/ 2-Way 3006-12/2 Silicone Coated Latex Foley Balloon Catheter Size 12 FG/ 2-Way 3006-14/2 Silicone Coated Latex Foley Balloon Catheter Size 14 FG/ 2-Way 3006-16/2 Silicone Coated Latex Foley Balloon Catheter Size 16 FG/ 2-Way 3006-18/2 Silicone Coated Latex Foley Balloon Catheter Size 18 FG/ 2-Way 3006-20/2 Silicone Coated Latex Foley Balloon Catheter Size 20 FG/ 2-Way 3006-22/2 Silicone Coated Latex Foley Balloon Catheter Size 22 FG/ 2-Way 3006-24/2 Silicone Coated Latex Foley Balloon Catheter Size 24 FG/ 2-Way 3006-16/3 Silicone Coated Latex Foley Balloon Catheter Size 16 FG/ 3-Way 3006-18/3 Silicone Coated Latex Foley Balloon Catheter Size 18 FG/ 3-Way 3006-20/3 Silicone Coated Latex Foley Balloon Catheter Size 20 FG/ 3-Way 3006-22/3 Silicone Coated Latex Foley Balloon Catheter Size 22 FG/ 3-Way 3006-24/3 Silicone Coated Latex Foley Balloon Catheter Size 24 FG/ 3-Way</p>	<p>specified.</p> <p>4. Shelf life evidence/data of applied product.</p>
12.	<p>M/s MEHER TRADERS Office No. A-21-22 First Floor Zeenat Medicine Market North Nappier Road, Karachi. (ELI-00128)</p>	<p>M/s Juye Forna Medical Instrument Co., Ltd NO. 173, Yongfeng Street, Juye County, Heze, Shandong China</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 07-03-2023</p>	<p>Wellmed Infusion Set</p> <p>Applied as.</p> <p>Class-B</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size: 180cm & 150cm</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid notarized LOA issued by the legal manufacturer. Valid legalized FSC of country of origin issued by the concerned regulatory authority. Valid legalized FSC any RRA or notarized CE

	<p>Date of R&I 03-09-2020</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 2037103</p>	<p>New copy of LOA dated 01-01-2024.</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Chamber of Commerce. Validity: 16-03-2025</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 13-12-2025.</p>		<p>(FQA). 4. Verifiable copy of fee slip.</p>
13.	<p>M/s. United Brothers., Karachi. ELI: 00451</p> <p>Date of R&I 16-02-2023</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 42340870786</p>	<p>TG MEDICAL SDN BHD, Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 04-12-2027</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Malaysia Validity: 18-11-2027</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 06-08-2024.</p> <p>EC Production QA: Type: Scan copy of non-notarized copy Validity: 06-08-2023</p>	<p>UB Latex Surgical Powder Free Glove</p> <p>Applied as Single.</p> <p>Class-B</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size: 5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0</p>	Approved.
14.	<p>Zybio Medical Pakistan (SMC-Private) Limited Address: House no. 323,</p>	<p>Legal manufacturer & Manufacturing site as per FSC (The Netherland): Zybio Inc. Address:</p>	<p>Zybio Uric Acid (UA) Kit (Uricase Method)</p> <p>Applied as Kit.</p>	Approved.

	<p>street no. 66, Sector 18/3, Islamabad. (ELI-01195)</p> <p>Date of R&I 20-02-2025</p> <p>Fee Details: Paid Fee: 31,000/-</p> <p>Challan No. 5344250133</p>	<p>No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA</p> <p>Manufacturing site as per Form-7A: Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 23-11-2028</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Validity: 03-11-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: The Netherland Validity: 03-05-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-11-2026.</p>	<p>Class-B</p> <p>Service Life: 18 months</p> <p>Model/Codes/Size: R1 30 mL × 3 R2 7.5 mL × 3</p> <p>R1 48 mL × 2 R2 12 mL × 2</p>	
15.	<p>M/S Health Tec. Rawalpindi, (ELI•00046)</p> <p>Date of R&I 22-04-2025</p> <p>Fee Details: Paid Fee: 62,000/-</p> <p>Challan No. 01034147086</p>	<p>SCW Medicath, China. Address: No.4, Baolong 6th Road, Baolong Industrial Town, Long gang District, 518116Shenzhen, Guangdong, China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 26-08-2029</p> <p>FSC Type: Scan copy of non-notarized copy</p>	<p>Guiding Catheter SCW Guiding Catheter</p> <p>Applied as Single.</p> <p>Class-D</p> <p>Service Life: 5 Yrs</p> <p>Model/Codes/Size: GC-6F-100-JL4.0, GC-6F-100-JR4.0, GC-6F-100-AL0.75, GC-6F-100-AL1.0, GC-6F-100-AL1.5, GC-6F-100-AL2.0, GC-6F-100-</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid notarized LOA issued by the legal manufacturer. Valid legalized FSC any RRA or notarized CE (FQA) plus Design Examination Certificate. Justification of multiple codes catalog & family fee. Codes as FSc shall also be specified.

		<p>Issued By: China Validity: 14-10-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 06-01-2026.</p> <p>EU QMS (MDR): Type: Scan copy of non-notarized copy Validity: 26-09-2029</p>	<p>EBU3.5, GC-6F-100-XB3.5, GC-6F-100-SAL0.75, GC-6F-100-SAL1.0, GC-6F-100-SAL1.5, GC-6F-100-IL, GC-6F-100-IR, GC-6F-100-TIG</p>	
16.	<p>M/S Health Tec. Rawalpindi, (ELI-00046)</p> <p>Date of R&I 02-09-2024</p> <p>Fee Details: Paid Fee: 50,000/-</p> <p>Challan No. 7434331418 for Tianck Medical Co Ltd. Guidewire (Hydrophilic ,PTCA ,PTFE coated guidewire)</p>	<p>Tianck Medical Co. Ltd. Address: 1-2 Floor, Buiding C, No. 16,Yinkui Road, Kuichong town , Dapeng new district, Shenzhen 518119, Guangdong, China.</p> <p>LOA unsigned</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Validity: 03-02-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 16-11-2026.</p> <p>EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2024</p>	<p>Hydrophilic, PTCA , PTFE Guide Wire</p> <p>Applied as Single.</p> <p>Class-D</p> <p>Service Life: 3 Yrs</p> <p>Model/Codes/Size: Normal Type Metal Guide Wire 0.014in x190cm(S),0.018in x190cm(S), 0.18in x45cm(S), 0.021in x 45cm(S), 0.025in x 45cm (S), 0.028in x 45cm(S), 0.035in x 45cm(S), 0.038in x 45cm(S), 0.025in x 60cm (S), 0.028in x 60cm(S), 0.032in x 60cm(S), 0.035in x 60cm(S), 0.038in x 60cm(S), 0.032in x 70cm(S), 0.035in x 70cm(S), 0.038in x 70cm (S), 0.014in x 190cm(J), 0.018in x 190cm (J), 0.018in x 46cm(J), 0.021in x 45cm(J), 0.025in x 45cm(J), 0.028in x 45cm(J),0.032x15cm(J), 0.035in x 45cm (J), 0.038in x 45cm (J),0.025in x 60cm (J), 0.028in x 60cm(J), 0.032in x 60cm(J), 0.035in x 60cm(J), 0.038in x 60cm(J), 0.032in x 70cm(J), 0.035inx70cm(J), 0.038in x 70cm(J), 0.038in x 70cm(J).plastic coated guide</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer. 2. Valid legalized FSC any RRA or notarized CE (FQA) plus Design Examination Certificate. 3. Justification of multiple codes catalog & family fee. Codes as FSc shall also be specified.

			<p>wire: 0.0251in x 150cm (S), 0.028in x 150cm(S), 0.032in x 150cm(S), 0.032in x 150cm(S), 0.035in x 150cm(S), 0.038in x 150cm(S), 0.032in x 180cm(S), 0.035in x 180cm (S), 0.038in x 180cm(S), 0.032in x 260cm(S), 0.032in x 260cm(S), 0.032in x 260cm (S), 0.035in x 260cm(S), 0.038in x 260cm(S), 0.032in x 150cm(S), 0.035in x 450cm(S), 0.038in x 450cm(S), 0.025in x 150cm(J), 0.025in x 150cm(J), 0.028in x 150cm(J), 0.032in x 180cm(J), 0.035in x 150cm(J), 0.035in x 150cm(J), 0.035in x 260cm(J), 0.035in x 180(J), 0.038in x 180cm(J), 0.032in x 260cm(J), 0.035in x 260cm, 0.035in260cm(J), 0.038in x 260cm(J), 0.032in x 450cm(J), 0.035in x 450cm(J),0.038in x 450cm (J). Hydrophilic coated guide wire: 0.032in x150cm(S), 0.035in x 150cm(S), 0.038in x 180cm(S), 0.032in x 180cm(S), 0.035in x180cm(S), 0.038in x 180cm(S), 0.032in x 260cm(S), 0.035in x 260cm(S), 0.038in x 260cm(S), 0.032in x 150cm(J), 0.035in x 160cm (J), 0.038in x 150cm(J), 0.032in x 180cm(J), 0.035in x 180cm(J), 0.038in x 180cm(J), 0.038in x 180cm(J), 0.032in x 260cm(J), 0.035in x 260cm(J), 0.038in x 260cm(J)</p>	
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17.	<p>Silpha Labs Pvt Ltd 99/6 Gulshan E Mehrun Nisa Ibrahim Hyderi Korangi Creek Karachi (ELI-00650)</p> <p>Date of R&I 24-03-2025</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 78614881</p>	<p>Guangdong Baihe Medical Technology Co Ltd 89 Taiyuan East Road Nanhai Foshan 528225 Guangdong Province China.</p> <p>Distribution Agreement Type: Scan copy of non-notarized copy. Validity: 31-12-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Chamber of Commerce Validity: 12-02-2027</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 06-08-2027.</p> <p>CE/RRA FSC not attached.</p>	<p>Silpha (Sterile Disposable 3-way Stopcock)</p> <p>Applied as Single.</p> <p>Class-B</p> <p>Service Life:</p> <p>Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of country of origin issued by concerned regulatory authority. 2. Valid legalized FSC any RRA or notarized CE . 3. Code as per FSc shall also be specified.
18.	<p>RHS International , Lahore. (ELI-00354)</p> <p>Date of R&I 29-10-2024</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 07996395391</p>	<p>JOYTECH Healthcare Co., Ltd. No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang, P.R. China</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 29-01-2029</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: China Chamber of Commerce Validity: 29-04-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-04-2028.</p> <p>EC (Production QA):</p>	<p>CERTEZA BR-540 Electric Breast Pump</p> <p>Applied as Single.</p> <p>Class-B</p> <p>Service Life: 400 hours</p> <p>Model/Codes/Size: BR-540</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of country of origin issued by concerned regulatory authority. 2. Shelf life evidence or data

		<p>Type: Scan copy of non-notarized copy Validity: 26-05-2024 With extension letter.</p>		
19.	<p>Gulf Marketing International</p> <p>ELI-000194</p> <p>Date of R&I 20-06-2023</p> <p>Fee Details: Paid Fee: 25,000/-</p> <p>Challan No. 21974751</p>	<p>Legal Manufacturer & Site (as per Form-7A):</p> <p>Yehsang Enterprises Corporation No. 154, Sec 1, Xinnan road, Lujhu District, Taoyuan City, 33858 Taiwan.</p> <p>Manufacturing Site (as per FSC): Bioptik Technology, Inc. (No.188, Jhonghua South Road Gongguan Village, Jhunan Township, Miaoli County, 35057 Taiwan, R.O.C.) for Yehshang Enterprise Corporation {No.156 Sec. 1 Xinnan Rd. Luzhu District. Taoyuan City 338. Taiwan R.O.C.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Mo Health & Welfare, Taiwan (China) Validity: 19-11-2024</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-10-2024 & 17-09-2024</p> <p>EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2025</p>	<p>Best Check Blood Glucose/Cholesterol/ Uric Acid Monitoring Device</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: 10 Yrs</p> <p>Model/Codes/Size: ET-3111</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer. 2. Valid legalized FSC of country of origin. 3. Valid legalized FSC any RRA or notarized CE . 4. Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall also be specified. 5. Form-7A properly filled with annexures & information. 6. Shelf life evidence or data 7. The product class shall be clarified & additional fee of Class-C will be needed

20.	<p>Gulf Marketing International</p> <p>ELI-000194</p> <p>Date of R&I 20-06-2023</p> <p>Fee Details: Paid Fee: 25,000/-</p> <p>Challan No. 390038628876</p>	<p>Legal Manufacturer & Site (as per Form-7A):</p> <p>Yehsang Enterprises Corporation No. 154, Sec 1, Xinnan road, Lujhu District, Taoyuan City, 33858 Taiwan.</p> <p>Manufacturing Site (as per FSC): Bioptik Technology, Inc. (No.188, Jhonghua South Road Gongguan Village, Jhunan Township, Miaoli County, 35057 Taiwan, R.O.C.)</p> <p>for Yehshang Enterprise Corporation {No.156 Sec. 1 Xinnan Rd. Luzhu District. Taoyuan City 338. Taiwan R.O.C.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Mo Health & Welfare, Taiwan (China) Validity: 19-11-2024</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-10-2024 & 17-09-2024</p> <p>EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2025</p>	<p>Best Check Blood Cholesterol Test Strip</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: 24 months</p> <p>Model/Codes/Size: SC119</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer. 2. Valid legalized FSC of country of origin. 3. Valid legalized FSC any RRA or notarized CE . 4. Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall also be specified. 5. Form-7A properly filled with annexures & information. 6. Shelf life evidence or data
21.	<p>Gulf Marketing International</p> <p>ELI-000194</p> <p>Date of R&I 20-06-2023</p>	<p>Legal Manufacturer & Site (as per Form-7A):</p> <p>Yehsang Enterprises Corporation No. 154, Sec 1, Xinnan road, Lujhu District,</p>	<p>Best Check Blood Glucose Test Strip</p> <p>Applied as Kit.</p> <p>Class-B</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid notarized LOA issued by the legal manufacturer. 2. Valid legalized FSC of

	<p>Fee Details: Paid Fee: 25,000/- Challan No. 1199766853</p>	<p>Taoyuan City, 33858 Taiwan.</p> <p>Manufacturing Site (as per FSC): Bioptik Technology, Inc. (No.188, Jhonghua South Road Gongguan Village, Jhunan Township, Miaoli County, 35057 Taiwan, R.O.C.) for Yehshang Enterprise Corporation {No.156 Sec. 1 Xinnan Rd. Luzhu District. Taoyuan City 338. Taiwan R.O.C. LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Mo Health & Welfare, Taiwan (China) Validity: 19-11-2024</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-10-2024 & 17-09-2024</p> <p>EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2025</p>	<p>Service Life: 24 months</p> <p>Model/Codes/Size: SG130</p>	<p>country of origin.</p> <ol style="list-style-type: none"> Valid legalized FSC any RRA or notarized CE . Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall also be specified. Form-7A properly filled with annexures & information. Shelf life evidence or data The product class shall be clarified & additional fee of Class-C will be needed
22.	<p>Gulf Marketing International</p> <p>ELI-000194</p> <p>Date of R&I 20-06-2023</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 57925198511</p>	<p>Legal Manufacturer & Site (as per Form-7A): Yehsang Enterprises Corporation No. 154, Sec 1, Xinnan road, Lujhu District, Taoyuan City, 33858 Taiwan.</p> <p>Manufacturing Site (as per FSC): Bioptik Technology, Inc. (No.188, Jhonghua South</p>	<p>Best Check Blood Uric Acid Test Strip</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: 24 months</p> <p>Model/Codes/Size: SU120</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid notarized LOA issued by the legal manufacturer. Valid legalized FSC of country of origin. Valid legalized FSC any RRA or notarized CE . Justification of multiple codes as system or family with catalog & family fee. Codes as FSc shall

		<p>Road Gongguan Village, Jhunan Township, Miaoli County, 35057 Taiwan, R.O.C.) for Yehshang Enterprise Corporation {No.156 Sec. 1 Xinnan Rd. Luzhu District. Taoyuan City 338. Taiwan R.O.C. LOA Type: Scan copy of non-notarized copy. Validity: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Mo Health & Welfare, Taiwan (China) Validity: 19-11-2024</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-10-2024 & 17-09-2024</p> <p>EC (FQA): Type: Scan copy of non-notarized copy Validity: 26-05-2025</p>		<p>also be specified.</p> <ol style="list-style-type: none"> 5. Form-7A properly filled with annexures & information. 6. Shelf life evidence or data 7. The product class shall be clarified & additional fee of Class-C will be needed
23.	<p>Gulf Marketing International Rawalpindi. ELI-000194</p> <p>Date of R&I 05-11-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006288 dated 21-10-2020</p>	<p>Diuri International Co., Ltd 95 Yunhe Street ,New & High Tech. Development Zone, Changchun China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 17-11-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: In Chinese Language without translation. Validity: 26-02-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy</p>	<p>Dirui General Chemistry Group</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC any RRA or notarized CE . 2. Form-7A properly filled with annexures & information. 3. Shelf life evidence or data 4. Justification of multiple codes as system or family or cluster with catalog & respective group fee. Codes as FSc shall also be specified. 5. Verifiable fee slip.

		<p>Validity: 01-03-2026</p> <p>EC (FQA) not attached instead CE technical Documentation Review Report has been attached.</p>		
24.	<p>Gulf Marketing International Rawalpindi. ELI-000194</p> <p>Date of R&I 05-11-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006287 dated 21-10-2020</p>	<p>Diuri International Co., Ltd 95 Yunhe Street , New & High Tech. Development Zone, Changchun China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 17-11-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: In Chinese Language without translation. Validity: 26-02-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 01-03-2026</p> <p>EC (FQA) not attached instead CE technical Documentation Review Report has been attached.</p>	<p>Dirui Substrates</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC any RRA or notarized CE . 2. Form-7A properly filled with annexures & information. 3. Shelf life evidence or data 4. Justification of multiple codes as system or family or cluster with catalog & respective group fee. Codes as FSc shall also be specified. 5. Verifiable fee slip.
25.	<p>Gulf Marketing International Rawalpindi. ELI-000194</p> <p>Date of R&I 05-11-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006286 dated 21-10-2020</p>	<p>Diuri International Co., Ltd 95 Yunhe Street ,New & High Tech. Development Zone, Changchun China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 17-11-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: In Chinese Language without translation. Validity: 26-02-2026</p> <p>ISO 13485: Type: Scan copy of non-</p>	<p>Dirui Enzymes</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: Model/Codes/Size:</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC any RRA or notarized CE . 2. Form-7A properly filled with annexures & information. 3. Shelf life evidence or data 4. Justification of multiple codes as system or family or cluster with catalog & respective group fee. Codes as FSc shall also be specified. 5. Verifiable fee slip.

		<p>notarized copy Validity: 01-03-2026</p> <p>EC (FQA) not attached instead CE technical Documentation Review Report has been attached.</p>		
26.	<p>Gulf Marketing International Rawalpindi. ELI-000194</p> <p>Date of R&I 05-11-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006289 dated 21-10-2020</p>	<p>Diuri International Co., Ltd 95 Yunhe Street ,New & High Tech. Development Zone, Changchun China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity: 17-11-2026</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: In Chinese Language without translation. Validity: 26-02-2026</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 01-03-2026</p> <p>EC (FQA) not attached instead CE technical Documentation Review Report has been attached.</p>	<p>Dirui Auto Chemistry analyzer</p> <p>Applied as Kit.</p> <p>Class-A</p> <p>Service Life: Model/Codes/Size: CS300B, CS-400</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid legalized FSC any RRA or notarized CE . Verifiable fee slip.
27.	<p>Elite Traders Rawalpindi ELI-00193</p> <p>Date of R&I 21-05-2024 Fee Details: Paid Fee: 25,000/- Challan No. 2047773803</p>	<p>Stem C Biyoteknoloji A.S., Address as per Form-7A: Merkez Mah. Baglar Cad, B Block No:27 Kagithane /Istanbul/Turkey.</p> <p>Address as per FSC: Gokturk Merkez Mh. Telekom SK. No:1/9 Eyupsultan, Istanbul.</p> <p>LOA Type: Scan copy of non-notarized copy. Date od issued: 05-06-2023</p>	<p>LIPOCUBE (Mechanical adipose tissue digestion and filtration device and accessories)</p> <p>Applied as Kit.</p> <p>Class-B</p> <p>Service Life: 3 Yrs</p> <p>Model/Codes/Size: Lipocube SVF Black Ref No: B-LSVF Lipocube Nano Ref No: L-Nano</p>	<p>Deferred for submission of the following:</p> <ol style="list-style-type: none"> Valid notarized LOA with validity date. Valid legalized FSC of country of origin. Valid legalized FSC any RRA or notarized CE . Form-7A properly filled with annexures & information. Shelf life evidence or data Justification of multiple codes as system or family or cluster with catalog & respective group fee. Codes as FSc shall also be specified.

		<p>Validity: Valid for duration of distribution contract. But the distribution contract not attached.</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Turkey Validity: 08-08-2027</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 09-12-2025</p> <p>EC (Production QA): Type: Scan copy of non-notarized copy Validity: 26-05-2025</p>		7. Clarification of Class as per MDR 2017
28.	<p>M/s ZH Traders ELI-00763</p> <p>Date of R&I 07-02-2025</p> <p>Fee Details: Paid Fee: 6,000/- Challan No. 1775987768 for Disposable vacuume urine tube</p>	<p>M/s Zhejiang Gongdong Medical Technology Co. Ltd No. 10 Beiyuan Ave, Economic Development Zone, Huangyan Taizhou, Zhejiang China 318020.</p> <p>LOA Type: Scan copy of non-notarized copy. Date od issued: 05-06-2023 Validity: 31-12-2030</p> <p>FSC Not attached</p> <p>ISO 13485: Type: Scan copy of non-notarized copy Validity: 28-02-2028</p> <p>EC (Production QA): Not attached</p>	<p>Disposable vacuum urine tube Urine tube for urine Collection.</p> <p>Applied as Single.</p> <p>Class-A</p> <p>Service Life: 15 months</p> <p>Model/Codes/Size: GDO105UB VACUUM URINE TUBE , YELLOW CAP BORIC ACID, 16 × 100 mm, 10.5 ml</p>	<p>Deferred for submission of the following:</p> <p>Valid legalized FSC of country of origin & code as per FSC.</p>

Local Manufacturing Products:

S. No	Name of Applicant(s)	Approved Section as per Form-3	Medical Device	Decision
1.	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055) Date of R&I 23-04-2024 Fee Details: Paid Fee: 20,000/- Challan No. 182667518	Surgical Sutures Section Ligatures Section GMP certificate valid up to 08-09-2023.	BT-PGA SUTURE Synthetic Absorbable Suture Braided Polyglycolic Acid Applied as Single. Class-B Service Life: 5 Yrs Model/Codes/Size: 0,1,2,2/0,3/0,4/0,5/0,6/0,7/0,8/0	Deferred for submission of the following: 1. The product is of Class-D while applied in Class-C, clarification is required with additional fee as per SRO. 2. Justification of multiple codes as family with catalog & family fee. 3. Form-7 properly filled with annexures & information including Steps of manufacturing process performed in the facility. 4. Valid GMP certificate. 5. Stability study data up to the shelf life
2.	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055) Date of R&I 23-04-2024 Fee Details: Paid Fee: 20,000/- Challan No. 47610803513	Surgical Sutures Section Ligatures Section GMP certificate valid up to 08-09-2023.	BT-Polypropylene Suture Propylene blue monofilament non-absorbable Suture Applied as Single. Class-B Service Life: 5 Yrs Model/Codes/Size: 0,1,2,2/0,3/0,4/0,5/0,6/0,7/0,8/0	Deferred for submission of the following: 1. The product is of Class-D while applied in Class-C, clarification is required with additional fee as per SRO. 2. Justification of multiple codes as family with catalog & family fee. 3. Form-7 properly filled with annexures & information including Steps of manufacturing process performed in the facility. 4. Valid GMP certificate. 5. Stability study data up to the shelf life

Evaluator: Ghayour Ahmad (Deputy Director)Subject:- **REGISTRATION/ENLISTMENT OF MEDICAL DEVICES TO IMPORT – PERSONAL HEARING NOTICE THEREOF.**

With reference to the application(s) for the registration/enlistment of following medical device applied by M/s Pharma Consultant Pakistan Pvt. Ltd., Suit # 206,207,207A & 209 Khan Tower, DHA Square, Walton Road Lahore Cantt., Lahore, it is to inform that Medical Device Board (MDB) considered it in its 104th & 108th meetings. The operative part of the decision is reproduced below:-

S.#	Name of Medical Device	Manufacturer's Detail	Decision of MDB Meetings
1.	PERSONA® The Personalized Knee System (M-104)	M/s Zimmer, INC. 1800 West Center Street Warsaw, Indiana 46580 USA	Furthermore, the Board decided to grant a personal hearing notice to M/s Rech International and Pharma Consultant Pakistan Pvt. Ltd. to verify the authorization of the medical devices.

Decision:

The Board observed that the matter is sub-judice in the court. Keeping in view of the decision of the court the Board unanimously decided to defer the application till the conclusive decision of the Hon'ble Court regarding authorization of the product. Furthermore, the Board directed the parties to apprise the Medical Device Board regarding the final outcome of the court case without failure for further processing into the matter.