

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

**DECISIONS OF 115<sup>TH</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 01-01-2026 (MANUAL APPLICATIONS PART-II)**

115<sup>th</sup> meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 1<sup>st</sup> January, 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 M Salik Zahid, Chief Drugs Inspector, Nominee of DGHS Baluchistan	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.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
5.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
7.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
8.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)
9.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore	Member (attended meeting through videolink)
10.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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

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

**(FRESH CASES-ELI):**

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s OBS Pharma (Pvt) Ltd, Office: 194/C OPD society phase 1, Lahore  Office/Godown: 108-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	Adnan Ahmad Jahangiri  B-Pharmacy	Approved
2.	M/s Medisonics,  Office/Godown: House No. 13, Street No. 09-Taj Mehal Park Road, Salamat Pura Lahore.	Faraz Mehmood  BS in Biomedical Engineering Technology	Approved. The firm shall submit an undertaking that the premises shall not be used for residential purposes and could be inspected any time without hindrance.

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

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

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Allied Surgicals, Office: Ist Floor 56-A, Unit No.1, Justice Inamullah Road, Block 7/8 KCHS Karachi.  Godown: Plot # 37/1 Unit No. 2 sector 15 , Korangi Industrial Area, Karachi  ELI-00238	Uzair Mumtaz  Pharm D	Muhammad Salman Mudassir  CEO	Approved
2.	M/s Combined Engineer, Office/Godown: Plot 300 sector 27, near National Flour Mills Korangi Industrial Area Karachi  ELI-00377	Shafaque Shahid  Pharm D	Muhammad Altash Butt Ch. Muhammad Nadeem Muhammad Saleem Anwar	Approved

3.	M/s Mehran International , Office/Godown: 498/C, Feroze Shah Mehta road, Karachi.  ELI-00351	Zahid Hussain  B-Pharmacy	Zainab Usman  CEO	Approved
4.	M/s Oriental Sales Corporation, Office/Godown: Building No. 16- C, Office No. 301 & 304, 3 <sup>rd</sup> & 4 <sup>th</sup> Floor, Shahbaz Commercial Area, Khayaban-e-Shahbaz, DHA, Phase-Vi, Karach.  ELI-00025	Anwar Ul Haque  Pharm D	Mansoor Younas Afshan Mansoor	Approved
5.	M/s Progressive Corporation, Office/Godown: 147-D, CBW Phase 8, DHA, Lahore.  ELI-00114	Akmal Asghar  Pharm D	Irfan Ayaz  CEO	Approved
6.	M/s Roche Pakistan Limited, Office: 37-C, Block 6, PECHS, Karachi.  Godown 5: Plot No. 5, Suleiman Market, Bazar No. 2, F-11/2, Islamabad.  ELI-00009	Muhammad Kamal e Mustafa  Pharm D	Hafsa Shamsie CEO  M.Waqas Siddiqui M Ashar Khan Badaruddin F. Vellani  Robert Ferraro	Approved.  (The rest of the godowns of the firm have been approved in 113 meeting of MDB.)
7.	M/s Renacon Pharma Ltd, Office/Godown: House No. 03, Street No. 1, 18-KM, Ferozpur, road, Mujahid Colony, Lahore.  ELI-00177	Saba shakeel  Pharm D	Dr. Salman Shakoh Mrs. Lubna Shakoh Syed Sheharyar Ali Syed Shahid Ali Shah JAmal Mustafa Siddiqui Muhammad Mohtashim Aftab Rizwan Atta	Approved.
8.	M/s Global Clinical Cure (Pvt) Ltd, Office/Godown: 44-1, Business Bay, Sector F, DHA, Phase I, Islamabad.  ELI-00196	Sonia Anum  Pham D	Hamza Ali  CEO	Approved
9.	M/s Matora Digionics (Pvt) Ltd,  Office/Godown: 7-A, Canal Bank road, Aziz Avenue, Gulberg-V, Lahore.  ELI-00083	Haifza Atia Mehwish  Pharm D	Muhammad Shakil Nabila Shah Zahid Jamil Rana suhail Ahmed	Approved subject to submission of differential fee for change of godown.

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

**Evaluator: Ammar Ashraf Awan (Deputy Director)**

**CMS CASES:**

<b>Sr. No.</b>	<b>Name of Applicant(s)</b>	<b>Name of Manufacturer</b>	<b>Medical Device</b>	<b>Decision</b>
<b>1.</b>	<p>M/s Safe Health Pakistan Bizcon. Address: Office # 25, 2nd Floor, Dilkusha Chamber, Marston Road, Karachi 74700. Pakistan</p> <p><b>(ELI-00275)</b></p> <p><b>R&amp;I Date:</b> 10-02-2025</p> <p><b>CMS tracking ID:</b> XRX-454-YVVY</p> <p><b>Fee:</b> 25,000/-</p>	<p><b>Manufacturer Name:</b> M/S. Jiangsu Kangbao Medical Equipment Co., Ltd. <b>Address:</b> 78#,North Suzhong Road, Baoying 225800 Yangzhou, Peoples Republic of China.</p> <p><b>LOA</b> <b>Notarization:</b> Yes <b>Valid:</b> 01-10-2029</p> <p>• <b>FSC</b> <b>Legalized:</b> Notarized <b>Issued by:</b> JSMPA, China <b>Valid:</b> 08-12-2025</p> <p><b>ISO – Certificate:</b> <b>Notarization:</b> No <b>Valid till:</b> 31-01-2026</p> <p><b>EC Certificate:</b> Valid till 26-05-2024</p>	<p><b>Brand Name:</b> VENOUS <b>Generic Name:</b> THREE WAY STOPCOCK</p> <p><b>Applied as:</b> Single <b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application:</b> Three-way valve</p> <p><b>Shelf life</b> 5 years</p>	<b>Deferred for submission of Legalized FSC</b>
<b>2.</b>	<p>M/s Siemens Healthcare Private Limited 4th Floor, State Life Building, 15-A, Davis Road, Lahore (ELI-00146)</p> <p><b>R&amp;I Date:</b> 26-11-2020</p> <p><b>CMS tracking ID:</b> YQG-RVE-AZUM</p> <p><b>Fee:</b> 25,000/-</p>	<p><b>Legal Manufacturer:</b> Siemens Healthcare GmbH Henkestr.127, 91052 Erlangen, Germany <b>Manufacturing Site: Facility 1:</b> Siemens Healthineers AG Magnetic Resonance (MR) Henkestr. 127, 91052 Erlangen Germany <b>Facility 2:</b> Siemens Healthineers AG Magnetic Resonance (MR) Allee am Rothelheimpark 2 91052 Erlangen, Germany</p> <p><b>LOA</b> <b>Notarization:</b> Yes <b>Valid:</b> 21-04-2029</p>	<p><b>Brand Name:</b> Magnetom Sola <b>Generic Name:</b> Magnetic resonance diagnostic device</p> <p><b>Applied as:</b> Single <b>Class:</b> B</p> <p><b>Models/Code/sizes (as per FSC &amp; application:</b> 11291455 <b>Service life</b> 10 years</p>	<b>Deferred for submission of Legalized FSC</b>

		<p>• <b>FSC</b>  <b>Legalized:</b> Notarized  <b>Issued by:</b> German Authority  <b>Valid:</b> 08-12-2025</p> <p><b>ISO – Certificate:</b>  <b>Notarization:</b> yes  <b>Valid till:</b> 14-05-2027</p> <p><b>EC Certificate:</b> Valid till 29-09-2025</p>		
3.	<p>M/s Siemens Healthcare Private Limited 4th Floor, State Life Building, 15-A, Davis Road, Lahore (ELI-00146)</p> <p><b>R&amp;I Date:</b> 26-11-2020  <b>CMS tracking ID:</b> 2DX-PGB-TVT6  <b>Fee:</b> 25,000/-</p>	<p><b>Legal Manufacturer:</b>  Siemens Shenzhen Magnetic Resonance Ltd.  <b>Address:</b>  Siemens MRI Center, Gaoxin C. Ave., 2nd, Hi-Tech Industrial Park, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA  <b>Manufacturing Site:</b> Siemens Shenzhen Magnetic Resonance Ltd. <b>Address:</b>  Siemens MRI Center, Gaoxin C. Ave., 2nd, Hi-Tech Industrial Park, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA  <b>LOA</b>  <b>Notarization:</b> Yes  <b>Valid:</b> 20-04-2030</p> <p>• <b>FSC</b>  <b>Legalized:</b> Notarized  <b>Issued by:</b> Provincial Supervision Body, China  <b>Valid:</b> 25-11-2026</p> <p><b>ISO – Certificate:</b>  <b>Notarization:</b> yes  <b>Valid till:</b> 05-07-2027</p> <p><b>EC Certificate:</b> Valid till 08-12-2025</p>	<p><b>Brand Name:</b> Magnetom Semptra  <b>Generic Name:</b> Magnetic resonance diagnostic device  <b>Applied as:</b> Single  <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application):</b> 10840815  <b>Service life</b> 10 years</p>	Deferred for submission of Legalized FSC
4.	<p>M/s Swiss Healthcare 165/BMCHS Sharfabad Karachi (ELI-00566)</p> <p><b>R&amp;I Date:</b> 01-04-2022  <b>CMS tracking ID:</b></p>	<p><b>Manufacturer:</b>  M/s HANGZHOU ROLLMEDD CO, LTD  <b>Address:</b> Room 913, Yuanmao Mansion. No.5 wen'er west Rd, Hangzhou, Zhejiang Province, P.R of China. Post Code: 31002  <b>LOA</b></p>	<p><b>Brand Name:</b> MED  <b>Generic Name:</b> NEBULISER MASK  <b>Applied as:</b> Single  <b>Class:</b> B</p>	Deferred for submission of Valid Legalized FSC issued by the relevant regulatory authority

	LNG-39L-7NWB  <b>Fee:</b> 25,000/-	<b>Notarization:</b> Yes <b>Valid:</b> Dec, 2029  • FSC <b>Legalized:</b> Apostille <b>Issued by:</b> China Chamber of Commerce <b>Valid:</b> 18-09-2026  <b>ISO – Certificate:</b> <b>Notarization:</b> yes <b>Valid till:</b> 2-01-2026  <b>EC Certificate:</b> Valid till 27-01-2024	<b>Models/Code/sizes (as per FSC &amp; application):</b> NRM1002 <b>Service life</b> 5 years	
5.	M/s Otsuka Pakistan Limited 30-B. Sindhi Muslim CoOperative Housing Society, Karachi-74400. (ELI-00243)  <b>R&amp;I Date:</b> 01-04-2022 <b>CMS tracking ID:</b> LNG-39L-7NWB  <b>Fee:</b> 25,000/-	<b>Manufacturer:</b> M/s Otsuka Electronics Co., Ltd., Shiga Plant 1-10, Sasagaoka, Minakuchi-cho, Koka-shi, Shiga, 528-0061, Japan  <b>LOA</b> <b>Notarization:</b> No <b>Issued:</b> 21-12-2023  • FSC <b>Legalized:</b> Legalized <b>Issued by:</b> MHLW, Japan <b>Issued:</b> 14-03-2023  <b>ISO – Certificate:</b> <b>Notarization:</b> No <b>Valid till:</b> 31-01-2028  <b>EC Certificate:</b> Valid till 20-12-2028	<b>Brand Name:</b> POConePlus Infrared Spectrophotometer <b>Generic Name:</b> Point-of-care infrared spectrometry breath analyzer IVID, automated <b>Applied as:</b> System <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application):</b> POConePlus-AS10 Auto Sampler <b>Service life</b> 6 years	Deferred for submission of LOA, ISO & CE certificate. The name of manufacturer mentioned in LOA is different form that mentioned on FSC
6.	M/s IBL HealthCare Limited Section A, 2nd Floor, One IBL Centre, Plot# 1, Block 7 & 8, Dehli Mercantile Muslim Cooperative Housing Society (DMCHS), Tipu Sultan Road, Off. Shahrah-e-Faisal, Karachi. (ELI-00119)  <b>R&amp;I Date:</b> 22-02-2021 <b>CMS tracking ID:</b>	<b>Manufacturer:</b> M/s Shandong Weigao Group Medical Polymer Co., Ltd <b>Address:</b> No.18 Xingshan Road, Torch Hi-tech Science Park, 264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA <b>LOA</b> <b>Notarization:</b> Yes <b>Issued:</b> 08-11-2026  • FSC <b>Legalized:</b> Apostille <b>Issued by:</b> China Chamber of	<b>Brand Name:</b> WEGO <b>Generic Name:</b> Blood Collection Tubes for Single us <b>Applied as:</b> Single <b>Class:</b> B  <b>Models/Code/sizes (as per FSC &amp; application):</b> As per FSC  <b>Service life</b> 2 years	Deferred for the following: FSC issued by China Chamber of commerce is submitted. While the FSC issued by German authority declares the manufacturing site different form that mentioned in application form.

	UJZ-EMX-WSPZ <b>Fee:</b> 25,000/-	Commerce <b>Valid:</b> 25-04-2026  <b>FSC from German Authority:</b> <b>Legalization:</b> Apostille <b>Issued date:</b> 31-03-2025  <b>ISO – Certificate:</b> <b>Notarization:</b> yes <b>Valid till:</b> 30-09-2026  <b>EC Certificate:</b> N/A		
--	--------------------------------------	---	--	--



**Imported Product Agenda (Application submitted in hard dossiers):**

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	<p><b>Intek Corporation Pvt Ltd</b> <b>ELI-00794</b></p> <p><b>Validity</b> <b>19-10-2026</b></p> <p><b>R&amp;I Date:</b> 18-07-2025</p> <p><b>Fee:</b> Rs 62030 Slip No:0481599214 Date:18-7-2025</p> <p>Slip no (codes fee) :7133353627 Rs:135,030</p> <p>Date: 18-7-2025</p> <p>Total Fee: Rs.197000/-</p> <p>(Total Sizes applied: 47)</p> <p>As per Fee SRO family fee is Rs. 100,000/- (for 20 sizes) &amp; Rs. 5000/- extra for each sizes. For 20 sizes: Fee Rs. 100,000/- &amp; for remaining 27 sizes fee is : 5000x27= 135,000/-</p> <p>Total fee for different sizes are: 100,000 + 135,000 = 235,000/-</p>	<p>OrbusNeich Medical (Shenzhen) Co., Ltd., No.1 Jinkui Road, 518038 Futian Free Trade Zone Shenzhen China</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 31-12-2028</p> <p>• <b>FSC</b> <b>Type:</b> original <b>Issued By:</b> Swiss Agency For Therapeutic Products ( Swiss Medic) <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 03-02-2026</p> <p>• <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 26-3-2026</p> <p>• <b>CE certificate (FQA):</b> <b>Type:</b> <b>Notarization:</b> Yes <b>Validity:</b> 20-4-2023</p> <p>• <b>CE certificate (Design Examination):</b> <b>Type:</b> <b>Notarization:</b> Yes <b>Validity:</b> 26-5-2024</p>	<p><b>Sapphire 3</b> Coronary Dilatation Catheter.</p> <p>Applied as: Family</p> <p>Class: D</p> <p>Shelf Life: 24 months</p> <p><b>Models/Code/sizes:</b> 208-053-6J 225-103-6J 208-103-6J 225-123-6J 210-053-6J 225-153-6J 210-083-6J 225-203-6J 210-103-6J 225-303-6J 210-153-6J 227-103-6J 212-053-6J 227-153-6J 212-083-6J 227-203-6J 212-103-6J 230-103-6J 212-153-6J 230-123-6J 215-103-6J 230-153-6J 215-123-6J 230-203-6J 215-153-6J 230-303-6J 215-203-6J 232-103-6J 217-103-6J 232-153-6J 217-153-6J 232-203-6J 217-203-6J 235-103-6J 220-103-6J 235-153-6J</p>	<p>Approved 39 codes mentioned in the FSC.</p> <p>The firm is advised to select 39 codes out of applied one.</p>

			220-123-6J 235-203-6J 220-153-6J 235-303-6J 220-203-6J 240-103-6J 222-103-6J 240-153-6J 222-153-6J 240-203-6J 222-203-6J	
2.	<b>Intek Corporation Pvt Ltd</b> <b>ELI-00794</b>  <b>Validity</b> <b>19-10-2026</b>  <b>R&amp;I Date:</b> 18-07-2025 <b>Fee:</b> Rs 62030 Slip No:6335343868 Date:18-7-2025  Slip no (codes fee) :0662689801 Rs:200,030  Date: 18-7-2025  Total Fee: Rs.262000/-  (Total Sizes applied: 58 while only 30 sizes are available in the FSC)	OrbusNeich Medical (Shenzhen) Co., Ltd., No.1 Jinkui Road, 518038 Futian Free Trade Zone Shenzhen China  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 31-12-2028 • <b>FSC</b> <b>Type:</b> original <b>Issued By:</b> Swiss Agency For Therapeutic Products (Swiss Medic) <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 16-04-2028  • <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 26-3-2026  <b>EU Technical documentation assessment certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 31-7-2029  <b>EU Quality Management System certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 25-4-2028	<b>Sapphire NC Ultra</b> Coronary Dilatation Catheter.  Applied as: Family  Class: D  Shelf Life: 24 months  Models/Code/sizes: 1.75 x 10mm, 1.75 x 12mm, 1.75 x 15mm, 1.75 x 18mm, 2.0 x 8mm, 2.0 x 10mm, 2.0 x 12mm, 2.0 x 15mm, 2.0 x 18mm, 2.25 x 8mm, 2.25 x 10mm, 2.25 x 12mm, 2.25 x 15mm, 2.25 x 18mm, 2.5 x 8mm, 2.5 x 10mm, 2.5 x 12mm, 2.5 x 15mm, 2.5 x 18mm, 2.75 x 8mm, 2.75 x 10mm, 2.75 x 12mm, 2.75 x 15mm, 2.75 x 18mm, 3.0x8mm, 3.0 x 10mm, 3.0 x 12mm, 3.0 x 15mm, 3.0 x 18mm, 3.25 x 8mm,	Approved 30 codes mentioned in the FSC.

3.	<p><b>Intek Corporation Pvt Ltd</b> <b>ELI-00794</b></p> <p><b>Validity</b> <b>19-10-2026</b></p> <p><b>R&amp;I Date:</b> 08-07-2025</p> <p><b>Fee:</b> Rs 62030 Slip No: 263246980794 Date:07-7-2025</p>	<p>Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing, China 102200</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Issuance Date:</b> 13-06-2025 <b>Validity date:</b> Not mentioned</p> <p>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Beijing Drug Administration. <b>Legalization/ Apostille:</b> No <b>Validity:</b> 09-01-2027</p> <p>• <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 6-3-2026</p> <p>• <b>CE certificate (FQA):</b> <b>Not provided</b></p>	<p><b>Thorcrack</b></p> <p>Peripheral IVL Balloon Dilatation Catheter</p> <p>Applied as: Kit</p> <p>Class: C Shelf Life: 24 months</p> <p><b>Models/Code/sizes:</b> LPAW3040, LPAW3060, LPAW3540, LPAW3560, LPAW4040, LPAW4060, LPAW4540, LPAW4560, LPAW5040, LPAW5060, LPAW5540, LPAW5560, LPAW6040, LPAW6060, LPAWG540, LPAW6560, LPAW7040, LPAW7060</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSC of any Reference Country or vaild notarized CE (FQA)</li> <li>2. Fee for family as per current SRO.</li> <li>3. Valid Legalized FSc of the country of origin.</li> <li>4. Valid notarized ISO 13485 &amp; LOA.</li> </ol>
4.	<p>Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi.</p> <p>ELI-00203</p> <p><b>Validity</b> <b>19-10-2023</b></p> <p>Copy of evidence of Renewal Submitted on 19-09-2023</p> <p><b>R&amp;I Date:</b> 08-04-2025</p> <p><b>Fee:</b> Rs 100,000/- Slip No:89173941 Date:08-04-2025</p>	<p>TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8- P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt.</p> <p><b>LOA: Not provided</b> <b>Type:</b> <b>Notarization:</b> No <b>Validity date:</b></p> <p><b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Egyptian drug Authority <b>Legalization/ Apostille:</b> No <b>Validity:</b> 25-03-2026</p>	<p><b>Egysteel Mono</b> Stainless Steel Wire, monofilament (316LVM)</p> <p>Applied as: Single</p> <p>Class: D Shelf Life: 24 months</p> <p><b>Models/Code/sizes:</b> CN9579, CN9679, CN9779, CN9478, CN9578, CN9678, CN9778, CN9229, CN9228, CN9478N, CN9578N, CN9577, CN9677, CN9777, CN9477, CN9576, CN9676, CN9776, CN9227, CN9226, CN9579TR, CN9679TR, CN9779TR, CN9578TR, CN9678TR, CN9778TR,</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSC of any Reference Country or vaild notarized CE (FQA) plus Design Examination Certificate wherein the applied product shall be included in its scope.</li> <li>2. Fee for family as per current SRO as 26 codes have been applied.</li> <li>3. Valid Legalized FSc of the country of origin with codes applied.</li> <li>4. Valid notarized ISO 13485 &amp; LOA.</li> </ol>

		<p>• <b>ISO 13485:</b> Type: Copy Notarization: No Validity: 13-02-2028</p> <p>• <b>CE certificate (FQA):</b> Type: Copy Notarization: No Validity: 26-05-2024 with extension letter.</p> <p>• <b>CE certificate (Design Examination):</b> Type: Copy Notarization: No Validity: 24-02-2024 with extension letter.</p>		
5.	<p>Unimed Technologies, 130-B, 2nd Floor, CCA, Block A, Khayaban-e-Ameen, Lahore</p> <p>ELI-01351</p> <p><b>Validity</b> <b>10-12-2029</b></p> <p><b>R&amp;I Date:</b> 02-06-2025</p> <p><b>Fee:</b> Rs 62,000/- Slip No:69456502 Date:21-05-2025</p>	<p>Eyekon Medical, Inc 2451 Enterprise Rd., Clearwater, Florida 33763, USA.</p> <p><b>LOA</b> Type: Copy Notarization: Yes Validity date: 31-12-2025.</p> <p><b>Export certificate instead of FSc</b> Type: Original Issued By: USFDA Legalization/ Apostille: Yes Validity: 16-03-2025</p> <p>• <b>ISO 13485:</b> Type: Copy Notarization: No Validity: 01-02-2026</p> <p>• <b>CE certificate (FQA):</b> Type: Copy Notarization: No Validity: 05-07-2020</p>	<p><b>ACURUS</b></p> <p>Hydrophilic Acrylic Intraocular Lens</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Shelf Life: 60 months</p> <p>Models/Code/sizes: <b>AR25</b></p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the country of origin wherein the product shall be on Free Sale.</li> <li>2. Valid notarized CE (FQA), ISO 13485.</li> </ol>
6.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p><b>Validity</b></p>	<p><b>Legal manufacturer</b> Origin Medical Devices Inc. Address: 23 Corporate Plaza Suite 150, Newport Beach CA 92660 USA. <b>Manufacturing Site:</b></p>	<p>Origin Panther 3 Ventilator with Accessories</p> <p><b>Generic Name:</b> Lung Ventilator (Respirator)</p> <p><b>Applied as:</b> Single</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the Reference Country with applied</li> </ol>

	<p>19-10-2023 Copy of evidence of Renewal Submitted on 11-08-2023</p> <p>R&amp;I Date: 16-06-2025 Fee: 62,000/- Slip # 069928506</p>	<p>Origin Medical Device Hunagry KFT H2600 VAC, Blegakert U.5. Hungary.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 30-04-2027</p> <p>• <b>FSC (Certificate to Foreign Govt) No. 337-10-2024-1</b> <b>Type:</b> original <b>Issued by:</b> USFDA <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 17-10-2026</p> <p>• <b>ISO 13485 (for Legal Manufacturer)</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 01-03-2028</p>	<p><b>Class:</b> C <b>Models/Code/sizes (as per FSC &amp; application Model):</b></p> <p><b>Shelf Life:</b> - NA</p>	<p>codes for the product &amp; their accessories or valid Legalized FSc of the country of origin with applied codes for the product &amp; their accessories along with CE (FQA) certificate.</p> <p>2. Valid notarized ISO 13485 of the manufacturing Site.</p> <p>5. Fee for System as per current SRO.</p>
7.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) <b>Validity</b> 19-10-2023 Copy of evidence of Renewal Submitted on 11-08-2023</p> <p>R&amp;I Date: 11-06-2025 Fee: 62,000/- Slip # 969947348345</p>	<p><b>Legal manufacturer</b> Origin Medical Devices Inc. Address: 23 Corporate Plaza Suite 150, Newport Beach CA 92660 USA. <b>Manufacturing Site:</b> Origin Medical Device Hunagry KFT H2600 VAC, Blegakert U.5. Hungary.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 30-04-2027</p> <p>• <b>FSC (Certificate to Foreign Govt) No. 337-10-2024-1</b> <b>Type:</b> original <b>Issued by:</b> USFDA <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 17-10-2026</p>	<p>Origin Panther 5 Ventilator <b>Generic Name:</b> Lung Ventilator (Respirator) <b>Applied as:</b> Single <b>Class:</b> C <b>Models/Code/sizes (as per FSC &amp; application Model):</b></p> <p><b>Shelf Life:</b> - NA</p>	<p>Deferred for submission of the followings:</p> <p>1. Valid Legalized FSc of the Reference Country with applied codes for the product or valid Legalized FSc of the country of origin with applied codes for the product along with CE (FQA) certificate.</p> <p>2. Valid notarized ISO 13485 of the manufacturing Site.</p> <p>3. Fee for System as per current SRO.</p>

		<b>• ISO 13485 (for Legal Manufacturer)</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 01-03-2028		
8.	M/s United Healthcare, Plot No. 330/B, 2nd Floor, DMCH, Bahadurabad, Karachi <b>(ELI-00293)</b>  <b>Validity</b> <b>22-10-2023</b> Copy of evidence of Renewal Submitted on 26-06-2023  <b>R&amp;I Date:</b> 10-07-2025 <b>Fee:</b> Rs 62030 Slip No:224546458 Date:30-06-2025	<b>Legal Manufacturer:</b> Intco Medical (HK) Co. Limited, <b>Address as FSC (UK):</b> Unit 04, 7/F Bright Way Tower, No. 33 Mong Kok Road. KL, Hong Kong. <b>Address as Form-7A:</b> Flat/RM 19C, Lockhart Centre, 301-307 Lockhart Road, Wan Chai, Hong Kong. P.R. China. <b>Manufacturing site:</b> Shanghai Intco Electrode Manufacturing Co., Ltd., No. 1358 Hubin Road, Fengxian District 201417 Shanghai. P. R. China.  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Issued Date:</b> 15-06-2025 <b>Validity date:</b> Not mentioned  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> MHRA, UK. <b>Legalization/ Apostille:</b> No <b>Issued Date:</b> 14-11-2018 <b>Validity date:</b> Not mentioned  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Chamber of Commerce for Import & Export of Medicines & Health Products. <b>Legalization/ Apostille:</b> No <b>Validity date:</b> 08-05- 2027	<b>Safety- Electrosurgical Pencils</b> Disposable Electrosurgical Pencils.  Applied as: Family  Class: C  Shelf Life: 36 months  <b>Models/Code/sizes:</b> <b>EP01, EP01-T, EP02,</b> <b>EP03,EP04</b>	Deferred for submission of the followings:  1. Valid Legalized FSc of the Reference Country with applied codes for the product or valid Legalized FSc of the country of origin issued by the concerned regulatory authority with applied codes along with CE (FQA) certificate. 2. Valid notarized ISO 13485 & LOA. 3. Fee for Family as per current SRO. 4. Justification of the difference in the address of legal manufacturer in FSC (MHRA, UK) & Form-7A.

		<ul style="list-style-type: none"> <li>• <b>ISO 13485 (for Legal as well as for Site):</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 15-12-2025</li> <li>• <b>CE certificate (FQA):</b> <b>Not provided.</b></li> </ul>		
9.	<p>M/s United Healthcare, Plot No. 330/B, 2nd Floor, DMCH, Bahadurabad, <b>Karachi</b> <b>(ELI-00293)</b></p> <p><b>Validity</b> <b>22-10-2023</b> Copy of evidence of Renewal Submitted on 26-06-2023</p> <p><b>R&amp;I Date:</b> 10-07-2025 <b>Fee:</b> Rs 62030 Slip No:11103797321 Date:30-06-2025</p>	<p><b>Legal Manufacturer:</b> Intco Medical (HK) Co. Limited, <b>Address as FSC (UK):</b> Unit 04, 7/F Bright Way Tower, No. 33 Mong Kok Road. KL, Hong Kong. <b>Address as Form-7A:</b> Flat/RM 19C, Lockhart Centre, 301-307 Lockhart Road, Wan Chai, Hong Kong. P.R. China. <b>Manufacturing site:</b> Shanghai Intco Electrode Manufacturing Co., Ltd., No. 1358 Hubin Road, Fengxian District 201417 Shanghai. P. R. China.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Issued Date:</b> 15-06-2025 <b>Validity date:</b> Not mentioned</p> <p>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> MHRA, UK. <b>Legalization/ Apostille:</b> No <b>Issued Date:</b> 14-11-2018 <b>Validity date:</b> Not mentioned</p> <p>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Chamber of Commerce for Import &amp; Export of Medicines &amp; Health Products. <b>Legalization/ Apostille:</b> No <b>Validity date:</b> 08-05- 2027</p>	<p><b>Safety- Electrosurgical Disposable Grounding Pads</b></p> <p>Electrosurgical Grounding Pads Applied as: Family Class: C Shelf Life: 36 months</p> <p><b>Models/Code/sizes:</b> <b>GP01, GCO1, GP02, GCO2, GP03, GCO3, GP04, GC04, GI01, GI02, GI03, GIO4.</b></p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the Reference Country with applied codes for the product or valid Legalized FSc of the country of origin issued by the concerned regulatory authority with applied codes along with CE (FQA) certificate.</li> <li>2. Valid notarized ISO 13485 &amp; LOA.</li> <li>3. Fee for Family as per current SRO.</li> <li>4. Justification of the difference in the address of legal manufacturer in FSC (MHRA, UK) &amp; Form-7A.</li> </ol>

		<ul style="list-style-type: none"> <li>• <b>ISO 13485 (for Legal as well as for Site):</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 15-12-2025</li> <li>• <b>CE certificate (FQA):</b> <b>Not provided.</b></li> </ul>		
10.	<p>Bio Indus, B-526, B Satellite Town, Rawalpindi.</p> <p>ELI-00979 <b>Validity</b> <b>20-10-2027</b></p> <p><b>R&amp;I Date:</b> 15-07-2025 <b>Fee:</b> Rs 62000 Slip No:021675947123 Date:10-7-2025</p>	<p>Singuway Biotech Inc. B1302 , Life Science Park, ShenchengTou Innovation factory, Julongshan A Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, 518122, China. <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> Not mentioned. Issued Date: 13-07-2025.</p> <ul style="list-style-type: none"> <li>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Chamber of Commerce for Import &amp; Export of Medicines &amp; Health Products. <b>Legalization/</b> Apostille: No <b>Validity date:</b> 09-04- 2027</li> <li>• <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 11-2-2026</li> <li>• <b>CE certificate (FQA):</b> <b>Not provided</b></li> <li>• <b>CE certificate (Design Examination):</b> <b>Not provided.</b></li> </ul>	<p><b>Nucleic Acid Detection Kit for Hepatitis B Virus (PCR-Fluorescence Probing)</b></p> <p>Nucleic Acid Detection Kit for Hepatitis B Virus (PCR-Fluorescence Probing) Applied as: Kit</p> <p>Class: D</p> <p>Shelf Life: 12 months</p> <p><b>Models/Code/sizes:</b> <b>HBV002</b></p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the Reference Country with applied code for the product or valid Legalized FSc of the country of origin issued by the concerned regulatory authority with applied codes along with CE (FQA) certificate plus Design Examination certificate.</li> <li>2. Valid notarized ISO 13485 &amp; LOA.</li> <li>3. Brand name of the product or its Justification.</li> </ol>
11.	<p>Bio Indus, B-526, B Satellite Town, Rawalpindi.</p> <p>ELI-00979</p>	<p>Singuway Biotech Inc. B1302 , Life Science Park, ShenchengTou Innovation factory, Julongshan A Road, Xiuxin Community,</p>	<p><b>Nucleic Acid Detection Kit for Hepatitis C Virus (PCR-Fluorescence Probing)</b></p> <p>Nucleic Acid Detection Kit</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the</li> </ol>



	<p><b>Validity</b> <b>20-10-2027</b></p> <p><b>R&amp;I Date:</b> 15-07-2025</p> <p><b>Fee:</b> Rs 62000 Slip No:8259638787 Date:10-7-2025</p>	<p>Kengzi Street, Pingshan District, Shenzhen City, 518122, China.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> Not mentioned. Issued Date: 13-07-2025.</p> <p>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Chamber of Commerce for Import &amp; Export of Medicines &amp; Health Products. <b>Legalization/ Apostille:</b> No <b>Validity date:</b> 09-04-2027</p> <p><b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 11-2-2026</p> <p>• <b>CE certificate (FQA):</b> <b>Not provided</b></p> <p>• <b>CE certificate (Design Examination):</b> <b>Not provided.</b></p>	<p>for Hepatitis C Virus (PCR-Fluorescence Probing) Applied as: Kit</p> <p>Class: D</p> <p>Shelf Life: 12 months</p> <p><b>Models/Code/sizes:</b> <b>HCV001</b></p>	<p>Reference Country with applied code for the product or valid Legalized FSc of the country of origin issued by the concerned regulatory authority with applied codes along with CE (FQA) certificate plus Design Examination certificate.</p> <p>2. Valid notarized ISO 13485 &amp; LOA.</p> <p>3. Brand name of the product or its Justification.</p>
12.	<p>Ayyan Molecular Products, 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town ELI-00240</p> <p><b>Validity</b> <b>04-07-2026</b></p> <p><b>R&amp;I Date:</b> 02-07-2025</p> <p><b>Fee:</b> Rs 62000 Slip No:2047476507 Date:30-06-2025</p>	<p>Ustar Biotechnologies (Hangzhou) Ltd., Bldg 1,2&amp;4, 611 Dongguan Road, Binjiang District 310053 Hangzhou Zhejiang Province, People's Republic of China.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 3-06-2028</p> <p>• <b>FSC</b> <b>Type:</b> original <b>Issued By:</b> Spain <b>Legalization/ Apostille:</b> Yes (from china) Date of Issue: 29-05-2023 <b>Validity:</b> Not mentioned</p>	<p><b>EasyNAT MTC/NTM Assay</b></p> <p>Mycobacterium Tuberculosis complex &amp; Non-Tuberculous myco bacteria Assay</p> <p>Applied as: Single</p> <p>Class: C Shelf Life: 12 months</p> <p><b>Models/Code/sizes:</b> <b>U201002-20</b></p>	<p>Approved</p>

		<p>• <b>ISO 13485:</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity:</b> 10-7-2026</p> <p>• <b>EU QMS certificate:</b>  <b>Type:</b> copy  <b>Notarization:</b> No  <b>Validity:</b> 10-07-2028</p>		
13.	<p>Ayyan Molecular Products, 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town ELI-00240</p> <p><b>Validity</b>  <b>04-07-2026</b></p> <p><b>R&amp;I Date:</b>  02-07-2025</p> <p><b>Fee:</b>  Rs 62000  Slip No:2177661219  Date:30-06-2025</p>	<p>Ustar Biotechnologies (Hangzhou) Ltd., Bldg 1,2&amp;4, 611 Dongguan Road, Binjiang District 310053 Hangzhou Zhejiang Province, People's Republic of China.</p> <p><b>LOA</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity date:</b> 3-06-2028</p> <p>• <b>FSC</b>  <b>Type:</b> original  <b>Issued By:</b> Spain  <b>Legalization/ Apostille:</b> Yes (<b>from china</b>)  Date of Issue: 29-05-2023  <b>Validity:</b> Not mentioned</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity:</b> 10-7-2026</p> <p>• <b>EU QMS certificate:</b>  <b>Type:</b> copy  <b>Notarization:</b> No  <b>Validity:</b> 10-07-2028</p>	<p><b>EasyNAT MTC Assay</b></p> <p>Mycobacterium Tuberculosis complex Assay</p> <p>Applied as: Single</p> <p>Class: C  Shelf Life: 12 months</p> <p><b>Models/Code/sizes:</b>  <b>U20103</b></p>	Approved
14.	<p>Health Tec, H. No. 10-B, St.24, Valley Road, Westridge 1, Rawalpindi ELI-00046</p> <p><b>Validity</b>  <b>03-08-2023</b></p> <p>Copy of evidence of Renewal Submitted on 22-06-2023</p>	<p>Dongguan TT Medical, Inc.  R401, Building B, No. 8, 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China.</p> <p><b>Address as per FSC (Netherlands)</b></p> <p>Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial</p>	<p><b>Dilator SC</b></p> <p>Coronary Dilatation Balloon Catheter (Semi-Compliance)</p> <p>Applied as:</p> <p>Class: D  Shelf Life: 24 months</p> <p><b>Models/Code/sizes:</b>  SD20010  SD22510</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSc of the Reference Country with applied brand name &amp; codes for the product.</li> <li>Justification that the applied brand name is available in the country of origin.</li> </ol>

	<p><b>R&amp;I Date:</b> 15-07-2025</p> <p><b>Fee:</b> Rs 62000</p> <p>Slip No:4936673857</p> <p>Date:10-07-2025</p>	<p>Park, Dongguan, Guangdong, 523808, PR China.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 07-05-2030</p> <p>• <b>FSC</b> <b>Type:</b> original <b>Issued By:</b> Netherlands <b>Legalization/ Apostille:</b> Yes Date of Issue: 31-03-2025 <b>Validity:</b> 31-12-2027</p> <p>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> China <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 08-04-2026</p> <p>• <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 19-06-2027</p>	<p>SD25010 SD27510 SD30010 SD32510 SD35010 SD37510 SD40010 SD20014 SD22514 SD25014 SD27514 SD30014 SD32514 SD35014 SD37514 SD40014 SD20018 SD22518 SD25018 SD27518 SD30018 SD32518 SD35018 SD37518 SD40018 SD20022 SD20026 SD22522 SD22526 SD25022 SD25026 SD27522 SD27526 SD30022 SD30026 SD32522 SD32526 SD35022 SD35026 SD37522 SD37526 SD40022 SD40026 SD20030 SD22530 SD25030 SD27530 SD30030 SD32530 SD35030 SD37530 SD40030 SD20034</p>	<p>3. Valid notarized ISO 13485, CE (FQA), Design Examination Certificate &amp; LOA.</p> <p>4. Fee for Family as per current SRO.</p> <p>Personal Hearing shall also be given the applicant with respect to the product (with other brand name) authorization to two other parties M/s Cure Lahore &amp; M/s Cardioline Systems.</p>
--	---	---	--	--

			SD20038 SD22534 SD22538 SD25034 SD25038 SD27534 SD27538 SD30034 SD30038 SD32534 SD32538 SD35034 SD35038 SD37534 SD37538 SD40034 SD40038	
15.	<p>Health Tec, H. No. 10-B, St.24, Valley Road, Westridge 1, Rawalpindi</p> <p>ELI-00046</p> <p><b>Validity</b> <b>03-08-2023</b> Copy of evidence of Renewal Submitted on 22-06-2023</p> <p><b>R&amp;I Date:</b> 15-07-2025 <b>Fee:</b> Rs 62000 Slip No:0640011362 Date:10-07-2025</p>	<p>Dongguan TT Medical, Inc. R401, Building B, No. 8, 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China.</p> <p><b>Address as per FSC (Netherlands)</b></p> <p>Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan, Guangdong, 523808, PR China.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 07-05-2030 <b>• FSC</b> <b>Type:</b> original <b>Issued By:</b> Netherlands <b>Legalization/ Apostille:</b> Yes Date of Issue: 31-03-2025 <b>Validity:</b> 31-12-2027 <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> China <b>Legalization/ Apostille:</b> Yes</p>	<p><b>Narrow CTO</b> Coronary Dilatation Balloon Catheter Applied as:  Class: D Shelf Life: 24 months</p> <p><b>Models/Code/sizes:</b> PD10010 PD10014 PD10018 PD10022 PD10026 PD10030 PD10034 PD10038 PD12510 PD12514 PD12518 PD12522 PD12526 PD12530 PD12534 PD12538 PD15010 PD15014 PD15018 PD15022 PD15026 PD15030 PD15034 PD15038 PD17510 PD17514</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSc of the Reference Country with applied brand name &amp; codes for the product.</li> <li>Justification that the applied brand name is available in the country of origin.</li> <li>Valid notarized ISO 13485, CE (FQA), Design Examination Certificate &amp; LOA.</li> <li>Fee for Family as per current SRO.</li> </ol> <p>Personal Hearing shall also be given the applicant with respect to the product (with other brand name) authorization to two other parties M/s Cure Lahore &amp; M/s Cardioline Systems.</p>

		<b>Validity:</b> 08-04-2026  <b>• ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 19-06-2027	PD17518 PD17522 PD17526 PD17530 PD17534 PDI7538	
16.	Health Tec, H. No. 10-B, St.24, Valley Road, Westridge 1, Rawalpindi  ELI-00046  <b>Validity</b> <b>03-08-2023</b> Copy of evidence of Renewal Submitted on 22-06-2023  <b>R&amp;I Date:</b> 15-07-2025 <b>Fee:</b> Rs 62000 Slip No:238658844 Date:10-07-2025	Dongguan TT Medical, Inc. R401, Building B, No. 8, 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China. <b>Address as per FSC</b> <b>(Netherlands)</b>  Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan, Guangdong, 523808, PR China.  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 07-05- 2030 <b>• FSC</b> <b>Type:</b> original <b>Issued By:</b> Netherlands <b>Legalization/ Apostille:</b> Yes Date of Issue: 31-03-2025 <b>Validity:</b> 31-12-2027  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> China <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 08-04-2026  <b>• ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 19-06-2027	<b>Max-NC</b> Coronary Dilatation Balloon Catheters (Non- Compliance)  Applied as:  Class: D Shelf Life: 24 months  <b>Models/Code/sizes:</b> NC20010 NC22510 NC25010 NC27510 NC30010 NC32510 NC35010 NC37510 NC40010 NC20014 NC22514 NC25014 NC27514 NC30014 NC32514 NC35014 NC37514 NC40014 NC20018 NC22518 NC25018 NC27518 NC30018 NC32518 NC35018 NC37518 NC40018 NC20022 NC22522 NC25022 NC27522 NC30022 NC32522 NC35022 NC37522	Deferred for submission of the followings:  1. Valid Legalized FSc of the Reference Country with applied brand name & codes for the product. 2. Justification that the applied brand name is available in the country of origin. 3. Valid notarized ISO 13485, CE (FQA), Design Examination Certificate & LOA. 4. Fee for Family as per current SRO.  Personal Hearing shall also be given the applicant with respect to the product (with other brand name) authorization to two other parties M/s Cure Lahore & M/s Cardioline Systems.

			NC40022 NC20026 NC22526 NC25026 NC27526 NC30026 NC32526 NC35026 NC37526 NC40026 NC20030 NC22530 NC25030 NC27530 NC30030 NC32530 NC35030 NC37530 NC40030 NC20034 NC22534 NC25034 NC27534 NC30034 NC32534 NC35034 NC37534 NC40034 NC20038 NC22538 NC25038 NC27538 NC30038 NC32538 NC35038 NC37538 NC40038	
17.	Health Tec, H. No. 10-B, St.24, Valley Road, Westridge 1, Rawalpindi  ELI-00046  <b>Validity</b> <b>03-08-2023</b> Copy of evidence of Renewal Submitted on 22-06-2023  <b>R&amp;I Date:</b> 15-07-2025	Dongguan TT Medical, Inc. R401, Building B, No. 8, 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China. <b>Address as per FSC</b> <b>(Netherlands)</b>  Bld-1, 1 Taoyuan Road, Songshan Lake National High-Tech Industrial Park, Dongguan,	<b>Paxci DCB</b>  Paclitaxel Coated Balloon Catheters  Applied as:  Class: D Shelf Life: 24 months  <b>Models/Code/sizes:</b> PCB20010 PCB22510 PCB25010 PCB27510 PCB30010	Deferred for submission of the followings:  1. Valid Legalized FSc of the Reference Country with applied brand name & codes for the product. 2. Justification that the applied brand name is available in the country of origin. 3. Valid notarized ISO 13485, CE (FQA),

	<b>Fee:</b> Rs 62000 Slip No:69230049319 Date:10-07-2025	Guangdong, 523808, PR China.  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 07-05-2030 • <b>FSC</b> <b>Type:</b> original <b>Issued By:</b> Netherlands <b>Legalization/ Apostille:</b> Yes Date of Issue: 31-03-2025 <b>Validity:</b> 31-12-2027  • <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> China <b>Legalization/ Apostille:</b> Yes <b>Validity:</b> 08-04-2026  • <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 19-06-2027	PCB32510 PCB35010 PCB37510 PCB40010 PCB20014 PCB22514 PCB25014 PCB27514 PCB30014 PCB32514 PCB35014 PCB37514 PCB40014 PCB20018 PCB22518 PCB25018 PCB27518 PCB30018 PCB32518 PCB35018 PCB37518 PCB40018 PCB20022 PCB22522 PCB25022 PCB27522 PCB30022 PCB32522 PCB35022 PCB37522 PCB40022 PCB20026 PCB22526 PCB25026 PCB27526 PCB30026 PCB32526 PCB35026 PCB37526 PCB40026 PCB20030 PCB22530 PCB25030 PCB27530 PCB30030 PCB32530 PCB35030 PCB37530 PCB40030 PCB20034 PCB22534 PCB25034 PCB27534	Design Examination Certificate & LOA. 4. Fee for Family as per current SRO.  Personal Hearing shall also be given the applicant with respect to the product (with other brand name) authorization to two other parties M/s Cure Lahore & M/s Cardioline Systems.
--	---	--	--	---

			PCB30034 PCB32534 PCB35034 PCB37534 PCB40034 PCB20038 PCB22538 PCB25038 PCB27538 PCB30038 PCB32538 PCB35038 PCB37538 PCB40038	
18.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200)  <b>Validity</b> <b>16-04-2029</b>  <b>R&amp;I Date:</b> 07-07-2025 <b>Fee:</b> Rs 100,000 Slip No: 33316897026 Date:30-06-2025	<b>Legal Manufacturer:</b> BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom <b>Manufacturing site:</b> BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria.  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 01-03-2027 • <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> MHRA, UK <b>Legalization/ Apostille:</b> No <b>Validity:</b> 06-10-2028  • <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 8-4-2027	<b>Brand Name:</b> BTL-4000 Smart /4000 Premium (Electro Therapy)  <b>Generic Name:</b> Electrotherapy Device  Applied as: Family  Class: C Shelf Life: 12 months  <b>Models/Code/sizes:</b> BTL-4620 Smart BTL-4620 Premium BTL-4625 Smart BTL-4625 Premium	Deferred for submission of the followings:  1. Valid Legalized FSc of the Reference Country or valid Legalized FSc of country of origin with CE (FQA). 2. Valid notarized ISO 13485 & LOA. 3. Justification of grouping as family.
19.	M/s Alpha 6 Private Limited, Plot No. 43, 1st Floor, Tech Tower, FECHS, North Commercial, E11/2, Islamabad (ELI-01354)  <b>Validity</b> <b>10-12-2029</b>	Demophoriosis Ltd., <b>Address:</b> 196 Archbishop Mararios III Ave. 3030 Limassol, Cyprus.  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 28-01-2028 • <b>FSC</b>	<b>Brand Name:</b> Demotek, Pediatric Blood Bags, BBQ240P <b>Generic Name:</b> Pediatric Blood Bags Pediatric Bag Quintuple CPDA-1 4x100ml Transfer bag, with needle protector  Applied as: Single	Deferred for submission of the followings:  1. Valid Legalized FSc of the Reference Country with applied codes or valid Legalized FSc of country of origin with applied



	<b>R&amp;I Date:</b> 17-06-2025 <b>Fee:</b> Rs 62,000 Slip No: 7933132370 Date:13-06-2025	<b>Type:</b> Copy <b>Issued By:</b> Medical And Public Health Services Cyprus Medical Devices Competent Authority  <b>Legalization/ Apostille:</b> No <b>Date of issuance: 17-06-2024</b> <b>Validity:</b> Not mentioned.  <b>• ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 24-5-2027	Class: C Shelf Life: 36 months  <b>Models/Code/sizes:</b> BBQ240P	codes & CE (FQA). 2. Valid notarized ISO 13485 & LOA.
20.	Taj Diagnostics, Office No. S-2, 2nd Floor, New Jama Mall, M.A. Jinnah Road, Saddar, Karachi  ELI-00589  <b>Validity</b> <b>16-08-2025</b>  <b>R&amp;I Date:</b> 15-07-2025 <b>Fee:</b> Rs 62,000 Slip No: 61735113944 Date:28-04-2025	Genesign Biotech (Xiamen) co ltd Address: Unit 03,8th Floor, Building B14, Xiamen Biomedical Industrial Park ,2076 Wengjiao West Road, Haicang District, Xiamen, Fujian , China  <b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Date of Issuance:</b> Not readable <b>Validity date:</b> For five year <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Spanish Agency of Medicines and Medical Devices <b>Legalization/ Apostille:</b> No <b>Date of issuance: 30-01-2024</b> <b>Validity:</b> Not mentioned.  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> China Chamber of Commerce <b>Legalization/ Apostille:</b> No <b>Validity:</b> 24-10-2025	<b>Gene Sign</b> FOB Rapid Test  Applied as: Kit  Class: B Shelf Life: 24 months  <b>Models/Code/sizes:</b> GS110701	Deferred for submission of the followings:  1. Valid Legalized FSc of the Reference Country with applied codes or valid Legalized FSc of country of origin with applied codes & CE (FQA). 2. Valid notarized ISO 13485 & LOA. 3. Clarification of the Class of the applied product.

		<p>• <b>ISO 13485:</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity:</b> 27-07-2024</p> <p>EC (FQA) not provided.</p>		
21.	<p>Shahco Medical Private Limited, Office No. 934, Shadman Colony 01, Lahore, Pakistan</p> <p><b>ELI-00230</b>  <b>Validity</b>  <b>18-10-2023</b>  Copy of evidence of Renewal Submitted on 16-08-2023</p> <p><b>R&amp;I Date:</b>  13-06-2025  <b>Fee:</b>  Rs 100,000/-  Slip No:480845058  Date:22-05-2025</p>	<p><b>Address as per Form-7A, ISO13485 &amp; EC:</b>  Hygea Medical Technology Co., Ltd., Floor 6&amp;7, West Area of Building No 08, NO. 30, Yuhua Road, Shunyi, 101318 Beijing, People's Republic of China.</p> <p><b>Address as per FSC:</b>  1101, 1<sup>st</sup> Floor, Building 17, No. 18, Zhongguanun South 3<sup>rd</sup> Street, Haidian District, Beijing.</p> <p><b>LOA</b>  <b>Type:</b> Copy  <b>Notarization:</b> Yes  <b>Validity date:</b> 03-03-2030</p> <p>• <b>FSC</b>  <b>Type:</b> Copy  <b>Issued By:</b> Beijing Drug Administration.  <b>Legalization/ Apostille:</b> Yes  <b>Validity:</b> 03-02-2026</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Yes  <b>Validity:</b> 08-01-2026</p> <p>• <b>CE certificate (FQA):</b>  <b>Type:</b> Copy  <b>Notarization:</b> Yes  <b>Validity:</b> 26-5-2024  <b>With extension letter.</b></p>	<p><b>Cryosurgical System (Co-Ablation System)</b></p> <p>General Cryosurgical System, Cryogengas, Electronic</p> <p>Applied as: System</p> <p>Class: C</p> <p>Shelf Life: NA</p> <p><b>Models/Code/sizes:</b>  <b>AI Epic S40</b></p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>Valid Legalized FSc of the Reference Country with applied codes or valid Legalized FSc of country of origin with applied codes.</li> <li>Clarification regarding the difference in address of manufacturer in FSC &amp; other documents (like ISO 13485, CE (FQA) &amp; Form-7A).</li> </ol>
22.	<p>Zodiac International, Suite No. 482, St No. 98, Sector G-9/4, Islamabad</p> <p>ELI-01020</p> <p><b>Validity</b></p>	<p>Eruondo S.p.A.  Via Dell' Artigianato n.7, 36030 Montecchio Precalcino (Vicenza) Italy.</p> <p><b>Manufacturing Site (as</b></p>	<p><b>Euronda Pro System Steam Sterilizing Unit; Euronda Pro System</b></p> <p>Autoclaves</p> <p>Applied as: System</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>Fee for System as per current SRO. One model / system</li> </ol>

	<p><b>26-12-2027</b></p> <p><b>R&amp;I Date:</b> 15-07-2025</p> <p><b>Fee:</b> Rs 62,000/- Slip No:226658137 Date:14-07-2025</p>	<p><b>per FSC):</b> Via Chizzalunga n.1, 36066, Sandrigo (VI) <b>Italy.</b></p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity date:</b> 31-12-2026</p> <p>• <b>FSC</b> <b>Type:</b> Original <b>Issued By:</b> Ministry of Health Italy. <b>Legalization/ Apostille:</b> Yes <b>Date of Issue:</b> 22-01-2024 <b>Validity:</b> Not mentioned</p> <p>• <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 28-10-2026</p> <p>• <b>EU QMS certificate</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 21-09-2026 <b>With extension letter.</b></p>	<p>Class: C</p> <p>Shelf Life: 8-10 years</p> <p><b>Models/Code/sizes:</b> E8-18L (SSU/E18L2018), E8-XD (SSU/E18L2018), E8-24L (SSU/E24L2018),, E9 Next-18L (SSU/M18L2015),, E9 Next-24L (SSU/M24L2015), E9 (SSU/M18L2023), E9 (SSU/M24L2023), E10- 18L (SSU/T18L2017), E10-24L (SSU/T18L2017), EXL (SSU/X24L2017),</p>	<p>will be considered in the current application &amp; the applicant will specify it. For the rest of the product the firm shall apply separately via online MDMC portal.</p>
23.	<p>M/s. Allmed Solutions Address: A-21/3, KDA Scheme No.1 (ext) Stadium Road, Karachi</p> <p>ELI-00029</p> <p><b>Validity</b> <b>03-08-2023</b></p> <p><b>R&amp;I Date:</b> 01-07-2025</p> <p><b>Fee:</b> Rs 62,000/- Slip No: 99530659480 Date:05-06-2025</p>	<p><b>Legal Manufacturer:</b> M/s CUREXO INC.</p> <p>Address: at 3rd, 4th Fl., Wiryesunhwan-ro, Songpa-gu, Seoul, 05814, Republic of Korea.</p> <p>Manufacturer (as per FSC): BK Electronics Co., Ltd., 8F, 11F, 88, Iljik-ro, Manan-gu, Anyang-si, Gyeonggi-do, 13901, Republic of Korea.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity date:</b> 31-12-2026.</p> <p>• <b>FSC</b> <b>Type:</b> Original</p>	<p><b>CUVIS-Joint</b> Orthopaedic Surgical Robot</p> <p>Applied as: System</p> <p>Class: C</p> <p>Shelf Life: 5 years</p> <p><b>Models/Code/sizes:</b> CJ150</p>	<p>Deferred for submission of the followings:</p> <ol style="list-style-type: none"> <li>1. Valid notarized CE (FQA) with the applied model in their scope or Legalized FSc of any reference country.</li> <li>2. Clarification regarding the difference in address of manufacturing site in FSC &amp; other documents (like ISO 13485, CE (FQA) &amp; Form-7A.</li> <li>3. Fee for System as per current SRO.</li> </ol>

		<p><b>Issued By: Mo Food &amp; Drug Safety, Korea</b>  <b>Legalization/ Apostille:</b> Yes  <b>Date of Issue: 08-05-2024</b>  <b>Validity:</b> Not mentioned</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Yes  <b>Validity:</b> 27-11-2025</p> <p>• <b>CE (FQA) certificate</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity:</b> 27-05-2024</p>		
24.	<p>Shirazi Trading  Comoany Pvt Ktd, 114 - C, Al-Murtaza  Commercial Lane 3, Off Khayaban-e-Iqbal,  Khayaban-e-Shaheen,  DHA Phase 8, Karachi 75500</p> <p>(ELI-00263  <b>Validity</b>  <b>22-10-2023</b>  Copy of evidence of  Renewal Submitted on  05-10-2023</p> <p><b>R&amp;I Date:</b>  04-06-2025  <b>Fee:</b>  Rs 62,000/-  Slip No:3845553610  Date:30-05-2025</p>	<p>GE Hangwei Medical  System Co., Ltd., West  Area of Building No. 3,  No. 1 Yongchang North  Road, Beijing Economic  and Technological  Development Area,  Beijing 100176, China</p> <p><b>LOA &amp; Distribution  Agreement</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity date:</b> 31-11-2025</p> <p>• <b>FSC</b>  <b>Type:</b> Original  <b>Issued By:</b> USFDA  <b>Legalization/ Apostille:</b> Yes  <b>Validity:</b> 23-07-2026</p> <p>• <b>ISO 13485:</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity:</b> 12-11-2026</p> <p>• <b>EU QMS certificate</b>  <b>Type:</b> Copy  <b>Notarization:</b> No  <b>Validity:</b> 12-01-2026</p>	<p><b>Revolution Advance</b>  Full Body CT System</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Shelf Life: 30 years</p> <p><b>Models/Code/sizes:</b></p>	<p>Deferred for  submission of the  followings:</p> <ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the Reference Country with applied model/code for the product or valid legalized FSC of country of origin with applied model/code for the product plus CE (FQA)</li> <li>2. Valid notarized ISO 13485 &amp; LOA.</li> <li>3. Fee for system as per current SRO.</li> </ol>
25.	<p>Scientific Supplies,  Office No. 2, Khan  Arcade, Syed Mouj  Darya Road, Lahore</p>	<p>Biochrom Ltd Unit 7,  Enterprise Zone, 3970  Cambridge Research  Park, Beach Drive,</p>	<p><b>Biochrom Ltd</b></p> <p>Amino Acid Analyzer with  Ultra Physiological Fluid</p>	<p>Deferred for  submission of the  followings:</p>

	<p>ELI-01337</p> <p><b>Validity</b> <b>13-01-2030</b></p> <p><b>R&amp;I Date:</b> 03-07-2025</p> <p><b>Fee:</b> Rs 62,000/- Slip No: 777994714598 Date:02-07-2025</p>	<p>Waterbeach, Cambridge, CB25 9PE, United Kingdom.</p> <p><b>LOA</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity date:</b> 2-07-2025.</p> <p>• <b>FSC</b> <b>Type:</b> Copy <b>Issued By:</b> MHRA, UK <b>Legalization/</b> Apostille: No <b>Validity:</b> 31-12-2028</p> <p>• <b>ISO 13485:</b> <b>Type:</b> Copy <b>Notarization:</b> Yes <b>Validity:</b> 31-10-2027</p> <p>• <b>CE (FQA) certificate</b> <b>Type:</b> Copy <b>Notarization:</b> No <b>Validity:</b> 26-05-2025</p>	<p>Chemical Kit</p> <p>Applied as: System</p> <p>Class: C</p> <p>Shelf Life: 18-24 months</p> <p><b>Models/Code/sizes:</b></p> <p>80-6000-53] BIO30+ System Physiological HP [80-6002-80] Physiological Standard [80-6001-06] Microvial 300pL (Pack of 100) [80-6001-08] Microvial Caps (Pack of 100) [80-6003-15] Ultra Physiological Fluid Kit [Lithium Buffer 1 NC Lithium Buffer 2 NC Lithium Buffer 3 NC Lithium Buffer 4 NC Lithium Buffer 5 NC Lithium Buffer 6 NC Lithium Loading Buffer NC Ultra Nin Solution NC Ultrosolve Plus NC Ultra Ninhydrin Kit 2L NC Ultra Ninhydrin Kit 8L NC EZ Nin Reagent Kit 2L NC EZ Nin Reagent Kit 4L NC EZ Nin Reagent Kit 8L NC Ultra Phys. Fluid</p>	<ol style="list-style-type: none"> <li>1. Valid Legalized FSc of the Reference Country with applied codes or valid Legalized FSc of country of origin with applied codes &amp; CE (FQA).</li> <li>2. Valid notarized ISO 13485 &amp; LOA.</li> <li>3. Clarification of the Class of the applied product.</li> <li>4. Justification of the grouping of the applied products &amp; fee will be required if justified as family/cluster.</li> </ol>
--	---	---	---	--

			Kit NC Ultra Phys. Routine Kit NC Lithium Buffer Start-Up Kit NC Lithium Buffer Routine Kit NC EZ Nin Reagent Bottle 2L NC	
--	--	--	--	--

**Evaluator: Rana Ahsan ul Haq Attar (Deputy Director)**

### Deferred Cases Agenda:

#### DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	<b>M/s SZ Surgical Supplier, Office #S, 12, 2<sup>nd</sup> Floor Ghulam Said Medicine Market Namak Mandi, Peshawar</b>  <b>ELI-00662</b>  Date of R& I 20-05-2025  Fee: PKR 25000/- Slip # 69256338410	M/s Taian Dalu Medical Instruments Co., Ltd., NO. 3988 Yitianmen Street, Hi-Tech Zone, Taian, Shandong, China 27100  LOA Issue date:  FSC: China Validity: 05-02-2027  ISO Validity: 21-10-2027  EU QA Certificate Issue :20-04-2028	Brand name: Spacer for Aerosol  Generic Name: Spacer for Aerosol  Class-B  Shelf life / service life: 5 Years  Models/ Specification: DL-01. DL-01A, DL-01B, DL-01C, DL-01D, DL-02, DL-02A. DL-02B. DL-03B. DL-03C. DL-04, DL-05, DL-06, DL-06A, DL-06B. DL-06C, DL-07. DL-08, DL-03A DL-08B. DL-08C, DL-08D, DL-09, DL-10, DL-11, DL-12, DL-13, DL-14. DL-15. DL-16. DL-17. DL-18. DL-19, DL-20, DL-21, DL-22, DL-23, DL-24, DL-25, DL-26, DL-27. DL-DD petite. La grande, Tur bo, Aeroget, Maclife, Salbomatic. Intec, Aeromate Plus, Aerospacer zeolos. Esencia, Soldist. Farmasol. Instaspacer. Universal-Chamber. AS175. Transpacer VM	Deferred (last opportunity) due to following: 1. Differential fee for the family of class B not submitted. 2. Clarification regarding models petite, La grande, Turbo, Aeroget etc mentioned on the FSC required. 3. Product Brochure/catalogue required. 4. Justification for applying multiple codes in single application required.

2.	<p>M/s SZ Surgical Supplier, Office No. S-12, 2<sup>nd</sup> Floor, Ghulam Said Medicine Market, Namak Mandi, Peshawar.</p> <p>(ELI-00662)</p> <p><b>Date of R&amp;I</b> 20-05-2025</p> <p><b>Fee Details:</b> Paid Fee: 6,000/- Slip: 305574915006</p>	<p><b>Name of Manufacturer:</b> M/s. Taian Dalu Medical Instrument Co., Ltd., West Part of Yitianmen Street, Hi- Tech Zone, Taian, Shandong, China.</p> <p>• <b>LOA</b> <b>Type:</b> Copy of attested <b>Notarization:</b> By CCPIT <b>Validity:</b> 23-04-2030</p> <p>• <b>FSC</b> <b>Type:</b> Copy of apostilled <b>Issued By:</b> Govt. Body <b>Attested By:</b> CCPIT <b>Legalization:</b> Appostilled <b>Validity:</b> 14-01-2026</p> <p>• <b>ISO Certificate</b> <b>Type:</b> Copy of attested <b>Attested By:</b> CCPIT <b>Validity:</b> 21-10-2027</p>	<p><b>Brand name:</b> Dry Powder Inhaler</p> <p><b>Generic Name:</b> Dry Powder Inhaler</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b> Not mentioned in application</p> <p><b>Applied as:</b> Single</p> <p><b>Shelf life:</b> 5 Years</p>	<p>Deferred (last opportunity) due to following:</p> <ol style="list-style-type: none"> <li>1. Differential fee for the family of class A not submitted.</li> <li>2. Clarification regarding models SciAir, Aerohaler, Robust, Slickhaler etc etc. mentioned on the FSC required.</li> <li>3. Product Brochure/catalogue required.</li> <li>4. Justification for applying multiple codes in single application required.</li> <li>5. stability studies/ aging data required.</li> </ol>
3.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3594 Submission date: 26/09/2022 <b>Evaluator:</b> DD-III</p>	<p><b>Legal Manufacturer:</b> A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Dengue NSI Ag Rapid Test Kit (Dengue NSI Ag Rapid Test Casette) Codes &amp; Sizes: As per FSC Class-C Shelf Life: 24 Months</p>	<p>Approved <b>Orient Gene Dengue NS1 Ag Rapid Test Cassette (Whole Blood/serum/plasma)</b> subject to submission of correct product label.</p>
4.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3589 Submission date: 26/09/2022 <b>Evaluator:</b> DD-III</p>	<p><b>Legal Manufacturer:</b> A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p> <p>FSC: not provided</p>	<p>Orient Gene Dengue NS1 Ag+IgM/IgG Combo Rapid Test Kit (Dengue NS1 Ag+IgM/IgG Combo Rapid Test kit) Codes &amp; Sizes: As per FSC Class-C Shelf Life: 24 Months</p>	<p>Approved <b>Orient Gene Dengue NS1 + IgM/IgG Combo Rapid Test Cassette (Whole Blood/serum/plasma)</b> subject to submission of correct product label.</p>
5.	<p>A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3133 Submission date: 11/05/2022 <b>Evaluator:</b></p>	<p><b>Legal Manufacturer:</b> A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China</p>	<p>Orient Gene Typhoid IgG.IgM rapid test (Pyphoid IgG/IgM Rapid test casette) Codes &amp; Sizes: As per FSC Class-C Shelf Life: 24 months</p>	<p>Approved <b>Orient Gene Typhoid IgG/IgM Rapid Test Cassette (Serum/plasma)</b> subject to submission of correct product label.</p>

	DD-III	FSC: not provided		
6.	A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 2994 Submission date: 26/04/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b>  A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China  FSC: not provided	Orient Gene H.Pylori Ab Rapid Test Kit (H.Pylori Ab Rapid Test Casette) Codes & Sizes: As per FSC <del>Class-C</del>  Class B  Shelf Life: 24 Months	Approved <b>Orient Gene H. Pylori Ab Rapid Test Cassette (Whole Blood/serum/plasma)</b> subject to submission of correct product label.
7.	A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3130 Submission date: 11/05/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b>  A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China  FSC: not provided	Orient Gene Malaria Pf/Pv Rapid Test Kit (Malaria Pf/Pv Ag Rapid Test Casette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 months	Approved <b>Orient Gene Malaria p.f./p.v. Ag Rapid Test Cassette (whole blood)</b> subject to submission of correct product label.
8.	A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3134 Submission date: 11/05/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b>  A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China  FSC: not provided	Orient Gene Malaria Pf/Pan Rapid Test Kit (Malaria Pf/Pan Ag Rapid Test Casette) Codes & Sizes: As per FSC Class-C Shelf Life: 24 month	Approved <b>Orient Gene Malaria p.f./pan Ag Rapid Test cassette (whole blood)</b> subject to submission of correct product label.
9.	A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3132 Submission date: 11/05/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b>  A Zhejiang Orient Gene Biotech Co., Ltd, 3787 #, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China  FSC: Belgium Issued on:13-05-2022	Orient Gene TB Rapid Test Kit  (TB IgG/IgG Rapid test Cassette) Codes & Sizes: GCTB-302a  Class-C Shelf Life: 24 months	Approved <b>Orient Gene Tuberculosis IgG/IgM Rapid Test cassette (serum/plasma)</b> subject to submission of correct product label.
10.	A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3591 Submission date: 21/09/2022 <b>Evaluator:</b> DD-III	<b>Legal Manufacturer:</b> Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America  <b>Manufacturing site:</b> Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030  FSC: China Valit till: 2023/01/17	Acon Mission Plus Hemoglobin(Hb) Testing strips (Hemoglobin (Hb) Testing strips) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Approved Mission® Plus Hemoglobin(Hb) Testing strips.



11.	A.S Enterprises, 03-Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3592 Submission date: 21/09/2022 Evaluator: DD-III	<b>Legal Manufacturer:</b> Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America  <b>Manufacturing site:</b> Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030  FSC: China Valit till: 2023/01/17	Acon Mission Plus Hemoglobin (Hb) Testing Meter (Hemoglobin (Hb) Testing System) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Approved Mission® Plus Hemoglobin(Hb) Testing Meter.
12.	M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore.  <b>(ELI- 00087)</b>  <b>R&amp;I detail</b> 08-07-2025 <b>Fee:</b> 70,000/- <b>Slip:</b> 75267236	<b>Legal Manufacturer:</b> Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany.  <b>Manufacturing Sites:</b> 1.Richard Wolf GmbH, DE-75438 Knittlingen, Pforzheimer Strabe 32, Germany. 2.Steute Technologies GmbH & Co.KG, DE-32584 Lohne, Bruckenstrasse 91, Germany. 3.PMT Shian-Lung Precision Industry, TW-000 Taichung City 42877, No. 81, Zhingshan 3 <sup>rd</sup> Road Taiwan. <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> Govt. Body <b>Legalization:</b> Legalized <b>Issue Date:</b> 26-06-2024  <b>• ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized	<b>Brand name:</b> Camera Head, Controller, Remote Control USB & Perforated Basket for Camera Head  <b>Generic Name:</b> Camera Head, Controller, Remote Control USB & Perforated Basket for Camera Head  <b>Applied as:</b> System  <b>Class:</b> A  <b>Model/Codes/Sizes (as per application &amp; FSC):</b> <b>• Light Source LED</b> 5160001 5161001 5163001 5164001 <b>• Light Source LED Blue</b> 5165001 5165002 <b>• Fiber Light Cable</b> 80662518 80662523 80662530 80663518 80663523 80663530 80663535 80665023 80665030 80665035 80673523 80655023	Approved following subject to submission of Brand name <b>Light Source LED</b> 5160001 5161001 5163001 5164001

		<b>Validity:</b> 28-11-2027	80655030 80655035 80661618 80661623 80661630 • <b>Adapter Endoscope Side</b> 809509 8095.07 8070.00 807001 807002 8087.00 8088.00 808801 8088.80 8088.81 8091.00 8095.05 809506 8096.811 • <b>Foot Control Rocker Switch</b> 2030.105  <b>Service life:</b> Not mentioned.	
13.	M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore.  <b>(ELI- 00087)</b>  <b>R&amp;I detail</b> 08-07-2025 <b>Fee:</b> 25,000/- <b>Slip:</b> 78805408660	<b>Legal Manufacturer:</b> Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany.  <b>Manufacturing Site:</b> 1. Richard Wolf GmbH, DE-75438 Knittlingen, Pforzheimer Strabe 32, Germany 2. ITD GmbH Office Neubiberg, DE-85579 Neubiberg, Lilienthalstr. 19, Germany.  • <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> Govt. Body	<b>Brand Name:</b> Unit Cart, Unit Cart Base & Flexon Port System  <b>Generic Name:</b> Unit Cart, Unit Cart Base & Flexon Port System  <b>Applied as:</b> System  <b>Class: A</b>  <b>Model/Codes/Sizes (as per application &amp; FSC):</b> • Unit Cart 32116011 (Unit Cart) 82116015 (Unit Cart Premium Electr. 220-230 V AC) • Unit Cart Base Electr. 220- 240V AC 32116014 • Flexon-Port 32116103 (Flexon-Port 350+400 (103CM)) 32116058 (Flexon-Port 300 (58CM))	Approved 32116011 (Unit Cart) only subject to submission of Brand Name.

		<b>Legalization:</b> Legalized <b>Issue Date:</b> 26-06-2024 <b>• ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 28-11-2027	32116068 (Flexon-Port 400 (68CM)) 32116093 (Flexon-Port 350+300 (93CM)) <b>Service life:</b> Not mentioned.	
14.	M/s Life-Tec, Unit B, 1 <sup>st</sup> Floor, Block 20D, G-8 Markaz, Islamabad.  ELI-00155  Date of R& I 08-05-2025  Fee: PKR 62,000/- Slip # 48400453 Dated: 16-04-2025	<b>Manufacturer:</b> Medica S.p.A, Via degli Artigiani, 7-41036, Medolla (Modena), Italy <b>• Distribution</b> <b>Contract:</b> <b>Type:</b> Copy <b>Notarization:</b> Not notarized <b>Validity:</b> 31-12-2027 <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Govt. Body <b>Legalization:</b> Not legalized <b>Issue Date:</b> Not mentioned <b>Validity:</b> Not Mentioned <b>• ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized. <b>Validity:</b> 23-03-2027 <b>• EU QMS</b> <b>Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized. <b>Validity:</b> 31-05-2028	<b>Brand Name:</b> Plasmart Plasmafilters <b>Generic Name:</b> Plasma Filters Applied as: Single Class: C <b>Codes:</b> M03863-PLASMART 50, M03864-PLASMART 100, M03865- PLASMART 200 <b>Shelf Life:</b> Not Mentioned	Approved.
15.	M/s Life-Tec, Unit B, 1 <sup>st</sup> Floor, Block 20D, G-8 Markaz, Islamabad.  ELI-00155  Date of R& I 05-05-2025  Fee: PKR 62,000/-	<b>Manufacturer:</b> Medica S.p.A, Via degli Artigiani, 7-41036, Medolla (Modena), Italy <b>• Distribution</b> <b>Contract:</b> <b>Type:</b> Copy <b>Notarization:</b> Not	<b>Brand Name:</b> AFERsmart Plus 110-230V <b>Generic Name:</b> Therapeutic Apheresis System Applied as: Single	Approved subject to submission of fee for the system.

	Slip # 341293648211 Dated: 16-04-2025	notarized <b>Validity:</b> 31-12-2027  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Govt. Body <b>Legalization:</b> Not legalized <b>Issue Date:</b> Not mentioned <b>Validity:</b> Not Mentioned  <b>• ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized. <b>Validity:</b> 23-03-2027  <b>• EU QMS Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized. <b>Validity:</b> 31-05-2028	Class: C  <b>Codes:</b> M90414  <b>Shelf Life:</b> Not Mentioned	
16.	M/s Life-Tec, Unit B, 1 <sup>st</sup> Floor, Block 20D, G-8 Markaz, Islamabad.  ELI-00155  Date of R& I 05-05-2025  Fee: PKR 62,000/- Slip # 693338700 Dated: 16-04-2025	<b>Manufacturer:</b> Medica S.p.A, Via degli Artigiani, 7-41036, Medolla (Modena), Italy  <b>• Distribution Contract:</b> <b>Type:</b> Copy <b>Notarization:</b> Not notarized <b>Validity:</b> 31-12-2027  <b>• FSC</b> <b>Type:</b> Copy <b>Issued By:</b> Govt. Body <b>Legalization:</b> Not legalized <b>Issue Date:</b> Not mentioned <b>Validity:</b> Not Mentioned  <b>• ISO – Certificate:</b> <b>Type:</b> Copy <b>Notarization:</b> Not Notarized. <b>Validity:</b> 23-03-2027	<b>Brand Name:</b> FRACTIOsmart  <b>Generic Name:</b> Plasma Fractionator  Applied as: Not selected  Class: C  <b>Codes:</b> M90099 (Small 2.0), M90100 (Medium 2.0), M90101 (Large 2.0), M90149 (Small 1.0), M90150 (Medium 1.0) M90151 (Large 1.0)  <b>Shelf Life:</b> Not Mentioned	Approved.

		<p>• <b>EU QMS Certificate:</b>  <b>Type:</b> Copy  <b>Notarization:</b> Not Notarized.  <b>Validity:</b> 31-05-2028</p>		
17.	<p>M/s. EA Global Star (Pvt.) Ltd., Basement # 12-DD, Sector D, Bahria Town, Lahore</p> <p><b>(ELI- 01363)</b></p> <p><b>R&amp;I detail</b>  18-04-2025  <b>Fee: 6000</b>  <b>Slip: 41182354675</b>  <b>Dated: 14-04-2025</b></p>	<p><b>Name of Manufacturer:</b>  M/s Zhejiang J&amp;J Mobility Co., Baiyang Street, Wuyi, Jinhua City, Zhejiang, China.</p> <p><b>LOA Validity:</b>  19-12-2029</p> <p><b>FSC issuance (China):</b>  19-12-2026</p> <p><b>ISO Validity:</b>  10-01-2027</p>	<p><b>Brand name:</b>  J&amp;J Electric Wheelchair</p> <p><b>Generic Name:</b>  Electric Wheelchair</p> <p><b>Class:</b> A</p> <p><b>Codes/Sizes:</b>  DESIRE, DESIRE SPORTS, BOLD, FRONT WHEEL, A2 PLUS, DELUXE, DELUXE BIG WHEEL, DELUXE SPORT, EXTREME, SUPER DELUXE, A2 PLUS RECLINING</p> <p>JJW-5001, JJW-500111, JJW-500112, JJW-500113, JJW-500114, JJW-500115, JJW-500116, JJW-500117, JJW-500118, JJW-500121, JJW-500131, JJW-500141, JJW-500151, JJW-500161, JJW-500171, JJW-500181, JJW-500155, JJW-500156,</p> <p>HPIE</p> <p>JJW-5001157, JJW-500118, JJW-500311, JJW-500312, JJW-500313,</p> <p>JJW-6001, JJW-600111, JJW-600112, JJW-600113, JJW-600114, JJW-600115, JJW-600116, JJW-600117, JJW-600118, JJW-600183, JJW-600184, JJW-600185, JJW-600186, JJW-600211, JJW-600221, JJW-600227, JJW-600127, JJW-600129, JJW-600321, JJW-600322, JJW-600325</p>	<p>Deferred (last opportunity) for submission of following:</p> <ol style="list-style-type: none"> <li>1. Fee for the family of class A.</li> <li>2. original, legalized/apostille valid FSC.</li> <li>3. Product catalogue/brochure.</li> </ol>

			<p>COOMHE</p> <p>JJW-7001, JJW-700221, JJW-700223, JJW-700225, JJW-700227, JJW-700229, JJW-700321, JJW-700323, JJW-700325, JJW-700327, JJW-700329 JJW-1001, JJW-100111, JJW-100112, JJW-100113, JJW-100114, JJW-100115, JJW-100116, JJW-100117, JJW-100118, JJW-100119</p> <p><b>Shelf life:</b> 05 Years</p>	
18.	<p><b>M/s MR Medical Pakistan Pvt Ltd,</b></p> <p><b>Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</b></p> <p><b>ELI-01008</b></p> <p>Date of R&amp; I 20-05-2025</p> <p>Fee: PKR 31,000/- Slip # 83660961935</p>	<p>M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China</p> <p>LOA Validity: 14-04-2027</p> <p>FSC: China Validity: 05-09-2026</p> <p>ISO Validity: 31-08-2026</p> <p>EU QA /CE Certificate Validity: 21-11-2029</p>	<p>Brand name: Mindray</p> <p>Generic Name: Electrocardiograph</p> <p>Class-B</p> <p>Shelf life: 10 Years</p> <p>Models/ Specification: BeneHeart R-900</p>	Approved.
19.	<p><b>M/s MR Medical Pakistan Pvt Ltd,</b></p> <p><b>Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</b></p> <p><b>ELI-01008</b></p> <p>Date of R&amp; I 20-05-2025</p> <p>Fee: PKR 31,000/- Slip # 3996222921</p>	<p>M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China</p> <p>LOA Validity: 14-04-2027</p> <p>FSC: China Validity: 05-09-2026</p>	<p>Brand name: Mindray</p> <p>Generic Name: Electrocardiograph</p> <p>Class-B</p> <p>Shelf life: 10 Years</p> <p>Models/ Specification: BeneHeart R-300</p>	Approved.

		ISO Validity: 31-08-2026  EU QA /CE Certificate Validity: 21-11-2029		
20.	<b>M/s MR Medical Pakistan Pvt Ltd,</b>  <b>Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</b>  <b>ELI-01008</b>  Date of R& I 20-05-2025  Fee: PKR 31,000/- Slip # 552846383	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China  LOA Validity: 14-04-2027  FSC: China Validity: 05-09-2026  ISO Validity: 31-08-2026  EU QA /CE Certificate Validity: 21-11-2029	Brand name: Mindray  Generic Name: Electrocardiograph  Class-B  Shelf life: 10 Years  Models/ Specification: BeneHeart R-90	Approved.
21.	<b>M/s MR Medical Pakistan Pvt Ltd,</b>  <b>Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</b>  <b>ELI-01008</b>  Date of R& I 20-05-2025  Fee: PKR 31,000/- Slip # 23844255	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, Peoples Republic of China  LOA Validity: 14-04-2027  FSC: China Validity: 05-09-2026  ISO Validity: 31-08-2026  EU QA /CE Certificate Validity: 21-11-2029	Brand name: Mindray  Generic Name: Electrocardiograph  Class-B  Shelf life: 10 Years  Models/ Specification: BeneHeart R70	Approved.
22.	<b>M/s MR Medical Pakistan Pvt Ltd,</b>  <b>Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue</b>	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park,	Brand name: Mindray  Generic Name: Electrocardiograph	Approved.

	<b>Area Islamabad.</b>  <b>ELI-01008</b>  Date of R& I 20-05-2025  Fee: PKR 31,000/- Slip # 4213117793	Nanshan, 518057 Shenzhen, Peoples Republic of China  LOA Validity: 14-04-2027  FSC: China Validity: 05-09-2026  ISO Validity: 31-08-2026  EU QA /CE Certificate Validity: 21-11-2029	Class-B  Shelf life: 10 Years  Models/ Specification: BeneHeart R30	
23.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 4154-p Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No. 785233881	<b>Legal Manufacturer:</b> M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.  FSC: China Valid till: 03/06/2024	<b>MINDRAY</b> (Carbohydrate Antigen 50) Codes & Sizes: (Packing specifications as per FSC) 2x50tests 2x100tests Class-C Shelf Life: Kit: Not provided Calibrator: 18 months	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. Or FSC of RRA 3. Stability study.
24.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 4138-p Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No. 7419503044 Evaluator DD-II	<b>Legal Manufacturer:</b> M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.  FSC: China Valid till: 26/09/2023	<b>MINDRAY</b> (Squamous Cell Carcinoma Antigen-SCCA (CLIA))  Codes & Sizes: (Packing specifications as per FSC) C0: 1x1.2ml C1: 1x1.0ml C2: 1x1.0ml Class-C Shelf Life: Kit: 18 months Calibrator: 18 months	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA.
25.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 4152-p Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No.	Legal Manufacturer: M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.	<b>MINDRAY</b> ProGRP (GASTRIN RELEASING PEPTIDE) (CLIA) Codes & Sizes: (Packing specifications as per FSC) 2x50tests 2x100tests Class-C Shelf Life:	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA.



	34318069748 Evaluator DD-II	FSC: China Valid till: 03/06/2024	Kit: 12 months	
26.	MR Medical Pakistan Private Limited, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad. ELI-01008 Dossier# 4140-p Submission date: 22/02/2023 Fee submitted: 50,000/- Challan No. 0863713915	<b>Legal Manufacturer:</b> M/s Shenzhen Mindray Bio Medical Electronics Co., Ltd Mindray Building Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.  FSC: China Valid till: 03/06/2024	<b>MINDRAY</b> (Carbohydrate Antigen242 (CLIA) Kit and Calibrators) <b>Codes &amp; Sizes:</b> (Packing specifications as per FSC) 2x50tests 2x100tests Class-C Shelf Life: Kit: not provided Calibrator: 18 months	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA.
27.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad  (ELI-01008	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	MINDRAY  GAMMA- GLUTAMYL TRANSFERASE KIT (Szasz Method/FCC Stand)	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA. 4. Undertaking on stamp paper.

**Item No. III:**

**PERSONAL HEARING CASES.**

**(Mr. Muhammad Amin, Deputy Director)**

**Case No.01:**

The following firms have applied for Renewal of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The recommendations of the panels and decision of MDB taken in its different meetings are as mentioned against each:-

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s 3M Pakistan (Pvt) Ltd., Islamic Chamber of Commerce Building, St-2/A, Block-9, KDA Scheme-5, Clifton, Karachi  Godown: Plot no. A-6, A-7, Qasim Logistics	M Bilal	Muhammad Tariq  CEO	<b>Mr. Ghalib of M/s RA Healthcare appeared before the board with authority letter from M/s 3M Saudi Arabia as 3M Pakistan no more exists. He informed the board that they are authorized agents of the firm in Pakistan and all the required products have been transferred under their name. Therefore, ELI: 00259 issued to M/s 3M Pakistan Karachi may be cancelled and any</b>

	Center North West Industrial Zone Port Qasim Karachi.  ELI: 00259			<p>remaining products registered under the name of this company may also be cancelled with immediate effect.</p> <p>The board after providing personal hearing to the firm decided to cancel the ELI: 00259 issued in the name of M/s 3M Pakistan (Pvt) Ltd, Karachi and all the registrations/ enlisted items of the firm shall also stand cancelled.</p>
2.	<p>M/s Sapphire international,</p> <p>Office / godown: Room no 903, 9<sup>th</sup> floor, Uni center, I.I. chundrigar, road, Karachi.</p> <p>ELI-00430</p>	<p>Mirza Adil baig</p> <p>Pharm D</p>	<p>M Nadeem Malik</p> <p>CEO</p>	<p>Mr. Nadeem Malik CEO of the firm appeared before the board and informed that their business plans have changed and they'd like to continue the ELI: 00430 issued in the name of M/s Sapphire international, Karachi. He further informed the board that he'd like to withdraw the previously submitted letter regarding cancellation of license to DRAP Karachi and requested to constitute a panel to renew the license. He also submitted a written letter in this regard.</p> <p>The board after listening to the firm took a linient view and decided to constitute following panel for renewal of ELI:00430 issued to M/s Sapphire international, Karachi.</p> <ul style="list-style-type: none"> <li>• Mr. Wajahat Ali, Biomedical Engineer, Member MDB, Islamabad.</li> <li>• Additional Director DRAP Karachi or his nominee.</li> </ul>
3.	<p>M/s Crystal HealthCare</p> <p>Office / Godown: 10-A, Main Market, Samanabad, lahore</p> <p>ELI-00166</p>	<p>Wameez Sohail</p>	<p>Muhammad Moien</p> <p>Ud Din</p> <p>Imtiaz Haq</p>	<p>The firm was served with notice of personal hearing at the address 10-A, Main Market, Samanabad, Lahore but nobody appeared before the board. Mr. Abdul Rasheed Shaikh, DD, DRAP Lahore was also assigned the task to inform the firm. He tried to contact Mr. Moin Uddin business partner of the firm but his</p>

	<b>M-110</b>			<p>phone calls were not answered.  The board therefore considered the report of Mr. Abdul Rasheed Shaikh, DD, DRAP Lahore wherein the officer informed the board that the company is no more interested, and decided to cancel ELI: 00166 issued in the name of M.s Crystal Health Care Lahore and all registrations/ enlisted items stands cancelled automatically under Medical Devices Rules 2017.</p>
--	--------------	--	--	---

## Additional Agenda Minutes

**Evaluator: Rana Ahsan Ul Haq Attar:**

### **Deferred Products:**

1.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad  (ELI-01008	SHENZHEN MINDRAY BIO- MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	HDL - CHOLESTERL KIT (DIR METHOD WITH CALIBRATORS (LAPIDS CALIBRATOR ) AND CONROLS (CLIN CHEM MULTI CONTROL)	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA. 4. Undertaking on stamp paper.
2.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad  (ELI-01008	SHENZHEN MINDRAY BIO- MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	LACTATE DEHYDROGENASE KIT (IFCC Method)	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA. 4. Undertaking on stamp paper.
3.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad  (ELI-01008	SHENZHEN MINDRAY BIO- MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	MINDRAY  UREA KIT (Urease-GLDH, UV Method)	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA. 4. Undertaking on stamp paper.
4.	MR Medical Pakistan Pvt, Ltd. Office in. 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad  (ELI-01008	SHENZHEN MINDRAY BIO- MEDICAL ELECTRONICS CO., LTD.MINDRAY BUILDING , KEJI 12TH ROAD SOUTH HIGH TECH INDUSTRIAL PARK NANSHAN , SHENZHEN CHINA	MINDRAY  IRON (FE) KIT (COLORIMETRIC ASSAY) WITH CALIBRATOR AND CONTROL	Deferred for submission of following. 1. Notarized EU Quality Management Certificate. 2. Notarized EU Technical Documentation Certificate. 3. or FSC of RRA. 4. Undertaking on stamp paper.
5.	<b>M/s MR Medical Pakistan Pvt Ltd,</b>  <b>Office No. 1101, 11th Floor, ISE Tower, Jinnah</b>	M/s Shenzhen Mindray Biomedical Electronics Co., Ltd., Mindray Building, Keji 12th Road South, High-Tech Industrial Park,	Brand name: Mindray  Generic Name: Electrocardiograph	Approved.

	<b>Avenue, Blue Area Islamabad.</b>  <b>ELI-01008</b>  Date of R& I 20-05-2025  Fee: PKR 31,000/- Slip # 71504569424	Nanshan, 518057 Shenzhen, Peoples Republic of China  LOA Validity: 14-04-2027  FSC: China Validity: 05-09-2026  ISO Validity: 31-08-2026  EU QA /CE Certificate Validity: 21-11-2029	Class-B  Shelf life: 10 Years  Models/ Specification: BeneHeart R700	
6.	Merlin International, Office No. 341, 3rd Floor, Land Mark Plaza, Jail Road, Lahore  ELI: 00569 5953-P Fee 31,000/- slip no. 962491027856	<b>Legal Manufacturer:</b> Chifeng Tianbo Medical Device Co., Ltd Zhongjing Industrial Park Economic Development Area, Ninhcheng District, Chifeng 024200, Inner Mongolia, P.R China.  LOA validity: Not clear  FSC validity 14-04-2025  ISP 13485 validity 17-02- 2025  Production QA certificate validity 17-02-2027	Well-Flow Infusion Set with Y-Port  Class-B  Shelf life: 5 years  Codes/Specifications: Model IS-G3-JMZ size 0.8x26TWLB.	Approved
7.	S. Ejazuddin & Co. P.O. Box 5629, 237- B, Block II, PECHS, Shahrah-e-Quaideen, Karachi ELI 00078	Sysmex Corporation 1-5- 1 Wakinoshama- Kaigandori, Chuo-Ku, Kobe 651-0073, Japan	Sysmex Automated Hematology Analyzer XQ-320 (XQ Series) BU954129  CDR_ASSY No. 569(v0.12- 00) CG336934	Approved.
8.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  <b>(ELI- 00244)</b>  <b>R&amp;I detail</b> 16-06-2025 <b>Fee: 6,000/-</b> <b>Slip: 6294763510</b>	<b>Name of Manufacturer:</b> M/s Intrumentation Laboratory Company, 180 Hartwell Road, Bedford Massachusetts, USA 01730.  <b>• LOA</b> <b>Type:</b> Original <b>Notarization:</b> Notarized	<b>Brand name:</b> ACL Elite Pro & Its Reagents  <b>Generic Name:</b> Blood Coagulation Analyzer & its reagents  <b>Applied as:</b> Cluster  <b>Class:</b> A	Approved ACL Elite Pro analyzer only subject to submission of manufacture statement regarding shelf life/ service life.

		<b>Validity:</b> 31-12-2026  <b>• FSC</b> <b>Type:</b> Original <b>Issued By:</b> US FDA <b>Legalization:</b> Apostilled <b>Validity:</b> 18-03-2026  <b>• ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 09-11-2027	<b>Model/Codes/Sizes:</b> Not clear  <b>Service life:</b> Not clear	
9.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi.  <b>(ELI- 00244)</b>  <b>R&amp;I detail</b> 16-06-2025 <b>Fee: 6,000/-</b> <b>Slip:</b> 495960806824	<b>Name of Manufacturer:</b> M/s Intrumentation Laboratory Company, 180 Hartwell Road, Bedford Massachusetts, USA 01730.  <b>• LOA</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 31-12-2026  <b>• FSC</b> <b>Type:</b> Original <b>Issued By:</b> US FDA <b>Legalization:</b> Apostilled <b>Validity:</b> 18-03-2026  <b>• ISO Certificate</b> <b>Type:</b> Original <b>Notarization:</b> Notarized <b>Validity:</b> 09-11-2027	<b>Brand name:</b> ACL Top 550 CTS & Its Reagents  <b>Generic Name:</b> Blood Coagulation Analyzer & its reagents  <b>Applied as:</b> Cluster  <b>Class:</b> A  <b>Model/Codes/Sizes:</b> Not clear  <b>Service life:</b> Not clear	Approved ACL Top 550 Analyzer only subject to submission of manufacture statement regarding shelf life/ service life.
10.	Varitron,  First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan.  ELI-00510  Date of R&I 23-04-2025  Fee Details: Paid Fee: 62030/- Fee Challan No: 60614559 16-04-2025	<b>Legal Manufacturer :</b> Varian Medical Systems, Inc  Address: 3100, Hansen Way Palo Alto CA 94304 USA.  <b>CH REP:</b>  Siemens Healthineers Intl. AG.  Hinterbergstrasse 14,6312 Steinhausen, Switzerland (CHRN-AR-2000721)	Ethos Radiotherapy System  Linear Accelerator  Class C  Shelf Life: N/A  Applied as: Single  Models/ Specification	Approved.

		<p>Manufacturing Sites:</p> <p>Varian Medical Systems, Inc Address: 911, Hansen Way Palo Alto CA 94304 USA.</p> <p>Varian Medical Systems China</p> <p>Co., Ltd. No.8 Yuncheng Street BDA Beijing, Beijing CHINA 100176</p> <p>Varian Medical Systems Imaging Laboratory GmbH</p> <p>Taefernstrasse 7 Daettwil, Argovia, Aargau SWITZERLAND CH-5405</p> <p>Varian Medical Systems, Inc 3290 Northside Parkway NW Suite 400 Atlanta, GA USA 30327</p> <p>Varian Medical Systems, Inc 6212 Hellyer Ave San Jose, CA USA 95138</p> <p>Varian Medical System Haan GmbH Rheinische Strasse 2 Haan, North Rhine-Westphalia GERMANY 42781</p> <p>Varian Medical Systems, Inc</p> <p>Corredor Tijuana-Rosarito, No 21702 col. El Realito Tijuana, Baja California MEXICO 22250</p> <p>Varian Medical Systems</p>		
--	--	--	--	--

		<p>Haan GmbH Manufacturing site Kemnath Building C10 Roentgenstrasse 19-21, Kemnath, Bavaria Germany 95478</p> <p>LOA Validity: 30-06-2027 (copy)</p> <p>FSC: USA Date of Validity: 06-01-2027. (Apostille)</p> <p>FSC: Neterlands Date of Issuance: 15-07-2026 (Apostille)</p> <p>ISO Validity: 10-02-2027 (Notarized) of Mexico site</p> <p>ISO Validity: 10-02-2027 (Notarized) of Germany site</p> <p>ISO Validity: 10-02-2027 (copy) of Legal manufacturer &amp; USA site</p> <p>EU QMS certificate 15-07-2026 (copy)</p>		
11.	<p>Varitron,  First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan.</p> <p>ELI-00510</p> <p>Date of R&amp;I 23-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 1300787541 16-04-2025</p>	<p>Legal Manufacturer:  Varian Medical Systems, Inc 3100, Hansen Way Palo Alto CA 94304 USA.</p> <p>Other Manufacturing SITE:  EU Representative: Varian Medical Systems Nederland B.V  Kokermolen 2 3994 DH Houten, The Netherlands</p>	<p>True Beam  TrueBeam Radiotherapy Delivery System  Class C  Shelf Life: N/A  Applied as: Single  Models/ Specification: True Beam</p>	Approved.



		<p>Manufacturing Sites:</p> <p>Varian Medical Systems China Co., Ltd. No.8 Yuncheng Street BDA Beijing, Beijing CHINA 100176</p> <p>Varian Medical Systems Imaging Laboratory GmbH</p> <p>Taefernstrasse 7 Daettwil, Argovia, Aargau SWITZERLAND CH- 5405</p> <p>Varian Medical Systems, Inc 3290 Northside Parkway NW Suite 400 Atlanta, GA USA 30327</p> <p><b>Varian Medical Systems, Inc 6212 Hellyer Ave San Jose, CA USA 95138</b></p> <p>Varian Medical System Haan GmbH</p> <p>Rheinische Strasse 2 Haan, North Rhine- Westphalia GERMANY 42781</p> <p><b>Varian Medical Systems, Inc Corredor Tijuana-Rosarito, No 21702 col. El Realito Tijuana, Baja California MEXICO 22250</b></p> <p>Varian Medical Systems Haan GmbH Manufacturing site Kemnath Building C10 Roentgenstrasse 19- 21, Kemnath,</p>		
--	--	--	--	--

		<p>Bavaria Germany 95478</p> <p>LOA Validity: 30-06-2027 (copy)</p> <p>FSC: USA Date of Validity: 06-01-2027. (Apostille)</p> <p>FSC: Neterlands Date of Issuance: 15-07-2026 (Apostille)</p> <p>ISO Validity: 10-02-2027 (Notarized) of Mexico site</p> <p>ISO Validity: 10-02-2027 (copy) of Legal manufacturer &amp; USA site</p> <p>EU QMS certificate 15-07-2026 (copy)</p>		
12.	<p>Healer International, Office Address Office No. 13, 3rd Floor Satellite Shopping Centre 6th Road Rawalpindi.</p> <p>ELI-01167 1232-P 5,000/-</p>	<p><b>Legal Manufacturer:</b> Hubei MeterOmega Technology Ltd, Biomedical Industrial Park, Jianqiu 5th Road, Duodao district, Jingmen City, Hubei Province China.</p> <p>FSC: China. Validity: 23-12-2025.</p>	<p>Arterial Hemostasis Compressor</p> <p>Class-A</p> <p>Shelf Life: 2 Years</p> <p>Codes as per FSC</p>	Approved.
13.	<p><b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</b></p> <p>Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b></p>	<p><b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA</p> <p><b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p><b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom</p> <p><b>Date of Issue:</b> 04-July-2023</p>	<p><b>VITROS Immunodiagnostic Product Anti-HBC IgM Reagent, Calibrator &amp; Control</b> Cal: <b>1100387</b> Rgt: <b>8577413</b> Cont: <b>6800834</b></p> <p><b>Shelf life:</b> Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks</p> <p><b>Storage Conditions:</b> 2-8°C</p>	<p>The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board;</p> <p>i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad.</p> <p>ii. Notarized Termination letter issued by the legal manufacturer, if any.</p>

		<b>Validity:</b> 26-May-2025	<b>Class: D</b>  <b>Fees:</b> 50,000/-  <b>Date of submission</b> <b>December 2022 then</b> 27-Sept-23	
14.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</b> Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product, Anti-HBe Reagent, Calibrator &amp; HBe Control</b> Cal: <b>1523984</b> Rgt: <b>8864860</b> Cont: <b>6800837</b>  <b>Shelf life:</b> Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks  <b>Storage Conditions:</b> Reagent: 2-8°C Calibrator: 2-8°C Control: +25°C  <b>Class: D</b> <b>Fees:</b> 50,000/-	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
15.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160</b> Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product HIV Combo Reagent &amp; Calibrator</b>  Cal: <b>6842780</b> Rgt: <b>6842779</b> <b>Shelf life:</b> Reagent: 52 weeks Calibrator: 52 weeks  <b>Storage Conditions:</b> 2-8°C  <b>Class: D</b>  <b>Fees:</b> 50,000/-	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
16.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA	<b>VITROS Immunodiagnostic Product AFP Reagent &amp; Calibrator:</b>	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for

	<b>Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b>	<b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	Cal: <b>1515154</b> Rgt: <b>1925551</b>  <b>Shelf Life:</b> Reagent: 52 weeks Calibrator: 52 weeks  <b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>  <b>Date of submission</b> 27-Sept-23	personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
17.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product CA 15-3 Reagent &amp; Calibrator:</b> Cal: <b>6800033</b> Rgt: <b>6800039</b>  <b>Shelf Life:</b> Reagent: 12 months Calibrator: 12 months  <b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
18.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b>	<b>VITROS Immunodiagnostic Product CA 125II Reagent &amp; Calibrator:</b> Cal: <b>6800034</b> Rgt: <b>6800038</b>  <b>Shelf Life:</b> Reagent: 32 weeks Calibrator: 32 weeks  <b>Storage Conditions:</b> 2-8°C	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.

		04-July-2023 <b>Validity:</b> 26-May-2025	<b>Class: C</b>  <b>Fees: 50,000/-</b>	
19.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product CA 19-9 Reagent &amp; Calibrator:</b>  <b>Cal: 6800035</b> <b>Rgt: 6800040</b>  <b>Shelf Life:</b> Reagent: 09 months Calibrator: 09 months  <b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.  M/s Martin Dow Specialty will submit undertaking on stamp paper.
20.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product CEA Reagent &amp; Calibrator:</b>  <b>Cal: 1062306</b> <b>Rgt: 1920115</b>  <b>Shelf Life:</b> Reagent: 32 weeks (+4 weeks post expiry) Calibrator: 32 weeks (+4 weeks post expiry)  <b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.  Martin Dow Specialty will provide undertaking of the stamp paper as required in Form 7A. The MDB under the MDR 2017 will consider the shelf life as per stability studies provided i.e 32 weeks only.
21.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road,</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics	<b>VITROS Immunodiagnostic Product HBeAg Reagent &amp; Calibrator:</b>  <b>Cal: 1914498</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board;

	<b>Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>Rgt: 8211880</b>  <b>Shelf Life:</b> Reagent: 52 weeks Calibrator: 52 weeks  <b>Storage Conditions:</b> 2-8°C  <b>Class: D</b>  <b>Fees: 50,000/-</b>	i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.  Martin Dow Specialty will provide undertaking of the stamp paper as required in Form 7A.
22.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b>  Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product HBsAg ES Reagent, Calibrator &amp; HBsAg Control :</b>  <b>Vitros Immunodiagnostic Product HBsAg ES Reagent and Calibrator.</b>  Cal: <b>6802132</b> Rgt: <b>6802131</b> Cont: <b>6800598</b>  <b>Shelf Life:</b> Reagent: <del>56</del> weeks 52 weeks Calibrator: <del>56</del> weeks 52 weeks Control: <del>56</del> weeks 52 weeks  <b>Storage Conditions:</b> 2-8°C  <b>Class: D</b>  <b>Fees: 50,000/-</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.  Martin Dow Specialty will provide undertaking of the stamp paper as required in Form 7A.
23.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b> <b>ELI-00160</b> Initial Submission:	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free</b>	<b>VITROS Immunodiagnostic Product hs Troponin-I Reagent &amp; Calibrator:</b> Cal: <b>6844437</b> Rgt: <b>6844436</b>  <b>Shelf Life:</b> Reagent: 52 weeks Calibrator: 60 weeks	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination

	<b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>	letter issued by the legal manufacturer, if any.
24.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrach-e-Faisal, Karachi ELI-00160</b> Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product FSH Reagent &amp; Calibrator:</b> Cal: <b>1901263</b> Rgt: <b>1931922</b> <b>Shelf Life:</b> Reagent: <del>52 weeks</del> 36 weeks Calibrator: <del>52 weeks</del> 36 weeks <b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
25.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrach-e-Faisal, Karachi ELI-00160</b> Initial Submission: <b>02-Dec-2022</b> Final Submission: <b>27-Sept-2023</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA  <b>Manufacturing site:</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom  <b>embassy attested Free Sale Certificate</b> Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom <b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>VITROS Immunodiagnostic Product LH Reagent &amp; Calibrator:</b>  Cal: <b>1090133</b> Rgt: <b>1350198</b> <b>Shelf Life:</b> Reagent: 52 weeks Calibrator: 52 weeks <b>Storage Conditions:</b> 2-8°C  <b>Class: C</b>  <b>Fees: 50,000/-</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
26.	<b>Martin Dow Specialties (Pvt) Limited 7th Floor,</b>	<b>Legal Manufacturer:</b> Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA	<b>VITROS Immunodiagnostic Product Progesterone Reagent &amp;</b>	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco

	<p><b>Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b>  <b>ELI-00160</b>  Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b></p>	<p><b>Manufacturing site:</b>  Ortho Clinical Diagnostics  Felindre Meadows Pencoed  Bridgend CF35 5PZ United Kingdom</p> <p><b>Embassy attested Free Sale Certificate</b>  Ortho Clinical Diagnostics  Felindre Meadows Pencoed  Bridgend CF35 5PZ United Kingdom</p> <p><b>Date of Issue:</b>  04-July-2023</p> <p><b>Validity:</b>  26-May-2025</p>	<p><b>Calibrator:</b>  Cal: <b>8254898</b>  Rgt: <b>1938570</b></p> <p><b>Shelf Life:</b>  Reagent: <del>52</del> weeks  30 weeks  Calibrator: <del>52</del> weeks  30 weeks</p> <p><b>Storage Conditions:</b>  2-8°C</p> <p><b>Class: C</b></p> <p><b>Fees: 50,000/-</b></p>	<p>Scientific Traders, for personal hearing with the direction to present following documents before the Board;</p> <p>i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad.</p> <p>ii. Notarized Termination letter issued by the legal manufacturer, if any.</p>
27.	<p><b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b>  <b>ELI-00160</b>  Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b></p>	<p><b>Legal Manufacturer:</b>  Ortho Clinical Diagnostics  ,100 Indigo Creek Drive  Rochester, NY, 14626 USA</p> <p><b>Manufacturing site:</b>  Ortho Clinical Diagnostics  Felindre Meadows Pencoed  Bridgend CF35 5PZ United Kingdom</p> <p><b>Embassy attested Free Sale Certificate</b>  Ortho Clinical Diagnostics  Felindre Meadows Pencoed  Bridgend CF35 5PZ United Kingdom</p> <p><b>Date of Issue:</b>  04-July-2023</p> <p><b>Validity:</b>  26-May-2025</p>	<p><b>VITROS Immunodiagnostic Product Testosterone</b>  <b>Reagent &amp; Calibrator:</b></p> <p>Cal: <b>1306026</b>  Rgt: <b>1435205</b></p> <p><b>Shelf Life:</b>  Reagent: 30 weeks  Calibrator: 30 weeks</p> <p><b>Storage Conditions:</b>  2-8°C</p> <p><b>Class: C</b></p> <p><b>Fees: 50,000/-</b></p>	<p>The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board;</p> <p>i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad.</p> <p>ii. Notarized Termination letter issued by the legal manufacturer, if any.</p>
28.	<p><b>Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&amp;B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi</b>  <b>ELI-00160</b>  Initial Submission: <b>02-Dec-2022</b>  Final Submission: <b>27-Sept-2023</b></p>	<p><b>Legal Manufacturer:</b>  Ortho Clinical Diagnostics  ,100 Indigo Creek Drive  Rochester, NY, 14626 USA</p> <p><b>Manufacturing site:</b>  Ortho Clinical Diagnostics  Felindre Meadows Pencoed  Bridgend CF35 5PZ United Kingdom</p> <p><b>Embassy attested Free Sale Certificate</b>  Ortho Clinical Diagnostics  Felindre Meadows Pencoed  Bridgend CF35 5PZ United Kingdom</p>	<p><b>VITROS Immunodiagnostic Product Prolactin</b>  <b>Reagent &amp; Calibrator:</b></p> <p>Cal: <b>1113596</b>  Rgt: <b>1849793</b></p> <p><b>Shelf Life:</b>  Reagent: 52 weeks  Calibrator: 52 weeks</p> <p><b>Storage Conditions:</b>  2-8°C</p>	<p>The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board;</p> <p>i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad.</p> <p>ii. Notarized Termination letter issued by the legal manufacturer, if any.</p>



		<b>Date of Issue:</b> 04-July-2023 <b>Validity:</b> 26-May-2025	<b>Class: C</b>  <b>Fees: 50,000/-</b>	
29.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)  R&I date: 26-03-2025  Fee Rs 31000/- vide Challan no. 8119755416	<b><u>Legal Manufacturer:</u></b> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany  LOA/sole agency :09-06-2025 (copy of LOA)  FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)  EC Certificate 28-10-2028 (Notarized EC certificate)  ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	AltoSa-SFT Tacking Balloon Catheter PTA Balloon Catheter  Class: B  Shelf life: 6 Years  Codes/Sizes as per FSC AL-46-65 AL-46-100	Approved subject to submission of fee for family of class B.
30.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)  R&I date: 26-03-2025  Fee Rs 31000/- vide Challan no. 8947697815	M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany  LOA/sole agency :09-06-2027 (copy of LOA)  FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)  EC Certificate 28-10-2028 (Notarized EC certificate)  ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)	Lokum L-Quest Guidewire  Guide Wire  Applied as : Single  Class: B  Shelf life: 5 Years Codes/Sizes:	Approved subject to submission of differential fee.
31.	M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near	M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany  LOA/sole agency :09-06-2027 (copy of LOA)	Lokum L-Quest MINI Guidewire  Generic Name : Guidewire  Applied as : Single	Approved subject to submission of differential fee.

	<p>ROHAIL KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&amp;I date: 26-03-2025</p> <p>Fee Rs 31000/- vide Challan no. 4746366812</p>	<p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Class: B</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes</p>	
32.	<p>M/s Global Biotech Medical Devices Private Limited First Floor of Plot No: 35-N/3, PECHS Block 6, Near ROHAIL KHUND SOCIETY KARACHI (ELI-01292)</p> <p>R&amp;I date: 18-03-2025</p> <p>Fee Rs 62000/- vide Challan no. 922023750630</p>	<p><b>Legal Manufacturer:</b> M/s AndraTec GmbH, Simmerner Str. 70, 56075 Koblenz Germany</p> <p>LOA/sole agency :09-06-2025 (copy of LOA)</p> <p>FSC (Germany) Issue date: 17-03-2024 (Notarized FSC)</p> <p>EC Certificate 28-10-2028 (Notarized EC certificate)</p> <p>ISO-13485 Validity: 13-10-2027(Notarized ISO Certificate)</p>	<p>Exeter Retrieval Snare preloaded</p> <p>Class: D</p> <p>Shelf life: 5 Years</p> <p>Codes/Sizes as per FSC</p>	<p>Approved <b>Exeter Retrieval Snare Micro Preloaded</b> subject to submission of fee for class D.</p>

<b>Name</b>	<b>Name</b>
<b>Address of Importer</b>	K.S. Agencies <b>Address of Importer</b> Office 210, 2 <sup>nd</sup> Floor, Business Arcade, Main University Road, Karachi
Detail of ELM/ELI	ELI- 00382
Name Address of Manufacturer	<b>(LEGAL MANUFACTUREUR)</b> Huaiyin Medical Instruments Company Limited <b>(Manufacturing site)</b> No.8 West Ming Yuan Road, 223003, Huaiyin, China
<b>Brand Name</b> <b>Generic name</b>	Glycryl PGLA PGLA (Polyglycolide-Co-L-Latctide)90%:10%
<b>Country of origin FSC</b>	<b>Fsc:</b> Original embassy attested Free Sale Certificate from China issued on 24-02-2023 and valid till 24-02-2025
Stability data/ service life	<b>Shelf Life:</b> 5 Years Stability study conducted for 60 months.
<b>Documents submitted</b>	<b>Marketing Authorization Letter:</b> Loa Valid till 31.12.2031 issuance date 15.09.2021 <b>Production Quality Management System Certificate ( Iso 13485)</b>

<b>Marketing Authorization Letter:</b>  <b>Production Quality Management System Certificate (Iso 13485)</b>  <b>Production Quality Assurance Certificate or Equivalent</b>  <b>Full Quality Assurance Certificate or Equivalent:</b>  <b>Design Examination</b>  <b>Declaration of Conformity (Doc) provided/not provided</b>	ISO13485 China Site Notifying Body DNV Valid till 27-Feb-25 issuance date 28-Feb-2022 <b>Production Quality Assurance Certificate Or Equivalent</b> Original Issued by Presafe on 26-04-2018 and Extension by DNV on 25-04-2023 which is valid till 31-12-2028  <b>Full Quality Assurance Certificate or Equivalent:</b> Original Issued by Presafe on 26-04-2018 and Extension by DNV on 25-04-2023 which is valid till 31-12-2028 <b>Design Examination</b> <b>Valid until 28.04.2024</b>  <b>Declaration of Conformity (Doc): Provided</b>
Codes/ sizes	Code & Size as per FSC Sizes 5/0, 4/0, 3/0, 2/0, 1/0, 0, 1, 2, 3, 4, 5, 6, 7, 8 diameter in all lengths and needles types with permanent needle attachment and rotating techniques.
<b>Decision</b>	Deferred for the following: <ol style="list-style-type: none"> <li>1. FSC China not valid (valid till 24.02.2025) and product not mentioned in it.</li> <li>2. FSC MHRA not valid (valid till 06.11.2023) and all applied codes not mentioned in it.</li> <li>3. Submit documentary evidences for the name and codes of the applied product.</li> </ol>

=====