

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

MINUTES OF 118th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 21-01-2026 (MANUAL APPLICATION PART-II)

118th 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 21st January, 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

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S. No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	Member (attended meeting through videolink)
3.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
4.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
9.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
10.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
11.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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

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

Dr. Hanif Ullah (Deputy Director-IX)

I. APPLICATIONS SUBMITTED IN CMS:

S.No.	Name of Importer	Manufacturer's Details	Name of Medical Device	Decision
1.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip #2244982394 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: RNX- 73V-U8U8	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Brand Name: EXACT DIAGNOSTICS EBV RUN CONTROLS Generic Name: External Quality control, Unassayed (EBV low run control EBVL101, EBV high run control EBVH102) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: EBVL101, EBVH102 Shelf Life: 36 month shelf life from the date of manufacturing whereas open vial stable at 2-8 °C for five days.	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Copy of the legalized CFG are required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Proof that the open vial is stable at 2-8 °C for five days. Justification for the applied grouping and fee thereof. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
2.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 50000/- Slip # 103152556	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes	Brand Name: EXACT DIAGNOSTICS HBV RUN CONTROLS Generic Name: External quality control, Unassayed (HBV low run control HBVL101, HBV high run control HBVH102) Applied as: Kit	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all

	<p>This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 8QJ-ED1-9LBZ</p>	<p>Validity: 31.12.2025 FSC Type: NIL Issued by: NIL Legalization: NIL Validity: NIL ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Class: D Models/Code/sizes (as per FSC & application: HBVL101, HBVH102 Shelf Life: 36 months</p>	<p>the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
3.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 50000/- Slip # 1368223971 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: YV8-68A-HVD2</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: NIL Issued by: NIL Legalization: NIL Validity: NIL ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Brand Name: EXACT DIAGNOSTICS HBV, HCV, HIV SCREEN CONTROL (Exact Diagnostics HBV DNA Screen Control – HBVSCREEN, Exact Diagnostics HCV RNA Screen Control – HCVSCREEN, Exact Diagnostics HIV-1 Screen Control – HIVSCREEN, Exact Diagnostics HIV, HBV, HCV Screen Control – VIRSCREEN) Generic Name: External quality control, Unassayed Applied as: Cluster Class: D Models/Code/sizes (as per FSC & application: HBVSCREEN (10 × 1.4 ml) HCVSCREEN (10 × 1.4 ml) HIVSCREEN (10 × 1.4 ml) VIRSCREEN (10 × 1.4 ml) Shelf Life: 18 months</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Make sure that the stability / shelf-life verification report is conclusive and includes all the applied codes / models. You have applied multiple products in the same application. Clarification is required.</p>
4.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS</p>	<p>Brand Name: EXACT DIAGNOSTICS HHV-6 RUN CONTROL Generic Name: External quality control, Unassayed</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the</p>

	<p>R&I Date: 13.09.2023 Fee: 25000/- Slip # 623029767 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 31G-1E9-N1UY</p>	<p>76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: HHV-6 low run control HV6L101, HHV-6 high run control HV6H102 5×1.0 ml Shelf Life: 24 months</p>	<p>product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Correct the shelf life in application form in line with the shelf life verification report. Make sure that the stability / shelf-life verification report is conclusive and includes all the applied codes / models.</p>
5.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 9537688272 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: VNH-H5H-H8QJ</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Brand Name: EXACT DIAGNOSTICS HSV-1 RUN CONTROL Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: HSV-1 low run control HSV1L101, HSV-1 high run control HSV1H102 5×1.0 ml Shelf Life: 36 months</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
6.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS</p>	<p>Brand Name: EXACT DIAGNOSTICS HSV-2 RUN CONTROL Generic Name: External quality control, Unassayed</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the</p>

	<p>R&I Date: 13.09.2023 Fee: 25000/- Slip # 37633950 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 4BT-RXA-VEMH</p>	<p>76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Applied as: NIL Class: B Models/Code/sizes (as per FSC & application: HSV-2 low run control HSV2L101, HSV-2 high run control HSV2H102 5×1.0 ml Shelf Life: 36 months</p>	<p>product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
7.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 6414957842 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 2MB-XNN-U25Q</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Brand Name: EXACT DIAGNOSTICS JCV CONTROL Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: JCV low run control JCVL101, JCV high run control JCVH102 5×1.0 ml Shelf Life: 24 months</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Make sure that the stability / shelf-life verification report is conclusive and includes all the applied codes / models. DOC has not been submitted.</p>
8.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/-</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA</p>	<p>Brand Name: Exact Diagnostics Parvovirus B19 Control Generic Name: External quality control, Unassayed Applied as: NIL Class: B</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC.</p>

	<p>Slip # 6414957842 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 2MB-XNN-U25Q</p>	<p>Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Models/Code/sizes (as per FSC & application: Parvovirus B19 low run control B19L101, Parvovirus B19 high run control B19H102 5×1.0 ml Shelf Life: 24 months</p>	<p>Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Make sure that the stability / shelf-life verification report is conclusive and includes all the applied codes / models.</p>
9.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 5139135703 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: SYL-8MM-RWMB</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Brand Name: Exact Diagnostics RP Control Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: RP Positive Run Control RPPOS RP Negative Run Control RPNEG 5×1.0 ml Shelf Life: 18 months</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Make sure that the stability / shelf-life verification report is conclusive and includes all the applied codes / models.</p>
10.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 469033548738 This evaluation is</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025</p>	<p>Brand Name: Exact Diagnostics Enterovirus Run Control Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application:</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required.</p>

	based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: S6M-Y7L-TQ6L	FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Enterovirus Run Control EVRC 5×1.0 ml Shelf Life: 36 months	Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee.
11.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 7728819609 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 494-MAS-R3X5	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Brand Name: EXACT DIAGNOSTICS SARS-CoV-2 Run controls Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: SARS-COV-2- NEGATIVE RUN CONTROL (COV000CE) SARS-COV-2- POSITIVE RUN CONTROL (COV019CE) SARS-COV-2-FLU RSV POSITIVE RUN CONTROL (COVFLU) SARS-COV-2-FLU RSV NEGATIVE RUN CONTROL (COVFLUNEG) 5 × 1.0 ml Shelf Life: 18-24 months	Deferred for: Clear description of the products shall be provided. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and exactly the same applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. The uploaded CFG does not contain the applied products and codes. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. The 18-24 months shelf life shall be clarified. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
12.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 0347385048 This evaluation is based on the on-line	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025	Brand Name: Exact Diagnostics VZV Controls Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: VZV Low run control	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required.

	data (documents mentioned in column II) submitted through E-App. Tracking ID: G97-97B-HLB9	FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	VZVL101 VZV High run control VZVH102 5 × 1.0 ml Shelf Life: 24 months	Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. The claimed shelf life of 24 months against the 36 months mentioned in stability / shelf-life verification report needs clarification. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
13.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 50000/- Slip # 79628637557 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: RE4-ZYS-VS6H	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Brand Name: Exact Diagnostics CMV Run Controls Generic Name: External quality control, Unassayed Applied as: Cluster Class: C Models/Code/sizes (as per FSC & application: CMV Low Run Control CMV L101 CMV High Run Control CMV H102 5 × 1.0 ml Shelf Life: 36 months	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
14.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 7183527222 This evaluation is	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes	Brand Name: Exact Diagnostics BKV Run Controls Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application:	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all

	based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: GL5-SLN-UABB	Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	BKV Low Run Control BKV L101 BKV High Run Control BKV H102 5 × 1.0 ml Shelf Life: 36 months	the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
15.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 0602093808 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: GLD-UP5-D7SU	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Brand Name: Exact Diagnostics Ehrlichia Run Control Generic Name: External quality control, Unassayed Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: Ehrlichia Run Control ERLRC 5 × 1.0 ml Shelf Life: 18 months	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Submit conclusive stability / shelf-life verification report.
16.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 7486377354 This evaluation is based on the on-line data (documents mentioned in column II)	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No	Brand Name: Exact Diagnostics Borrelia Run Control Generic Name: External quality control, Unassayed Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: Borrelia Run Control BORRC 5 × 1.0 ml Shelf Life: 18 months	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required.

	submitted through E-App. Tracking ID: L67-4LA-1URB	Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028		Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Submit conclusive stability / shelf-life verification report.
17.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 033658942 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: EA2-847-8RY5	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Brand Name: Exact Diagnostics Bartonella Run Control Generic Name: External quality control, Unassayed Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: Bartonella Run Control BRTRC 5 × 1.0 ml Shelf Life: 18 months	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Submit conclusive stability / shelf-life verification report.
18.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 82272434483 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 5LD-ZBW-AW98	Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028	Brand Name: Exact Diagnostics Babesia Run Control Generic Name: External quality control, Unassayed Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: Babesia Run Control BABRC 5 × 1.0 ml Shelf Life: 18 months	Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Submit conclusive stability / shelf-life verification report.

19.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 809864676064</p> <p>This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 88V- 1DU-M12D</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Brand Name: Exact Diagnostics Anaplasma Run Control Generic Name: External quality control, Unassayed Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: Anaplasma Run Control ANARC 5 × 1.0 ml Shelf Life: 18 months</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Submit conclusive stability / shelf- life verification report.</p>
20.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 13.09.2023 Fee: 25000/- Slip # 005235811 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: Z6U- H1H-LHS1</p>	<p>Legal manufacturer: EXACT DIAGNOSTICS LLC, 100 SOUTH JONES STREET SUITE 100 FORT WORTH TEXAS 76104 USA LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy Issued by: USFDA Legalization: No Validity: 26.03.2027 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 26.05.2028</p>	<p>Brand Name: Exact Diagnostics Adenovirus Run Controls Generic Name: External quality control, Unassayed Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application: Adenovirus low run control ADVL101, Adenovirus high run control ADVH102 5 × 1.0 ml Shelf Life: 36 months</p>	<p>Deferred for: Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA by Exact Diagnostics LLC. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and fee. Submit conclusive stability / shelf- life verification report. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
21.	<p>Chemical House, 6C Skinder Malhi</p>	<p>Legal manufacturer: BIO-RAD Laboratories,</p>	<p>Brand Name: Lymphochek urine bone</p>	<p>Deferred for: Clarification is required about the mentioned</p>

	<p>Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 381759249262 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: NHY-YLJ-9TZU</p>	<p>Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: No Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>markers control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: 406-Bilevel (6×2ml), 406X– Minipak (2×2ml) Shelf Life: 1080 days at 2-8 °C.</p>	<p>generic name. Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA, Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
22.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 154489434655 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: Y9J-XP1-J5M2</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: No Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>Brand Name: Lymphochek Hypertension Markers Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: 600- Trilevel (6×2ml), 600X– Minipak (3×2ml) Shelf Life: 720 days shelf life from the date of manufacturing at 2-8 °C.</p>	<p>Deferred for: Clarification is required about the mentioned generic name. Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA, Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is</p>

				<p>required.</p> <p>Copy of valid ELI is required.</p> <p>Justification for the applied grouping.</p> <p>Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
23.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 2629170037 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: NE4- TG2-RZPM</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: No Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>Brand Name: Lymphochek Fertility Control Generic Name: Multiple Human hormone IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: 480- trilevel (12×5ml), 481 – Level 1(12×5ml), 482- Level 2 (12×5ml), 483- Level 3 (12×5ml), 480X- Minipak(3×5ml) Shelf Life: 1170 days shelf life from the date of manufacturing at 2- 8 °C.</p>	<p>Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA, Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. The codes have not been mentioned in the LOA. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
24.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 75651489 This evaluation is based on the on-line data (documents mentioned in</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: No Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA</p>	<p>Brand Name: Lymphochek Endocrine Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: 535 535X</p>	<p>Deferred for: Clarification is required about the mentioned generic name. Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA, Submission of relevant LOA (having the applied product</p>

	column II) submitted through E-App. Tracking ID: 4TP- WM1-LYMW	Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028	Shelf Life: 810 days shelf life from the date of manufacturing at 2- 8 °C.	and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
25.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 60987046621 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 7L4- Q4H-2PD3	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: No Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028	Brand Name: Liquichek Lipid Control Generic Name: Multiple Lipid analyte IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: 641-level 1 (6×3ml), 642 –Level 2(6×3ml), 640X– Minipak (2×3ml) Shelf Life: 1080 days shelf life from the date of manufacturing and product stored at - 20°C to -70 °C.	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA, Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
26.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America	Brand Name: Liquichek Cardiac Advance Control Generic Name: Multiple Cardiac	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required.

	<p>R&I Date: 14.02.2024 Fee: 25000/- Slip # 3755003694 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 4ZW-EPD-QBGN</p>	<p>LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>markers IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12016447 level 1(6×3ml), 12016448 level 2(6×3ml), 12016449 level 3(6×3ml), 12016450 level 4(6×3ml) Shelf Life: 28 months shelf life from the date of manufacturing and product stored at -20 °C to -70 °C.</p>	<p>LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized copy of LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. The applied product has not been mentioned in the LOA. Clarification is required. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
27.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 20564325 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 6BG-Q4W-J656</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>Brand Name: Liquichek Blood Gas Plus EGL Control Generic Name: Multiple Blood gas / Haemoximetry / Electrolyte analyte IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 511- level 1 (30×1.7ml), 512 –level 2 (30×1.7ml), 513- level 3 (30×1.7ml), 510x-minipak (9×1.7ml) Shelf Life: 36 months when stored at 2-8°C, with an optional 12 months of that duration at 20-25°C</p>	<p>Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. The applied product has not been mentioned in the LOA.</p>

				Clarification is required. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
28.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 611681782 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: WXR- NV3-6J2E	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028	Brand Name: Liquichek AMH Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12006327 Shelf Life: 1170 days shelf life from the date of manufacturing at 2- 8 °C.	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. The applied product has not been mentioned in the LOA. Clarification is required. Clarification is required about the mentioned generic name.
29.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 66761136 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App.	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy	Brand Name: InteliQ Urine Chemistry Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12009995 Level1(12×3ml), 12009996 Level 2(12×3ml), 12009997 Bilevel	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate

	Tracking ID: 5MR-UJ3-5GMY	Notarization: No Validity: 17.05.2028	Minipack (2×3ml) Shelf Life: 24 months shelf life from the date of manufacturing at 2-8 °C.	is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Clarification is required about the mentioned generic name. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
30.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 10771347584 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 9PG-9VG-WUUT	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: NIL Notarization: NIL Validity: NIL	Brand Name: InteliQ Tumor Marker Control Generic Name: Multiple tissue associated protein, / tumor marker IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12008289 Level 1(6×2ml), 12008290 Level 2(6×2ml), 12008291 Level 3(6×2ml), 12008292 Minipak (3×2ml) Shelf Life: 28 months shelf life from the date of manufacturing at -20°C to -70 °C whereas 30 days onboard stability at 2-8°C for most of analytes. 10 days open vial stability at 2-8°C.	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
31.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 634135777153	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC	Brand Name: InteliQ Specialty Immunoassay Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA is required.

	<p>This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: N1W-HU1-Z1SZ</p>	<p>Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>per FSC & application): 12008276 Level LTA(6×4ml), 12008277 Level 1(6×4ml), 12008278 Level 2(6×4ml), 12008279 Level 3(6×4ml), 12008280 Minipak(4×4ml) Shelf Life: 24 months shelf life from the date of manufacturing at - 20°C to -70 °C whereas 30 days off board stability at 2-8°C for most of analytes.</p>	<p>Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Clarification is required about the mentioned generic name. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
32.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 97744929910 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: E8Z-U3Y-A9PN</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: NIL Notarization: No Validity: NIL</p>	<p>Brand Name: InteliQ Immunology Control Generic Name: Multiple clinical chemistry analyte IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12009941 Level 1(6×3ml), 12009942 Level 2(6×3ml), 12009943 Level 3(6×3ml), 12009944 Minipak(3×3ml) Shelf Life: 24 months shelf life from the date of manufacturing at - 20°C to -70 °C</p>	<p>Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Submit stability / shelf life verification report for all the codes. Clarification is required about the mentioned generic name. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
33.	<p>Chemical House, 6C Skinder Malhi</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd,</p>	<p>Brand Name: InteliQ Immunoassay Plus Control</p>	<p>Deferred for: The brand names shall be the same in application and LOA.</p>

	<p>Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: NIL Fee: 25000/- Slip # NIL This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: BN4-N73-4Z4Z</p>	<p>Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: NIL Notarization: No Validity: NIL</p>	<p>Generic Name: Multiple clinical chemistry analyte IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12009949 Level 1(12×4ml), 12009949 Level 2(12×4ml), 12009950 Level 3(12×4ml), 12009951 Trilevel Minipak (3×4 ml) Shelf Life: 28 months shelf life from the date of manufacturing at - 20°C to -70 °C. Refrigerator storage—All instruments, off-board, 10 days for most analytes (2 to 8°C)</p>	<p>Clarification about the fee submission date and proof of R&I submission along with fee challan. Clarification for applying as 12009949 Level 1(12×4ml) and 12009949 Level 2(12×4ml). Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Make sure that the stability / shelf-life verification report includes all the applied codes. Clarification is required about the mentioned generic name. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
34.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 27797996 This evaluation is based on the on-line data (documents mentioned in column II)</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 Jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026</p>	<p>Brand Name: InteliQ Homocysteine Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12004309 Level 1(6×1ml), 12004310 Level 2(6×1ml),</p>	<p>Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required.</p>

	submitted through E-App. Tracking ID: YHU-9RG-GSHM	ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028	12004311 Level 3(6×1ml), 12004312 Minipak(3×1ml) Shelf Life: 36 months at -20°C to -70 °C.	Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Clarification is required about the mentioned generic name. Correct the shelf life in application form in line with the shelf life verification report. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.
35.	Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 460353640767 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: JAX-HN4-BBZU	Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028	Brand Name: InteliQ Ethanol/ Ammonia Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 12008299 Level 1(6×2ml), 12008300 Level 2(6×2ml), 12008301 Level 3(6×2ml), 12008302 Minipak(3×2ml) Shelf Life: Shelf Life: 24 months (2 to 8°C)	Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio-Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Clarification is required about the mentioned generic name. Correct the shelf life in application form in line with the shelf-life verification report. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.

36.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 326399227 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: JHV- 6TB-2R34</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>Brand Name: InteliQ Cardiac Marker Control Generic Name: Multiple cardiac marker IVD control Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application): 12009955 Level 1 (6 × 3 ml), 12009956 Level 2 (6 × 3 ml), 12009957 Level 3 (6 × 3 ml), 12009958 Level 1A (6 × 3 ml), 12009959 Level 1B (6 × 3 ml), 12009960 Level 1C (6 × 3 ml), 12009961 Level 1 Minipak (1 × 3 ml), 12009962 Level 2 Minipak (1 × 3 ml), 12009963 Level 3 Minipak (1 × 3 ml), 12009964 Level 1A Minipak (1 × 3 ml), 12009965 Level 1B Minipak (1 × 3 ml), 12009966 Level 1C Minipak (1 × 3 ml), InteliQ Cardiac Advance Control – Code Models 12016484 Level 1 (6 × 3 ml), 12016485 Level 2 (6 × 3 ml), 12016486 Level 3 (6 × 3 ml), 12016487 Level 4 (6 × 3 ml) Shelf Life: Shelf Life: 36 months (-20 to - 70°C)</p>	<p>Deferred for: The brand names shall be the same in application and LOA. Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Clarification is required about the mentioned generic name. Correct the shelf life in application form in line with the shelf-life verification report. Shelf-life verification report for all the codes shall be submitted. Clarification for applying three different products (InteliQ Cardiac Advance Control [Cat. Nos. 12016484, 12016485, 12016486, 12016487] InteliQ Cardiac Markers Plus Control LT [Cat. Nos. 12009955, 12009956, 12009957, 12009961, 12009962, 12009963] InteliQ Cardiac Markers Plus Control LT [Cat. Nos. 12009958, 12009959, 12009960, 12009964, 12009965, 12009966]) in the instant single application. DOC for all the applied product and codes shall be submitted. Justification that the stability / shelf-life verification report does not cover all the applied codes /</p>
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				models.
37.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 14.02.2024 Fee: 25000/- Slip # 2992144198 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App. Tracking ID: 7ZE- XVB-E8YM</p>	<p>Legal manufacturer: BIO-RAD Laboratories, Inc., 9500 jeronimo Rd, Irvine CA 92618 United States of America LOA Type: scanned copy Notarization: Yes Validity: 31.12.2025 FSC Type: scanned copy of CFG Issued by: USFDA Legalization: No Validity: 12.05.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 17.05.2028</p>	<p>Brand Name: InteliQ Assayed Multiquel Control Generic Name: Multiple clinical chemistry protein IVD control Applied as: kit Class: B Models/Code/sizes (as per FSC & application): 12008256 Level 1(12×3ml), 12008257 Level 2(12×3ml), 12008258 Level 3(12×3ml), 12008259 Minipak(3×3ml) Shelf Life: 28 months at -20°C to -70 °C Refrigerator storage—All instruments, off-board, 10 days for most analytes (2 to 8°C)</p>	<p>Deferred for: Clarification about the fee submission date. Clarification / applying with proper class of the device in line with the DOC is required. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Scanned legalized CFG is required. Notarized LOA and ISO certificate is required. Clarification about multiple addresses in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping. Clarification is required about the mentioned generic name. Correct the shelf life in application form in line with the shelf-life verification report. Justification that the stability / shelf-life verification report does not cover all the applied codes / models.</p>
38.	<p>Chemical House, 6C Skinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 R&I Date: 02.05.2025 Fee: 6000/- Slip # 86600669871 This evaluation is based on the on-line data (documents mentioned in column II) submitted through E-App.</p>	<p>Product Owner: Bio-Rad Laboratories Inc. Address: 4000 Alfred Nobel Drive Hercules, CA, USA 94547 Manufacturer Name: M/s BIO-RAD LABORATORIES (SINGAPORE) PTE LTD Manufacturing Site Address: 1 KAKI BUKIT VIEW, #03-01 TECHVIEW SINGAPORE 415941</p>	<p>Brand Name: CFX OPUS DX Generic Name: CFX Opus 96 DX CFX Opus 384 DX CFX Maestro DX SE Software Applied as: Family Class: A Models/Code/sizes (as per FSC & application): CFX Opus 96 DX (12014330) CFX OPUS 384 DX (12014335) CFX Opus Deepwell</p>	<p>Deferred for: Clarification for variation of applicant and product owner in the FSC (origin). CFX Opus Deepwell DX (12016687) has not been mentioned in the generic name as well as FSC. LOA has been issued by the Bio- Rad Europe, Switzerland, while the product is manufactured and sold in USA and Singapore. Submission of relevant LOA (having the applied product and all the applied codes) is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required.</p>

	Tracking ID: 7ZE-XQ7-9V9-D2H6	LOA Type: scanned copy Notarization: Yes Validity: 31.12.2026 FSC Type: scanned copy Issued by: Health Sciences Authority, Singapore Legalization: No Issue date: 08.04.2021 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 20.06.2026	DX (12016687) CFX Maestro DX SE Software (12014349) Shelf Life: NIL	Scanned legalized FSC (origin) is required. Notarized copy of ISO certificate is required. Clarification about multiple addresses (without the address of the product owner) in the ISO certificate is required. Copy of valid ELI is required. Justification for the applied grouping and classification along with product description of specific device. Scanned notarized CE certificate / legalized FSC (reference country) is required. Submit conclusive shelf-life verification report for all the models/ codes.
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PRODUCTS APPLIED FOR IMPORT:

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	<p>CSM Pakistan (Guarantee) Limited 23-C Commercial Area, Old Sunset Boulevard, DHA Phase 2, Karachi. Pakistan (ELI-00418)</p> <p>Date of R&I 10-08-2020 Fee Details: Paid Fee: 50,000/- Fee Challan No: 2030602.</p>	<p>Innotatex (Thailand) Limited E 1-6, Export Processing Zone, Southern Industrial estate, Village 4, Chalung SUB-District, Hatyai District, Songkhla, 90110 Thailand.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 22-04-2028</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: FDA Thailand</p> <p>Validity: 09-10-2027</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 05-05-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 09-10-2027.</p>	<p>1-Excite Imported Studded, 2-Excite Refreshing Plain & Flavored 3-Fire Xtacy, Flavoured dotted ribbed & coloured, 4-Xtacy Super Studded Nature Rubber Latex Male Condoms</p> <p>Applied as Family: Class-C</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin of the applied product with demanded codes or Valid Legalized Free Sale Certificate of Reference Country</p> <p>2. Valid notarized LOA wherein the applied product shall be mentioned.</p> <p>One type of condom will be considered in current application while other types shall be applied through online MDMC portal.</p>
2.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 08-04-2021 Fee Details: Paid Fee: 25,000/- Fee Challan No: 2044584.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of</p>	<p>Foyomed Connecting Tubes with Yankauer Handle</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes: LB61</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes.</p> <p>2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA)</p>

		<p>Commerce, China</p> <p>Validity: 18-06-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: MHRA UK</p> <p>Issuance Date: 27-06-2018</p> <p>Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 20-07-2026</p> <ul style="list-style-type: none"> • EC : Not provided 		
3.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 18-03-2022</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 480095795483.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity date: 07-07-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Chamber of Commerce, China</p> <p>Validity: 18-06-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: MHRA UK</p> <p>Issuance Date: 27-06-2018</p> <p>Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 20-07-2026</p> <ul style="list-style-type: none"> • EC : Not provided 	<p>Foyomed Disposable Anesthesia Breathing circuit</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

4.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 18-03-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 56096964495.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 18-06-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non- notarized copy Validity: 20-07-2026</p> <p>• EC : Not provided</p>	<p>Foyomed Nasal Oxygen Cannula</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.
5.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 21-04-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 3618835324.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p>	<p>Foyomed Anesthesia Mask</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

		<p>Validity: 18-06-2027</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 20-07-2026 • EC : Not provided 		
6.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 21-04-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 31588976.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China Validity: 18-06-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 20-07-2026 • EC : Not provided 	<p>Foyomed Manual Resuscitator</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

7.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 21-04-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 1593494174.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 18-06-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non- notarized copy Validity: 20-07-2026</p> <p>• EC : Not provided</p>	<p>Foyomed Nelaton Catheter Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.
8.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 21-04-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 07053885190.</p>	<p>M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p>	<p>Foyomed Foyomed Venturi Mask</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

		Validity: 18-06-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 20-07-2026 • EC : Not provided		
9.	Hakimsons, Karachi- (ELI-00396) Date of R&I 31-04-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 154921253	M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China. Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china. LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China Validity: 18-06-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 20-07-2026 • EC : Not provided	Foyomed Oxygen Mask with Reservoir Bag Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.
10.	Hakimsons, Karachi- (ELI-00396)	M/s: Ningbo MFLAB Medical Instruments Co. Ltd., China.	Foyomed Heat and Moisture Exchanger	Deferred for submission of the followings” 1. Valid Legalized Free Sale

	<p>Date of R&I 21-04-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 07059980.</p>	<p>Address: No.508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 18-06-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: MHRA UK Issuance Date: 27-06-2018 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 20-07-2026</p> <p>• EC : Not provided.</p>	<p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes.</p> <p>2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA)</p> <p>3. Codes as per FSC & justification grouping if multiple codes.</p>
11.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 8518667959.</p>	<p>Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Kejiao District, Shaoxing City 3120250 Zhejiang Province, China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 06-09-2023</p> <p>• ISO 13485:</p>	<p>CRR Disposable Anesthesia Breathing Circuits</p> <p>Applied as Set: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes.</p> <p>2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA)</p> <p>3. Codes as per FSC & justification grouping if multiple codes.</p>

		Type: Scan copy of non-notarized copy Validity: 29-09-2026 EC : Not provided.		
12.	Hakimsons, Karachi- (ELI-00396) Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 23248454.	Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Keqiao District, Shaoxing City 3120250 Zhejiang Province, China LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China Validity: 06-09-2023 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-09-2026 EC : Not provided.	CRR Disposable Anesthetic Mask Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.
13.	Hakimsons, Karachi- (ELI-00396) Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 398112567.	Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Keqiao District, Shaoxing City 3120250 Zhejiang Province, China LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China Validity: 06-09-2023	CRR Disposable Breathing Bag Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-09-2026</p> <p>EC : Not provided.</p>		
14.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 0158235792.</p>	<p>Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Keqiao District, Shaoxing City 3120250 Zhejiang Province, China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 06-09-2023</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-09-2026</p> <p>EC : Not provided.</p>	<p>CRR Disposable Breathing System Filters</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.
15.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 6312012907.</p>	<p>Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Keqiao District, Shaoxing City 3120250 Zhejiang Province, China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 06-09-2023</p>	<p>CRR Disposable Laryngeal Mask Airways</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-09-2026</p> <p>EC : Not provided.</p>		
16.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 5401924378.</p>	<p>Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Keqiao District, Shaoxing City 3120250 Zhejiang Province, China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p> <p>Validity: 06-09-2023</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-09-2026</p> <p>EC : Not provided.</p>	<p>CRR Disposable Oxygen Mask</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.
17.	<p>Hakimsons, Karachi- (ELI-00396)</p> <p>Date of R&I 31-01-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 32006266.</p>	<p>Shaoxing Career Medical Appliance Co.,Ltd. Add: Pingxing Road, Loujia village, Pingshui Town, Keqiao District, Shaoxing City 3120250 Zhejiang Province, China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 07-07-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Chamber of Commerce, China</p>	<p>CRR Disposable Tracheal Tubes</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 60 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Codes as per FSC & justification grouping if multiple codes.

		Validity: 06-09-2023 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 29-09-2026 EC : Not provided.		
18.	Hakimsons, Karachi- (ELI-00396) Date of R&I 14-12-2021 Fee Details: Paid Fee: 25,000/- Fee Challan No: 330745727730	Biometrix S.R.O. Vicenzy 16 93101 Samorin, Slovakia. LOA Type: Scan copy of notarized copy. Validity date: 24-05-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Slovak Chamber of Commerce. Validity: 24-05-2024 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 07-05-2022 EC : Not provided.	Biometrix Foley Catheters Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Valid Notarized LOA & ISO 13485 4. Codes as per FSC & justification grouping if multiple codes.
19.	Hakimsons, Karachi- (ELI-00396) Date of R&I 14-12-2021 Fee Details: Paid Fee: 25,000/- Fee Challan No: 729771520	Biometrix S.R.O. Vicenzy 16 93101 Samorin, Slovakia. LOA Type: Scan copy of notarized copy. Validity date: 24-05-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Slovak Chamber of Commerce. Validity: 24-05-2024 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 07-05-2022 EC : Not provided.	Biometrix PTCA Accessories Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Valid Notarized LOA & ISO 13485 4. Codes as per FSC & justification grouping if multiple codes with catalog & fee.
20.	Hakimsons, Karachi-	Biometrix S.R.O. Vicenzy 16 93101 Samorin, Slovakia.	Biometrix Thoracic Catheter	Deferred for submission of the followings”

	(ELI-00396) Date of R&I 14-12-2021 Fee Details: Paid Fee: 25,000/- Fee Challan No: 0230843026	LOA Type: Scan copy of notarized copy. Validity date: 24-05-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Slovak Chamber of Commerce. Validity: 24-05-2024 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 07-05-2022 EC : Not provided.	Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Valid Notarized LOA & ISO 13485 4. Codes as per FSC & justification grouping if multiple codes with catalog & fee.
21.	Hakimsons, Karachi- (ELI-00396) Date of R&I 14-12-2021 Fee Details: Paid Fee: 25,000/- Fee Challan No: 23946624524	Biometrix S.R.O. Vicenzy 16 93101 Samorin, Slovakia. LOA Type: Scan copy of notarized copy. Validity date: 24-05-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Slovak Chamber of Commerce. Validity: 24-05-2024 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 07-05-2022 EC : Not provided.	Biometrix Trocar Catheter Applied as Single: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Valid Notarized LOA & ISO 13485 4. Codes as per FSC & justification grouping if multiple codes with catalog & fee.
22.	Hakimsons, Karachi- (ELI-00396) Date of R&I 14-12-2021 Fee Details: Paid Fee: 25,000/- Fee Challan No: 3881983663	Biometrix S.R.O. Vicenzy 16 93101 Samorin, Slovakia. LOA Type: Scan copy of notarized copy. Validity date: 24-05-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Slovak Chamber of Commerce.	Biometrix Manifold Sets Applied as Set: Class-B Shelf life: 60 months Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Legalized Free Sale Certificate of Reference Country or valid notarized CE (FQA) 3. Valid Notarized LOA & ISO

		Validity: 24-05-2024 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 07-05-2022 EC : Not provided.		13485 4. Codes as per FSC & justification grouping if multiple codes with catalog & fee.
23.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) Date of R&I 7-11-2023 Fee Details: Paid Fee: 25,000/- Fee Challan No: 480095795483.	Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025 EU QMS Certificate (IVDR) Validity: 14-12-2025	β2-Microglobulin (CLIA) (β2-Microglobulin) Applied as Kit: Class-C Shelf life: 4 Weeks Codes/Model/Sizes: 130254001M- 100 Test Kit 130654001M- 50 Test Kit	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.
24.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) Date of R&I 7-11-2023	Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China. LOA Type: Scan copy of notarized copy.	free β-HCG (CLIA) (Free β-Human chorionic gonadotropin) Applied as Kit: Class-C Shelf life: 4 Weeks Codes/Model/Sizes:	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes.

	<p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 2733894424.</p>	<p>Validity date: 31-12-2025</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language</p> <p>Validity: 24-06-2024</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>	<p>130214005M- 100 Test Kit 130614005M- 50 Test Kit.</p>	<p>2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed.</p> <p>Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.</p>
25.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 28083004185.</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language</p> <p>Validity: 24-06-2024</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned</p>	<p>SCCA (CLIA) (Squamous cell carcinoma antigen)</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 4 Weeks</p> <p>Codes/Model/Sizes: 130201041M- 100 Test Kit 130601041M- 50 Test Kit</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed.</p> <p>Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about</p>

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>		the said product.
26.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 2741315069.</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>	<p>ProGRP (CLIA) (Pro- Gastrin-releasing peptide)</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 4 Weeks</p> <p>Codes/Model/Sizes: 130201523M- 100 Test Kit 130601523M- 50 Test Kit</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. <p>Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.</p>
27.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of</p>	<p>Pepsinogen I (CLIA) (Proenzyme of gastric pepsin)</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 4 Weeks</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded

	<p>7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 055995187.</p>	<p>notarized copy. Validity date: 31-12-2025 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025 EU QMS Certificate (IVDR) Validity: 14-12-2025</p>	<p>Codes/Model/Sizes: 130251019M- 100 Test Kit 130651019M- 50 Test Kit</p>	<p>codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.</p>
28.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 272183139676.</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned</p>	<p>Calcitonin (CLIA) (Calcitonin) Applied as Kit: Class-C Shelf life: 4 Weeks Codes/Model/Sizes: 130261002M- 100 Test Kit 130661002M- 50 Test Kit</p>	<p>Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid</p>

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>		Letter of Authorization about the said product.
29.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 015281808662.</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>	<p>EBV EA IgG (CLIA) Epstein-Barr virus</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 4 Weeks</p> <p>Codes/Model/Sizes: 130265001M- 100 Test Kit 130665001M- 50 Test Kit</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. <p>Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.</p>
30.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of</p>	<p>EBV NA IgG (CLIA) Epstein-Barr virus NA IgG</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 4 Weeks</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded

	<p>7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 0962318699.</p>	<p>notarized copy. Validity date: 31-12-2025 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025 EU QMS Certificate (IVDR) Validity: 14-12-2025</p>	<p>Codes/Model/Sizes: 130265006M- 100 Test Kit 130665006M- 50 Test Kit</p>	<p>codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.</p>
31.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 7-11-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 4008693569.</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 19-09-2022 Validity: Not mentioned</p>	<p>EBV VCA IgA (CLIA) Epstein-Barr virus VCA IgA</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 4 Weeks</p> <p>Codes/Model/Sizes: 130265005M- 100 Test Kit 130665005M- 50 Test Kit</p>	<p>Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid</p>

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>		Letter of Authorization about the said product.
32.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 11-10-2023 Fee Details: Paid Fee: 5000/- Fee Challan No: 4305015568.</p>	<p>Shenzhen New Industries Biomedical Engineering Co., Ltd. No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 30-12-2025</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: In Chinese Language Validity: 24-06-2024</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 29-09-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2025</p> <p>EU QMS Certificate (IVDR) Validity: 14-12-2025</p>	<p>Sample Diluent (Consumables) Sample Release Agent (Consumables) Alkaline Wash (Consumables) Hitergent (Consumables)</p> <p>Applied as Kit: Class-A</p> <p>Shelf life: 130299039M – (24 months) 130299038M – (24 months) 130299037M – (24 months) 130299036M – (24 months) 130299026M –06 months 130299034M –06 months 1305990001 –18 months 1305990010 –18 months 1305990011 –18 months 1305990003 –18 months</p> <p>Codes/Model/Sizes: 130299039M – (1X25ml) 130299038M – (1X25ml) 130299037M – (1X25ml) 130299036M – (1X25ml) 130299026M – (4x0.2 g) 130299034M – (1x25 mL)</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin plus CE(FQA) or FSC RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping if multiple codes with catalog & fee. 4. Revised Form7A duly signed. <p>Furthermore, the MDB decided to call for personal hearing to both the firms i.e M/s. Nextek Healthcare Karachi. and M/s Snibe Diagnostic Pakistan (SMC-Private) Limited, Karachi for clarification about the valid Letter of Authorization about the said product.</p>

			1305990001 – (1×2000 g) 1305990010 – (2×60 g) 1305990011 – 1305990003 – (1x500g)	
33.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) Date of R&I 23-04-2025 Fee Details: Paid Fee: 31,000/- Challan No. 2676581931	DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany. LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 18-08-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 21-11-2025	TruLab CRP Level 1 (C-reactive protein control) TruLab CRP Level 2 (C-reactive protein control) TruLab CRP hs Level 1 (C-reactive protein control) TruLab CRP hs Level 2 (C-reactive protein control) Applied as Cluster: Class-B Shelf life: 596009910045 – 18 months 596109910045 – 18 months 597309910046 – 24 months 597409910046 – 24 months Codes/Model/Sizes 596009910045 (3x2mL) 596109910045 (3x2mL) 597309910046 (3x1mL) 597409910046 (3x1mL)	Deferred for submission of the followings” 1. Valid Notarized ISO 13485 2. Codes as per FSC & justification grouping if multiple codes with catalog & fee.
34.	M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619) Date of R&I 23-04-2025 Fee Details: Paid Fee: 31,000/- Challan No. 153453655	DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany. LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 18-08-2022 Validity: Not mentioned	TruLab Albumin U/CSF Level 1 (Albumin control) TruLab Albumin U/CSF Level 2 (Albumin control) Applied as Cluster: Class-B Shelf life: 597109910046 – 18 months 597209910046 – 18 months. Codes/Model/Sizes	Deferred for submission of the followings” 1. Valid Notarized ISO 13485 2. Codes as per FSC & justification grouping if multiple codes with catalog & fee.

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 21-11-2025</p>	<p>597109910046 (3x1mL) 597209910046 (3x1mL)</p>	
35.	<p>M/s. Nextek Healthcare Plot No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 23-04-2025 Fee Details: Paid Fee: 31,000/- Challan No. 398102295838</p>	<p>DiaSys Diagnostic Systems GmbH. Alte Strasse 9, 65558 Holzheim, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 18-08-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 21-11-2025</p>	<p>TruLab HbA1C liquid Level 1 (Hemoglobin A1c control) TruLab HbA1c liquid Level 2 (Hemoglobin A1c control) TruLab HbA1c net Level 1 (Hemoglobin A1c control) TruLab HbA1c net Level 2 (Hemoglobin A1c control)</p> <p>Applied as Cluster: Class-B</p> <p>Shelf life: 597909910060 – 15 months 597909910074 – 15 months 598009910060 – 15 months 598009910074 – 15 months 599309910076 – 18 months 599409910076 – 18 months</p> <p>Codes/Model/Sizes 597909910060 (1x0.25mL) 597909910074 (4x0.25mL) 598009910060 (1x0.25mL) 598009910074 (4x0.25mL) 599309910076 (6x1mL) 599409910076 (6x1mL)</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Notarized ISO 13485 2. Codes as per FSC & justification grouping if multiple codes with catalog & fee.</p>
36.	<p>M/s. Nextek Healthcare Plot</p>	<p>DiaSys Diagnostic Systems GmbH.</p>	<p>TruLab Cystatin C Level 1</p>	<p>Deferred for submission of the followings”</p>

	<p>No. 24-C, Lane-9, Khayaban-e-Ghazi, D.H.A. Phase 6, Karachi. (ELI- 00619)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 31,000/- Challan No. 82003225702</p>	<p>Alte Strasse 9, 65558 Holzheim, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 18-08-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 21-11-2025</p>	<p>(Cystatin C control) TruLab Cystatin C Level 2 (Cystatin C control)</p> <p>Applied as Cluster: Class-B</p> <p>Shelf life: 598709910046 – 12 weeks 598809910046 – 12 weeks</p> <p>Codes/Model/Sizes 598709910046 (3x1mL) 598809910046 (3x1mL)</p>	<p>1. Valid Notarized ISO 13485</p> <p>2. Codes as per FSC & justification grouping if multiple codes with catalog & fee.</p>
37.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 13-01-2023</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 8869045835</p>	<p>Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023</p>	<p>Glyde File Prep</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 2 Years</p> <p>Codes/Model/Sizes A0901000000000, A0902000000000, A0903000000000, A0905000000000,</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes.</p> <p>2. Valid Notarized LOA & ISO 13485</p> <p>3. Codes as per FSC & justification grouping multiple codes with catalog & fee.</p> <p>4. Revised Form7A duly signed.</p> <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
38.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p>	<p>Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963.</p>	<p>Dycal Dentin Standard Package (Radiopaque Calcium Hydroxide Composition)</p> <p>Daycal</p> <p>Applied as Family: Class-B</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes.</p> <p>2. Valid Notarized LOA & ISO</p>

	<p>Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 9799598829</p>	<p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023</p>	<p>Shelf life: 3 Years Codes/Model/Sizes</p>	<p>13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed.</p> <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
39.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 13-01-2023 Fee Details: Paid Fee: 5,000/- Challan No. 94839053915</p>	<p>Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023</p>	<p>M access Endodontic Instruments Applied as Family: Class-B</p> <p>Shelf life: 5 Years Codes/Model/Sizes A12MA, BNCMAFL, A11MA, A16MA and files GMDN: 40529 – Rotary endodontic rasp, reusable</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed. <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
40.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 13-01-2023 Fee Details:</p>	<p>Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC</p>	<p>QuiXfil Resin</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 1.5 Years Codes/Model/Sizes TTLCEM-A2 TTLCEM-TR TCEM3-VPA2 TCEM3-VPTR ECHTLCEM</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog

	<p>Paid Fee: 25,000/- Challan No. 2765099604</p>	<p>Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023</p>		<p>& fee.</p> <p>4. Revised Form7A duly signed.</p> <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
41.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 82816381</p>	<p>Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023</p>	<p>Calibra Universal Resin</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes 607400 607402 607403 607405 607406 607407 607410 607086</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed. <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
42.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 69844954792</p>	<p>Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of notarized & Embassy attested copy</p>	<p>Neo Spectra Resin</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 3 Years</p> <p>Codes/Model/Sizes Neo Spectr ST Neo Spectra ST Effects</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed.

		Issued By: Swiss medic Validity: 17-01-2026 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023		Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
43.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 28455929	Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023	SDR Plus Resin (Dental filling material) Applied as Family: Class-B Shelf life: 3 Years Codes/Model/Sizes	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
44.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 2875582962	Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026 • ISO 13485:	Protaper Gold Protaper Gold Applied as Family: Class-B Shelf life: 5 Years Codes/Model/Sizes	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided the application shall be processed after decision on

		Type: Scan copy of non-notarized copy Validity: 27-11-2023		the Renewal case.
45.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 291859048	Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023	TC Cavity Burs TC Cavity Burs Applied as Family: Class-B Shelf life: 5 Years Codes/Model/Sizes	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
46.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 13-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 1948908	Legal Manufacturer & Manufacturing Site (as per Form-7A: M/s Dentsply LLC (Dentsply Caulk) 38, West Clarke Avenue, Milford, De USA 19963. LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Swiss medic Validity: 17-01-2026 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 27-11-2023	Diamond Burs Diamond Burs Applied as Family: Class-B Shelf life: 5 Years Codes/Model/Sizes	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin or FSC of any RRA issued by concerned regulatory Authority of the applied product with demanded codes. 2. Valid Notarized LOA & ISO 13485 3. Codes as per FSC & justification grouping multiple codes with catalog & fee. 4. Revised Form7A duly signed. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
47.	M/s Hasnain Scientific.	Legal Manufacturer M/s. Kommanditgesellschaft	Cuvette Racks & Ball for 800 Tests	Deferred for submission of valid apostilled and notarized

	<p>16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi.</p> <p>ELI-00197</p> <p>Date of R&I 23-01-2023</p> <p>Fee Details: Paid Fee: 5,000/- Challan No. 54653978285</p>	<p>Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany.</p> <p>Manufacturing Site M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance date: 29-06-2022 Validity: Not mentioned.</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-11-2023</p>	<p>Assay Stirring Set</p> <p>Applied as Single: Class-A</p> <p>Shelf life: 4 Years Codes/Model/Sizes 050210</p>	LOA and ISO 13485.
48.	<p>M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi.</p> <p>ELI-00197</p> <p>Date of R&I 23-01-2023</p> <p>Fee Details: Paid Fee: 5,000/- Challan No. 3421866301</p>	<p>Legal Manufacturer M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany.</p> <p>Manufacturing Site M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of notarized & Embassy</p>	<p>Cuvette Racks for 2.320 Tests Assay Stirring Set</p> <p>Applied as Single: Class-A</p> <p>Shelf life: 4 Years Codes/Model/Sizes 54420</p>	Deferred for submission of valid apostilled and notarized LOA and ISO 13485.

		<p>attested copy Issued By: Germany Issuance date: 29-06-2022 Validity: Not mentioned.</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-11-2023</p>		
49.	<p>M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi.</p> <p>ELI-00197</p> <p>Date of R&I 23-01-2023 Fee Details: Paid Fee: 5,000/- Challan No. 525775824070</p>	<p>Legal Manufacturer M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany. Manufacturing Site M/s. Kommanditgesellschaft Behnk Elektronik GmbH. & Co. Hans-Bockler-Ring 27, 22851 Norderstedt, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance date: 29-06-2022 Validity: Not mentioned.</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 12-11-2023</p>	<p>Cuvette Racks 8-Fold CP for 2.320 Tests Assay Stirring Set Applied as Single: Class-A Shelf life: 4 Years Codes/Model/Sizes 54520</p>	<p>Deferred for submission of valid apostilled and notarized LOA and ISO 13485.</p>
50.	<p>M/s Hasnain Scientific. 16 - Shalimar Floor Aries Tower, (Maryam Halls) Shamasabad Muree Road, Rawalpindi.</p> <p>ELI-00197</p>	<p>M/s. BIOLABO S.A.S. Les Hautes Rives, 02160 Maizy, France.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2025 FSC Type: Scan copy of notarized & Embassy</p>	<p>BE FIB Reagent for quantitative determination of Fibrinogen (FIB) in human plasma.</p> <p>Applied as Family: Class-B Shelf life: 3 Years Codes/Model/Sizes</p>	<p>Deferred for submission of valid apostilled and notarized LOA and ISO 13485.</p>

	Date of R&I 23-01-2023 Fee Details: Paid Fee: 25,000/- Challan No. 11354502	attested copy Issued By: CCI France Issuance date: 01-06-2025 Validity: Not mentioned. • ISO 13485: Type: Scan copy of non-notarized copy Validity: 23-12-2024	771300 & 771301	
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ADDITIONAL AGENDA CASES

EVALUATOR: RANA AHSAN-UL-HAQ ATHAR

DEFERRED CASES AGENDA FOR 118 MDB MEETING TO BE HELD ON 21-01-2026.

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Applicant Name: Nees International, Office No. 602, 6th Floor, Al-Hafeez Hights, Lahore ELI-01426 Date of R&I 18-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 3470975434	Name of Manufacturer: Professional Derma SA, Riva A. Caccia 1/d, 6900 Lugano- Switzerland Manufacturing site: Agri-Bio-Eco Laboratori riuniti S.r.l.via delle Albicoche 19,00071 Pomezia (Roma)-Italy FSC Copy. LOA Validity: 06-05-2030 (Copy) FSC: Validity: 15-12-2026 (Copy) ISO Validity: 11-03-2027 (Copy) EU QA/ EC Certificate(copy) Validity: 26-05-2024 (expired) Design Examination certificate, expired (copy) Validity: 26-05-2024	Brand name: JALUPRO HMW Generic Name: Jalupro HMW Class-D Shelf life: 36 MONTHS Models/ Specification	Deferred (last opportunity) for the followings: 1. Notarized ISO 13485 of legal manufacturer and manufacturing site. 2. Formulation/pack size not provide. 3. Establishment of link b/w legal manufacturer and manufacturing site through any document issued by Notified Body or Health Regulatory Authority.

2.	<p>Applicant Name: Nees International, Office No. 602, 6th Floor, Al-Hafeez Hights, Lahore</p> <p>ELI-01426</p> <p>Date of R&I 18-07-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 898446811424</p>	<p>Name of Manufacturer: Professional Derma SA, Riva A. Caccia 1/d, 6900 Lugano- Switzerland</p> <p>Copy of LOA PROVIDED</p> <p>FSC: Apostilled Validity: 15-12-2026 (Original)</p> <p>ISO Validity: 11-03-2027 (Colored copy)</p> <p>EC Certificate (colored copy) validity: 26-05-2024</p> <p>Design Examination certificate (colored copy) validity: 26-05-2024</p>	<p>Brand name: JALUPRO SUPER HYDRO</p> <p>Generic Name: Jalupro Super Hydro</p> <p>Class-D</p> <p>Shelf life: 36 months</p> <p>Models/ Specification</p>	<p>Deferred (last opportunity) for the followings:</p> <ol style="list-style-type: none"> 1. Notarized ISO 13485 of legal manufacturer and manufacturing site. 2. Formulation/pack size not provide. 3. Establishment of link b/w legal manufacturer and manufacturing site through any document issued by Notified Body or Health Regulatory Authority.
3.	<p>Applicant Name: Nees International, Office No. 602, 6th Floor, Al-Hafeez Hights, Lahore</p> <p>ELI-01426</p> <p>Date of R&I 18-07-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 943450949312</p>	<p>Name of Manufacturer: Professional Derma SA, Riva A. Caccia 1/d, 6900 Lugano- Switzerland</p> <p>Manufacturing site: Agri-Bio-Eco Laboratori riuniti S.r.l.via delle Albicoche 19,00071 Pomezia (Roma)-Italy</p> <p>LOA Validity: 05-05-2030 (Copy)</p> <p>FSC: apostille Validity: 15-12-2026 (Copy)</p> <p>ISO Validity: 11-03-2027 (Copy)</p> <p>EU QA/ EC Certificate (copy)</p>	<p>Brand name: JALUPRO YOUNG EYE</p> <p>Generic Name: Jalupro young eye</p> <p>Class-D</p> <p>Shelf life: 36 MONTHS</p> <p>Models/ Specification</p>	<p>Deferred (last opportunity) for the followings:</p> <ol style="list-style-type: none"> 1. Notarized ISO 13485 of legal manufacturer and manufacturing site. 2. Formulation/pack size not provide. 3. Establishment of link b/w legal manufacturer and manufacturing site through any document issued by Notified Body or Health Regulatory Authority.

		<p>Validity: 26-05-2024 (expired)</p> <p>Design Examination Certificate (copy) validity: 26-5-2024 (Expired)</p>		
4.	<p>M/s Nwill Healthcare, Office No. B-9, Royal Garden Hotel Building, 19-Birdwood Road, Lahore</p> <p>ELI-00164</p> <p>Date of R&I 16-05-2025</p> <p>Fee Details: Paid Fee: 31,000/- Fee Challan No: 8125667137</p>	<p>M/s Thai Nippon Rubber Public Company Limited,</p> <p>Manufacturing Site: 789/139 Moo 1 Nongkham, Sriracha Chonburi 20110, Thailand</p> <p>Head Office: 1 Charoenrat Road, Thungwatdon, Sathon, Bangkok, 10120, Thailand</p> <p>LOA Validity: 18-05-2030</p> <p>FSC: Thailand Issue date: 16-02-2027</p> <p>ISO Validity: 11-02-2026</p> <p>EU Quality Assurance Certificate/CE Certificate Validity: 30-05-2027</p>	<p>Brand name: Niptex</p> <p>Generic Name: Lubricants Water Based-Intended to provide additional vaginal lubrication & Reduce the discomfort caused by vaginal dryness.</p> <p>Class-B</p> <p>Shelf life: 03 years.</p> <p>Models/ Specification</p>	<p>The Board deferred (last opportunity) the case for further deliberation and directed the applicant to submit a written justification explaining the rationale for the use of different flavors in the lubricant.</p>
5.	<p>M/s. Care Scientific, 13-14, C/A 1st Floor, Chuburji Center, Multan Road, Lahore.</p> <p>(ELI- 00487)</p> <p>R&I detail 06-05-2025 Fee: 6,000/- Slip: 34199615</p>	<p>Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan.</p> <p>• LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027</p> <p>• FSC</p>	<p>Brand name: Bilirubin Test Kit</p> <p>Generic Name: Bilirubin Test Kit</p> <p>Class: A</p> <p>Codes/Sizes: CS002 (Bilirubin Direct, JENDRASSIK-GROF) CS003 (Bilirubin Total, JENDRASSIK-GROF) CS004 (Bilirubin Total & Direct, JENDRASSIK-</p>	<p>Deferred (last opportunity) for the following:</p> <ol style="list-style-type: none"> 1. submission of the fee as per SRP1399(I)/2025 dated 1st August 2025. 2. justification for applying in class A as DRAP has registered the same in class B.

		Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	GROF) CS024 (Bilirubin Total, DMSO Method) CS025 ((Bilirubin Direct, DMSO Method) Applied as: Kit Shelf life: 18 Months	
6.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 26645291	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Calcium Arsenazo III Test Kit Generic Name: Calcium Arsenazo III Test Kit Class: A Codes/Sizes: CE007 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
7.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 36338382	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy	Brand name: Urea UV (Urease-GLDH Method) Test Kit Generic Name: Urea UV (Urease-GLDH Method) Test Kit Class: A Codes/Sizes: CS027 Applied as: Kit	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Shelf life: 18 Months	
8.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 58986401	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: CK-MB Test Kit Generic Name: CK-MB Test Kit Class: A Codes/Sizes: RT020 Applied as: Kit Shelf life: 18 Months	Deferred for the justification for applying in class A and provision of brand name.
9.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 28035328	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA	Brand name: LDL Cholestrol Test Kit Generic Name: LDL Cholestrol Test Kit Class: A Codes/Sizes: CS011 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
10.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 08436258168	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Phosphorus UV Molybdate Generic Name: Phosphorus UV Molybdate Class: A Codes/Sizes: CE003 Applied as: Kit Shelf life: 18 Months	Deferred for the clarification that applied name is Phosphorus UV Molybdate while name as per FSC is Phosphorus Test.
11.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 1842271266	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA	Brand name: AST/GOT (SL), UV IFCC Generic Name: AST/GOT (SL), UV IFCC Class: A Codes/Sizes: CZ005 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
12.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 86233789045	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Biotrol (Level I & Level II) Generic Name: Biotrol Normal & Abnormal Control Class: A Codes/Sizes: CC001, CC002 Applied as: Kit Shelf life: 18 Months	Deferred for the followings: 1. The applied name of the device Biotrol (Level I & Level II) while name as per FSC is Biotrol Normal Control (Bovine Serum). Biotrol Abnormal Control (Bovine Serum). 2. Fee for the family required.
13.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 146317502816	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not	Brand name: Lipase Test Kit Generic Name: Lipase Test Kit Class: A Codes/Sizes: CZ011 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
14.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 72493029	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Sodium Reagent Test Generic Name: Sodium Reagent Test Class: A Codes/Sizes: CE006 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
15.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 71292525	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized	Brand name: Zinc Test Kit Generic Name: Zinc Test Kit Class: A Codes/Sizes: CE004 Applied as: Kit Shelf life: 18 Months	Deferred for clarification that name as per FSC is Zinc (Colorimetric Test with 5-Brom-PASS) while applied name is Zinc Test.

		Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
16.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 258336330	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: CK-NAC Test Kit Generic Name: CK-NAC Test Kit Class: A Codes/Sizes: CZ009 Applied as: Kit Shelf life: 18 Months	Deferred for the followings: 1. clarification that name of the device as per FSC is Creatine Kinase NAC while applied name is CK-NAC Test Kit. 2. Justification for applying in class A.
17.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 4862879997	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027	Brand name: Triglycerides (SL), GPO-PAP Test Kit Generic Name: Triglycerides (SL), GPO-PAP Test Kit Class: A Codes/Sizes: CS016 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 		
18.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 73142997	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Alkaline Phosphatase (SL) DGKC Test Kit Generic Name: Alkaline Phosphatase (SL) DGKC Test Kit Class: A Codes/Sizes: CZ001 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
19.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 243104863	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 	Brand name: Creatinine Kinetic, Jafee Reaction Test Kit Generic Name: Creatinine Kinetic, Jafee Reaction Test Kit Class: A Codes/Sizes: CS006 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
20.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 4975580020	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Cholesterol Test Kit Generic Name: Cholesterol Test Kit Class: A Codes/Sizes: CS005 Applied as: Kit Shelf life: 18 Months	Deferred for clarification that name of the device as per FSC is Cholesterol (SL), CHOD-PAP while applied name is Cholesterol Test Kit.
21.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 03926147	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027	Brand name: HDL Cholestrol Precipitation Test Kit Generic Name: HDL Cholestrol Precipitation Test Kit Class: A Codes/Sizes: CS009 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 		
22.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 3493260707	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: HDL-C Direct With Calibrator Test Kit Generic Name: HDL-C Direct With Calibrator Test Kit Class: A Codes/Sizes: CS020 Applied as: Kit Shelf life: 18 Months	Deferred for the clarification name of the device as per FSC HDL Cholesterol (D) while applied name is HDL-C Direct With Calibrator Test Kit.
23.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 62431582101	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 	Brand name: LDH (SL), SCE Test Kit Generic Name: LDH (SL), SCE Test Kit Class: A Codes/Sizes: CZ008 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
24.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 80596930	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Albumin BCG Test Kit Generic Name: Albumin BCG Test Kit Class: A Codes/Sizes: CS001 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
25.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 153709445357	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027	Brand name: Alpha Amylase (SL) CNPG3 Test Kit Generic Name: Alpha Amylase (SL) CNPG3 Test Kit Class: A Codes/Sizes: CZ002 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 		
26.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 893505769918	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Gamma GT (SL), SZASZ Test Kit Generic Name: Gamma GT (SL), SZASZ Test Kit Class: A Codes/Sizes: CZ007 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
27.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 80698320753	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 	Brand name: Potassium Reagent Test Kit Generic Name: Potassium Reagent Test Kit Class: A Codes/Sizes: CE005 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 		
28.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 4985192382	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Urea Berthelot Test Kit Generic Name: Urea Berthelot Test Kit Class: A Codes/Sizes: CS017 Applied as: Kit Shelf life: 18 Months	Deferred for the clarification that name as per FSC is Urea (SL) Endpoint-Berthelot while applied name is Urea Berthelot Test Kit.
29.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 0778842478	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 	Brand name: Uric Acid (Uricase-PAP) Test Kit Generic Name: Uric Acid (Uricase-PAP) Test Kit Class: A Codes/Sizes: CS018 Applied as: Kit Shelf life: 18 Months	Deferred for the clarification that name of the device as per FSC is Uric Acid (SL), Uricase-Pap while applied name is Uric Acid (Uricase-PAP) Test Kit.

		<ul style="list-style-type: none"> • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 		
30.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 859383709555	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025 	Brand name: Total Protein, Biouret Test Kit Generic Name: Total Protein, Biouret Test Kit Class: A Codes/Sizes: CS015 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
31.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 12729284082	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 	Brand name: Iron Ferrozine Test Kit Generic Name: Iron Ferrozine Test Kit Class: A Codes/Sizes: CS028 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
32.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 8872838295	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025	Brand name: Magnesium Xylidyl Blue Kit Generic Name: Magnesium Xylidyl Blue Kit Class: A Codes/Sizes: CE002 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.
33.	M/s. Care Scientific, 13-14, C/A 1 st Floor, Chuburji Center, Multan Road, Lahore. (ELI- 00487) R&I detail 06-05-2025 Fee: 6,000/- Slip: 1124659042	Name of Manufacturer: M/s. Bioresearch for Medical Diagnostics, Muslim Al-Attar Street, Northern Marka, Amman, Jordan. • LOA Type: Copy Notarization: Not notarized Validity: 02-04-2027 • FSC Type: Copy Issued By: JFDA Legalization: Not Legalized Validity: 14-04-2027	Brand name: ALT/GPT (SL), UV IFCC Test Kit Generic Name: ALT/GPT (SL), UV IFCC Test Kit Class: A Codes/Sizes: CZ003 Applied as: Kit Shelf life: 18 Months	Approved. The firm shall submit the brand name of applied product duly authorized by the exporter.

		• ISO Certificate Type: Copy Notarization: Not notarized Validity: 06-07-2025		
34.	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 Fees: Rs 62000 Challan # 341787471002 Date of R& I 05-05-2025	<u>Legal Manufacturer:</u> Foshan Biosun Medical Technology Co, Ltd Address: 1-5F Building 4, No. 89 Taoyuan East road, Shishan, Nanhai, 528225, Foshan, Guangdong, People's Republic of China. <u>LOA:</u> Sole Agency Agreement Validity date: 25-10-2027 (Original Notarized) <u>FSC: China</u> Valid Until: 26-11-2026 (Original Notarized) <u>FSC: Spain</u> Issue date: 12-03-2024 (Original Notarized) EC Certificate valid until: 05-08-2029 (Original Notarized) <u>ISO:</u> Valid till: 17-06-2027 (Original Notarized)	BIOSKY - DISPOSABLE HEMOPERFUSION CARTRIDGE Class C Shelf Life: 3 years Codes/Sizes: MG80, MG100, MG120, MG130, MG150, MG180, MG200, MG230, MG250, MG280, MG300, MG330, MG350, MG380, MG400	Deferred for clarification that LAO is issued by Gaungdong Baihe Medical Technology Co., Ltd. instead of manufacturer. Original, notarized and valid LOA issued by Foshan Biosun Medical Technology Co, Ltd required.
35.	Eastern Medical Care Pvt Ltd, 7-A Block N, Model Town Extension, Lahore. ELI-00130 Fees: Rs 62000 Challan #	<u>Legal Manufacturer:</u> Foshan Biosun Medical Technology Co, Ltd Address: 1-5F Building 4, No. 89 Taoyuan East road, Shishan, Nanhai, 528225, Foshan, Guangdong, People's Republic of China. <u>LOA:</u>	Biosky-Disposable Bilirubin Adsorption Column Class C Shelf Life: 3 years Codes/Sizes: DX100, DX150, DX250,	Deferred for clarification that LAO is issued by Gaungdong Baihe Medical Technology Co., Ltd. instead of manufacturer. Original, notarized and valid LOA issued by Foshan Biosun Medical Technology Co, Ltd required.

	287678899 Date of R& I 05-05-2025	Sole Agency Agreement Validity date: 25-10-2027 (Original Notarized) <u>FSC: China</u> Valid Until: 26-11-2026 (Original Notarized) FSC: Spain Issue date: 12-03-2024 (Original Notarized) EC Certificate valid until: 05-08-2029 (Original Notarized) <u>ISO:</u> Valid till: 17-06-2027 (Original Notarized)	DX350, DX400	
36.	M/s Eastern Medical Care Pvt. Ltd., 7-A Block N, Model Town Extension, Lahore Date of R& I 05-05-2025 Fee: PKR 31,000/- Slip # 22113086603	M/s Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China LOA Validity: 25-10-2027 FSC: China Validity: 24-04-2026 FSC: Spain Issue Date: 23-01-2025 ISO Validity: 06-08-2027 EU QA /CE Certificate Validity: 21-11-2019	Brand name: ABLE Generic Name: Disposable Blood Lines Class-B Shelf life: 3 Years Models/ Specification: FB-A001V01, FB-A001V02, FB-A001V03, FB-A001V04, FB-A001V05, FB-A002V01, FB-A002V02, FB-A002V03, FB-A002V04, FB-A002V05, FB-A003V01, FB-A003V02, FB-A003V03, FB-A003V04, FB-A003V05, FB-A004V01, FB-A004V02, FB-A004V03, FB-A004V04, FB-A004V05, FB-A005V01, FB-A005V02, FB-A005V03, FB-A005V04, FB-A005V05, FB-A006V01, FB-A006V02, FB-A006V03, FB-	Deferred for the following: 1. clarification that product not mention in submitted FSC China valid till 11.03.2027. 2. Justification for applying various models in single application.

			A006V04, FB-A006V05, FB-A101V11, FB-A101V12, FB-A102V11, FB-A102V12, FB-A103V11, FB-A103V12, FB-A104V11, FB-A104V12	
37.	<p>M/s Eastern Medical Care (Pvt.) Ltd., 7A, Block N, Model Town Extension Lahore</p> <p>ELI-00130</p> <p>Date of R& I 05-04-2025</p> <p>Fee: PKR 62,000/- Slip # 9148161257 Dated: 17-04-2025</p>	<p>Manufacturer: Guangdong Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, China.</p> <p>• Sole Distribution Agreement: Type: Original Notarization: By CCPIT Validity: 25-10-2027</p> <p>• FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 24-04-2026</p> <p>• ISO – Certificate: Type: Original Notarization: By CCPIT Validity: 06-08-2027</p> <p>• FSC (Spain): Type: Original Issued By: Govt. Body Legalization: Apostilled Date of Issue: 23-01-2025 Validity: Not mentioned</p>	<p>Brand Name: Able-Disposable Silicon Foley Catheter</p> <p>Generic Name: Disposable Silicon Foley Catheter</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Sizes: 1-Way without balloon (6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR)</p> <p>2-Way with balloon (6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR, 20FR, 22FR, 24FR)</p> <p>3-Way (16FR, 18FR, 20FR, 22FR, 24FR, 26FR)</p> <p>Shelf Life: 36 Months</p>	Approved.
38.	<p>M/s Eastern Medical Care (Pvt.) Ltd., 7A, Block N, Model Town Extension Lahore</p> <p>ELI-00130</p> <p>Date of R& I 05-04-2025</p>	<p>Manufacturer: Foshan Biosun Medical Technology Co., Ltd., 1-5F Building 4, No.89 Taoyuan East Road, Shishan, Nanhai, 528115, Foshan Guangdong, China</p> <p>• LOA: Not submitted.</p>	<p>Brand Name: Biosky Disposable Bilirubin Adsorption Column</p> <p>Generic Name: Disposable Bilirubin Adsorption Column</p> <p>Applied as: Single</p>	Repeated application. Firm is directed to submit the copy of the initial application, fee challan, undertaking and requisite documents.

	<p>Fee: PKR 62,000/- Slip # 287678899 Dated: 17-04-2025</p>	<p>• FSC Type: Original (in other file) Issued By: Govt. Body Legalization: Apostilled Validity: 05-11-2026</p> <p>• ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 17-06-2027</p> <p>• EU QMS Certificate: Type: Copy Notarization: By CCPIT Validity: 05-08-2029</p>	<p>Class: C</p> <p>Codes/Models/Sizes: DX100, DX150, DX250, DX350, DX400</p> <p>Shelf Life: 24 Months</p>	
39.	<p>Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road Rawalpindi</p> <p><i>ELI-01172</i> R&I Date: 15-07-2025 Fee: Rs. 6,000 vide deposit slip no. 21121666296</p>	<p>Name of Manufacturer: Xi'an Friendship Ivledical Electronics Co., Ltd., Address: No. 9 Gao Xin 1st Road, High-Tech Developer Tlent Zone, IXI an, 710075 Shaanxi, P.R. China LOA Type: Copy Notarization: No Validity date: 01-01-2028</p> <p>• FSC: Type: Copy Issued By: -- Legalization: No Validity: 24-03-2026</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 17-11-2025</p>	<p>Brand Name: Cables for EMG Concentric Needle Electrodes Generic Name: EMG (EEG) Cables Applied as: Single Class: A Models/Code/sizes (as per FSC & application) CCN 400 3000 Shelf Life: 5 years</p>	<p>Deferred for the following:</p> <ol style="list-style-type: none"> 1. LOA has been issued by Friendship Europe ApS instead of the manufacturer i.e. Xi'an Friendship Ivledical Electronics Co., Ltd. 2. FSC (China) valid till 27.03.2026 has been apostilled from Columbia instead of China (country of origin). 3. valid ISO 13485 required. 4. Clarification of the codes. <p>1.</p>
40.	<p>Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road</p>	<p>Name of Manufacturer: Xi'an Friendship Ivledical Electronics Co., Ltd., Address: No. 9 Gao Xin</p>	<p>Brand Name: Disposable EMG Concentric Needle Electrodes Generic Name: EMG Needle Electrode</p>	<p>Deferred for the following:</p> <ol style="list-style-type: none"> 1. LOA has been issued by Friendship Europe ApS instead of the manufacturer i.e. Xi'an Friendship Ivledical Electronics

	<p>Rawalpindi (ELI-01172)</p> <p>R&I Date: 15-07-2025 Fee: 31,000/- Slip # 7383749529.</p>	<p>1st Road, High-Tech Developer Tlont Zone, IXI an, 710075 Shaanxi, P.R. China LOA: Type: Copy Notarization: No Validity: 01-01-2028 FSC: Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 04-06-2027 ISO – Certificate: Type: Copy Notarization: No Validity: 17-11-2025</p>	<p>Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: Shelf life: 3 years</p>	<p>Co., Ltd. 2. FSC (China) valid till 27.03.2026 has been apostilled from Columbia instead of China (country of origin). 3. valid ISO 13485 required. 4. Clarification of the codes. 5. the product name Disposable EMG Concentric Needle Electrodes not mentioned in the FSC.</p>
41.	<p>M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi</p> <p>ELI-00203 Renewal application: MDIR-0000504 R & I dated: 29-07-2024</p> <p>Fee submitted 25,000/- 33135598297</p> <p>Differential fee 32,400/- 772190565964</p>	<p>Legal Manufacturer: M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand.</p> <p>Attested copy of FSC of Thailand valid till 04-07-2026.</p> <p>FSC of MHRA without legalization valid till 31-01-2028.</p>	<p>Cocoon PFO Occluder Accessory Set (PFO Occluder Delivery System) Class D Shelf Life: 3 years</p> <p>Codes: CPF8F CPF9F</p>	<p>Approved subject to verification of the fee.</p>
42.	<p>M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi</p> <p>ELI-00203 Renewal application MDIR-0000505</p> <p>R&I date: 29-07-2024</p>	<p>Legal Manufacturer: M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand.</p> <p>Attested copy of FSC of Thailand valid till 04-07-2026.</p> <p>FSC of MHRA without legalization valid till 31-</p>	<p>Cocoon VSD Occluder Accessory Set II (VSD Occluder Delivery System) Class D Shelf Life: 3 years</p> <p>Codes: COV116F COV117F</p>	<p>Approved subject to verification of the fee.</p>

	<p>Fee Submitted 25,00/- 3683101218</p> <p>Differential fee 32,4000/- 531162153878</p>	01-2028.		
43.	<p>M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi</p> <p>ELI-00203</p> <p>Renewal application MDIR-0000506</p> <p>R&I date: 29-07-2024</p> <p>Fee Submitted 25,00/- 320968988</p> <p>Differential fee 32,4000/- 07414530375</p>	<p><u>Legal Manufacturer:</u> M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand.</p> <p>Attested copy of FSC of Thailand valid till 04-07-2026.</p> <p>FSC of MHRA without legalization valid till 31-01-2028.</p>	<p>Cocoon Duct Occluder Accessory Set (PDA Occluder Delivery System)</p> <p>Class D</p> <p>Shelf Life: 3 years</p> <p>Codes: COP6F COP7F COP8F COP9F</p>	Approved subject to verification of the fee.
44.	<p>M/s Easha Enterprises, 2B-04, Third Floor Adyala Towers Adyala Road, Rawalpindi</p> <p>ELI-00203</p> <p>Renewal application MDIR-0000503</p> <p>R&I date: 29-07-2024</p> <p>Fee Submitted 25,00/- 34674009513</p>	<p><u>Legal Manufacturer:</u> M/s Vascular Innovations Co., Ltd 88/38 Moo 1, 345 Rd., Bangtanai Pakkret, Nonthaburi-11120, Thailand.</p> <p>Attested copy of FSC of Thailand valid till 04-07-2026.</p> <p>FSC of MHRA without legalization valid till 31-01-2028.</p>	<p>Cocoon Septal Occluder Accessory Set (ASD Occluder Delivery System)</p> <p>Class D</p> <p>Shelf Life: 3 years</p> <p>Codes: COA6F COA7F COA8F COA9F COA10F COA12F COA14F</p>	Approved subject to verification of the fee.

	Differential fee 32,4000/- 72535025			
45.	<p>Applicant Name: M/s TEK Enterprises, Office No. MZ-9 Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore.</p> <p>ELI-00189</p> <p>R& I dated 29-05-2025</p> <p>Fee details: Amount paid: PKR 100,000 /- Paid Slip/ challan No. 147406503113</p>	<p>Legal Manufacturer: M/s Neurosafe Medical Co., Ltd., Building B, NO. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone Zhuahi, Guangdong, China</p> <p>LOA Validity: 31-12-2026(Original) Apostille Attached</p> <p>FSC: Spain Issue date: 18-11-2024 (Original) Notarized</p> <p>ISO Validity: 08-10-2025(copy) Apostille Attached</p> <p>EU QA/ EC Certificate Validity: 27-5-2024 (Original) Apostille Attached</p>	<p>Brand name: Glutton Aspiration Catheter</p> <p>Generic Name: Aspiration Catheter</p> <p>5F-115 5F-125 5F-132 6F-105 6F-115 6F-125 6F-115BGC 6F-125BGC 6F-132BGC 6F-115S 6F-125S 6F-132S</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification</p>	Approved.
46.	<p>Applicant Name: M/s TEK Enterprises, Office No. MZ-9 Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore.</p> <p>ELI-00189</p> <p>R& I dated 29-05-2025</p> <p>Fee details: Amount paid: PKR 100,000 /- Paid Slip/ challan No. 8505649726</p>	<p>Legal Manufacturer: M/s Neurosafe Medical Co., Ltd., Building B, NO. 10, Keji 1st Rd, Hi-Tech Industrial Development Zone Zhuahi, Guangdong, China</p> <p>LOA Validity: 31-12-2026(Copy) Apostille Attached</p> <p>FSC: Spain Issue date: 18-11-2024 (Copy) Notarized</p> <p>ISO Validity: 08-10-2025(Copy)</p>	<p>Brand name: Dredger</p> <p>Generic Name: Revascularization Device</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification Dredger Revascularization Device</p> <p>RD-3-20 RD-3-30 RD-4-20 RD-4-30 RD-4-40 RD-5-20</p>	Approved.

		<p>Apostille Attached</p> <p>EU QA/ EC Certificate Validity: 27-5-2024 (Copy) Apostille Attached</p>	<p>RD-5-30 RD-5-40 RD-6-24 RD-6-30 RD-6-42 RD-7-30 RD-7-42</p>	
47.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G- 11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7248-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok- gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82- 43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.c o.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01- 06-2027</p> <p>CE certificate validity 26- 05-2024 with extension notification</p>	<p>DiaEtch</p> <p>Class-B</p> <p>Shelf Life: 2 Years</p> <p>Sizes: 5gm tubes + Applicator tips 5x5gm tube + Applicator tips</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>
48.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G- 11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7252-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok- gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82- 43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.c o.kr</p>	<p>DiaFill Flow</p> <p>Class-B</p> <p>Shelf Life: 2 Years</p> <p>Sizes 2gm tube + Applicator tips</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>

		<p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>		
49.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 633244061096</p> <p>Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co.,Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building,Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Single Axis Hip Joint</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (7E7/C7E7-S)</p>	<p>Deferred for the following reason:</p> <ol style="list-style-type: none"> 1. Fee for the family required. 2. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 3. Product brochure/catalogue required. 4. Justification of grouping required.
50.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co.,Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Four Bar Hip Joint</p> <p>Class-A</p> <p>Shelf life: 05 years</p>	<p>Deferred for the following reason:</p> <ol style="list-style-type: none"> 1. Fee for the family required. 2. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 3. Product brochure/catalogue required. 4. Justification of grouping

	<p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 969833159</p> <p>Dated: 21-04-2025</p>	<p>Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Models/ Specification (7E6/C7E6-S)</p>	<p>required.</p>
51.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 985392323819 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Female Three Jaws</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (4F41)</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.</p>
52.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device</p>	<p>Brand name: Wounderfu</p> <p>Generic Name:</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority</p>

	<p>Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 2089131286 Dated: 21-04-2025</p>	<p>Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Female Four Jaws for Children</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (4S63-F)</p>	<p>required.</p> <p>2. Product brochure/catalogue required.</p>
53.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 77519063744 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Single Axis Knee Joint with Manual Lock</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (3F17)</p>	<p>Deferred for the following reason:</p> <p>1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required.</p> <p>2. Product brochure/catalogue required.</p>

		ISO Validity: 05-05-2027		
54.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 436735795 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Four Axis Knee Joint Class-A Shelf life: 05 years Models/ Specification (4F20)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
55.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 0815835285	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by:	Brand name: Wounderfu Generic Name: Locked Four Axis Knee Joint Class-A Shelf life: 05 years Models/ Specification	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

	Dated: 21-04-2025	China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	(3F35B)	
56.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 34188012 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Knee Joint For Knee Disarticulation with/without lock Class-A Shelf life: 05 years Models/ Specification (3F21/3F22)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. Fee for the family required. 4. Justification for grouping required.
57.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,	Brand name: Wounderfu Generic Name: Aluminium Four Bar Knee Joint For Children With/without Lock. Class-A	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. Fee for the family required. 4. Justification for grouping required.

	Fee Details: Paid Fee: 6,000/- Fee Challan No: 574479249863 Dated: 21-04-2025	China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Shelf life: 05 years Models/ Specification (3F65/3F65-1)	
58.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 098460896 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Aluminium Knee Disarticulation For Children With/without Lock. Class-A Shelf life: 05 years Models/ Specification (3F66/3F66-1)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. Fee for the family required. 4. Justification for grouping required.
59.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit,	Brand name: Wounderfu Generic Name: Lock Tube Adapter	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. Fee for the family required.

	<p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 30979212618</p> <p>Dated: 21-04-2025</p>	<p>2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (4F21/3S21)</p>	<p>4. Justification for grouping required.</p>
60.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 74552426487</p> <p>Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Integrate Tube</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (2F3/2F2,3S4/3S2)</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.</p>
61.	<p>Applicant Name: PAK Mobilizers</p> <p>Address:</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu</p>	<p>Brand name: Wounderfu</p> <p>Generic Name:</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by</p>

	<p>Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 0652588686850 Dated: 21-04-2025</p>	<p>Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Sach Foot Adapter CNC</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (2R8-M10, 2R8-M8)</p>	<p>Health Regulatory Authority required.</p> <p>2. Product brochure/catalogue required.</p> <p>3. Fee for the family required.</p> <p>4. Justification for grouping required.</p>
62.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 88489062465 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Double Axis Foot Adapter</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (As per applied dossier and same is mentioned in FSC) (2F11)</p>	<p>Deferred for the following reason:</p> <p>1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required.</p> <p>2. Product brochure/catalogue required.</p>

63.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 61914934 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: SYME Foot Adapter Class-A Shelf life: 05 years Models/ Specification (SF-M10)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
64.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 11593366770 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and	Brand name: Wounderfu Generic Name: Cap For Sach Foot Class-A Shelf life: 05 years Models/ Specification (1FSC)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

		orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027		
65.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 21068833624 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Cap For Dynamic Foot Class-A Shelf life: 05 years Models/ Specification (1FDC)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
66.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No:	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030	Brand name: Wounderfu Generic Name: Prosthetic Sach Foot Class-A Shelf life: 05 years Models/ Specification (1F10)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

	321187642220 Dated: 21-04-2025	FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027		
67.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 6253786257 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabiliton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Single Axis Foot Class-A Shelf life: 05 years Models/ Specification (1F41)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
68.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabiliton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District,	Brand name: Wounderfu Generic Name: Prosthetic Syme Foot Beige Class-A Shelf life: 05 years	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

	23-04-2025	Shijiazhuang, Hebei,	Models/ Specification (1SY10P)	
	Fee Details: Paid Fee: 6,000/- Fee Challan No: 63690240800 Dated: 21-04-2025	China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027		
69.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 73278976247 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: AK Cosmetic Foam Cover Water Proof Class-A Shelf life: 05 years Models/ Specification (AKFC-6F22)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
70.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilaton Device Technology Co., Ltd Address:	Brand name: Wounderfu Generic Name: Velvet Beauty Decoration AK Socks Class-A	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

	<p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 61005270609 Dated: 21-04-2025</p>	<p>Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Shelf life: 05 years</p> <p>Models/ Specification (3CSS-AK)</p>	
71.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 74798017630 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitation Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Male Four Jaws</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (4F63-M/3S63)</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. Fee for the family required. 4. Justification for grouping required.</p>
72.	<p>Applicant Name: PAK Mobilizers</p>	<p>Name of Manufacturer: M/s. Shijiazhuang</p>	<p>Brand name: Wounderfu</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille,</p>

	<p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 522871614 Dated: 21-04-2025</p>	<p>Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Generic Name: Male Three Jaws</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (4F42)</p>	<p>original and valid FSC issued by Health Regulatory Authority required.</p> <p>2. Product brochure/catalogue required.</p>
73.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 0254614220 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity:</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: BK Cosmetic Foam Cover (Water Proof)</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (BKFC-6F19)</p>	<p>Deferred for the following reason:</p> <p>1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required.</p> <p>2. Product brochure/catalogue required.</p>

		05-05-2027		
74.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 3450524343 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Double Mouth Tube Adapter Class-A Shelf life: 05 years Models/ Specification (4F27)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. Model mentioned in FSC is 4F27SS.
75.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 7612794746 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale	Brand name: Wounderfu Generic Name: Shuttle Lock Class-A Shelf life: 05 years Models/ Specification (GCL602/GCL603)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

		of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027		
76.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 42767566 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Drop Ring Lock Class-A Shelf life: 05 years Models/ Specification (17B38)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
77.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/-	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030	Brand name: Wounderfu Generic Name: Ankle Foot Fixator Class-A Shelf life: 05 years Models/ Specification (WDF-309L)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

	<p>Fee Challan No: 73275519306 Dated: 21-04-2025</p>	<p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>		
78.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 7363634590 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu Generic Name: VELCRO Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (FLBV)</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.</p>
79.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial</p>	<p>Brand name: Wounderfu Generic Name: Soft Ankle Joint Class-A</p> <p>Shelf life: 05 years</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.</p>

	<p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 72854356 Dated: 21-04-2025</p>	<p>Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Models/ Specification (FSAJ-1)</p>	
80.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 6177168559 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: PVA sheeting</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (PVAS -001)</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.</p>
81.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: PP Sheet</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required.</p>

	<p>Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 01815686 Dated: 21-04-2025</p>	<p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (FPP-S)</p>	<p>2. Product brochure/catalogue required.</p>
82.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 5280261291 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitation Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Low Temperature Thermoplastic plate</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (FLTTP)</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.</p>
83.	<p>Applicant Name:</p>	<p>Name of Manufacturer:</p>	<p>Brand name:</p>	<p>Deferred for the following reason: 1. FSC valid till 31.12.2025,</p>

	<p>PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 60581765313 Dated: 21-04-2025</p>	<p>M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p> <p>ISO Validity: 05-05-2027</p>	<p>Wounderfu</p> <p>Generic Name: EVA SHET</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (FPP-S)</p>	<p>issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required.</p> <p>2. Product brochure/catalogue required.</p>
84.	<p>Applicant Name: PAK Mobilizers</p> <p>Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore.</p> <p>(ELI-01197)</p> <p>Date of R&I 23-04-2025</p> <p>Fee Details: Paid Fee: 6,000/- Fee Challan No: 96835352752 Dated: 21-04-2025</p>	<p>Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd</p> <p>Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei,</p> <p>China LOA Validity: 01-03-2025 _ 01-03-2030</p> <p>FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025</p>	<p>Brand name: Wounderfu</p> <p>Generic Name: Plaster File</p> <p>Class-A</p> <p>Shelf life: 05 years</p> <p>Models/ Specification (PFR-1/PEHR-1/PFF-1)</p>	<p>Deferred for the following reason:</p> <ol style="list-style-type: none"> 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. fee for the family required. 4. Justification of the grouping required. 5. The name of the devices on FSC is <ul style="list-style-type: none"> i. Plaster File Flat Blade (PFF-1). ii. Plaster File Half Round (PFHR-1). iii. Plaster File Round (PFR-1)

		ISO Validity: 05-05-2027		
85.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 72068339610 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Prosthetic Hand Class-A Shelf life: 05 years Models/ Specification (CCAEH/CCMH/MAEH-2/MBEH-2)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required. 3. fee for the family required. 4. Justification of the grouping required.
86.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 03058911 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of	Brand name: Wounderfu Generic Name: SILICONE GLOVE Class-A Shelf life: 05 years Models/ Specification (FMHGS)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.

		Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027		
87.	Applicant Name: PAK Mobilizers Address: Shop # G-34, Jeff Heights, Main Boulevard Road, Gulberg III, Lahore. (ELI-01197) Date of R&I 23-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 546726388321 Dated: 21-04-2025	Name of Manufacturer: M/s. Shijiazhuang Wounderfu Rehabilitaton Device Technology Co., Ltd Address: Area A, 5 Floor, 3 Unit, 2 Building, Tianshan Wanchuang Industrial Park, Luandou Road, Luancheng District, Shijiazhuang, Hebei, China LOA Validity: 01-03-2025 _ 01-03-2030 FSC issued by: China Association of Assistive products (Certificate of free sale of prosthetic and orthopaedic products). Validity: 31-12-2025 ISO Validity: 05-05-2027	Brand name: Wounderfu Generic Name: Transfer Paper Class-A Shelf life: 05 years Models/ Specification (FTP)	Deferred for the following reason: 1. FSC valid till 31.12.2025, issued by China Association of Assistive Products. Apostille, original and valid FSC issued by Health Regulatory Authority required. 2. Product brochure/catalogue required.
88.	Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik Sarwar plaza, main service Golra road Opp G-11/1.Islamabad ELI-00982 Issue Date: 21.10.2022 7253-P 31,000/-	Legal Manufacturer: M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea Telephone number: 82-43-266-2315 Official website: www.diadent.co.kr Email: www.diadent@diadent.co.kr	Diadent DiaFil Class-B Shelf Life: 2 Years Sizes 4gm tubes	Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.

		<p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>		
89.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7254-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82-43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>Diadent Diapex Plus Regular Kit Type-A Class-B Shelf Life: 2 Years</p> <p>Sizes 2gm tube + Applicator tips</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>
90.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982</p>	<p><u>Legal Manufacturer:</u> M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82-43-266-2315</p> <p>Official website:</p>	<p>Diadent DiaPaste Regular Kit Type-A Class-B Shelf Life: 2 Years</p> <p>Sizes</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>

	<p>Issue Date: 21.10.2022 7249-P 31,000/-</p>	<p>www.diadent.co.kr</p> <p>Email: www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>2gm tube + Applicator tips</p>	
91.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7255-P 31,000/-</p>	<p>Legal Manufacturer: M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82-43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>Diadent DiaPlus Class-B Shelf Life: 2 Years</p> <p>Sizes 5ml Bottle</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>
92.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-</p>	<p>Legal Manufacturer: M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do,</p>	<p>Diadent DiaPrep Pro Class-B Shelf Life: 2 Years</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>

	11/1.Islamabad ELI-00982 Issue 21.10.2022 7250-P 31,000/-	28161, South Korea Telephone number: 82-43-266-2315 Official website: www.diadent.co.kr Email: www.diadent@diadent.co.kr FSC: Korea Issued on: 18.03.2025 LOA Validity: 01.12.2029 ISO 13485 validity 01-06-2027 CE certificate validity 26-05-2024 with extension notification	Sizes 6gmx2 tubes + Applicator tips	
93.	Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad ELI-00982 Issue 21.10.2022 7256-P 31,000/-	Legal Manufacturer: M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea Telephone number: 82-43-266-2315 Official website: www.diadent.co.kr Email: www.diadent@diadent.co.kr FSC: Korea Issued on: 18.03.2025 LOA Validity: 01.12.2029 ISO 13485 validity 01-06-2027 CE certificate validity 26-05-2024 with extension notification	Diadent E-Temp Class-B Shelf Life: 2 Years Sizes 30gm jar	Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.
94.	Applicant Name: M/s. Future	Legal Manufacturer: M/s Diadent Group	Diadent Gutta Percha points	Rejected due to following reasons.

	<p>Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue 21.10.2022 7257-P 31,000/-</p> <p>Date:</p>	<p>International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82-43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Pkt of 120 & Pkt of 60</p>	<p>1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>
95.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue 21.10.2022 7247-P 31,000/-</p> <p>Date:</p>	<p>Legal Manufacturer: M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82-43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p>	<p>Diadent Paper Points</p> <p>Class-B</p> <p>Shelf Life: 5 Years</p> <p>Sizes Pkt of 120 & Pkt of 200</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>

		CE certificate validity 26-05-2024 with extension notification		
96.	<p>Applicant Name: M/s. Future Technologies Office no 2, First Floor Malik sarwar plaza,main service golra road opp G-11/1.Islamabad</p> <p>ELI-00982 Issue Date: 21.10.2022 7251-P 31,000/-</p>	<p>Legal Manufacturer: M/s Diadent Group International Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu Cheongju-si Chungcheong buk-do, 28161, South Korea</p> <p>Telephone number: 82-43-266-2315</p> <p>Official website: www.diadent.co.kr</p> <p>Email: www.diadent@diadent.co.kr</p> <p>FSC: Korea Issued on: 18.03.2025</p> <p>LOA Validity: 01.12.2029</p> <p>ISO 13485 validity 01-06-2027</p> <p>CE certificate validity 26-05-2024 with extension notification</p>	<p>Diadent Dia Proseal</p> <p>Class-B</p> <p>Shelf Life: 2 Years</p> <p>Sizes 8gmx2 tubes + Applicator tips 2gmx2 tubes + Applicator</p>	<p>Rejected due to following reasons. 1. submitted copy of the LOA is notarized by Advocate Muhammad Usman, Notary Public Islamabad instead of country of origin.</p>
97.	<p>Applicant Name: M/s. Opti Med, 2nd Floor Hassan Plaza 6-A Jail Road, Lahore.</p> <p>(ELI- 00501)</p> <p>R&I detail 18-07-2025 Fee: 62,000/- Slip: 674366403433</p>	<p>Name of Manufacturer: Pharmpur GmbH, Messerschmitt 33, 86343 Konigsbrunn, Germany.</p> <p>• LOA Type: Original Notarization: Notarized Issue Date: 20-02-2025 Validity: Not mentioned.</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Not Legalized. Issue Date: 24-10-2024 Validity: Not mentioned</p> <p>• ISO Certificate</p>	<p>Brand name: Ophthafuture® hpmc 2%</p> <p>Generic Name: Ophthalmic Viscoelastic solution</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Model/Codes/Sizes (as per application & FSC): 500518 (0518)</p> <p>Shelf life: 24 Months</p>	<p>Approved.</p>

		Type: Original Notarization: Notarized Validity: 04-09-2027		
98.	Applicant Name: M/s. Opti Med, 2 nd Floor Hassan Plaza 6-A Jail Road, Lahore. (ELI- 00501) R&I detail 18-07-2025 Fee: 31,000/- Slip: 3354570172	Name of Manufacturer: Pharmpur GmbH, Messerchmittring 33, 86343 Konigsbrunn, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 20-02-2025 Validity: Not mentioned. • FSC Type: Original Issued By: Govt. Body Legalization: Not Legalized. Issue Date: 24-10-2024 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 04-09-2027	Brand name: Ophthafuture® deca Generic Name: Perfluorodecalin solution for vitreoretinal surgery Applied as: Single Class: C Model/Codes/Sizes (as per application & FSC:. 500501 (0501) Shelf life: 36 Months	Approved.
99.	M/s M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e- Jami, Block 9, Clifton, Karachi. (ELI-00006) Fee Challan No.: 797937441920 PKR: 25,000/-	M/s. Aesculap AG. Am Aesculap-Platz, 78532 Tuttlingen, Germany.	Aesculap® Surgical Instruments Class: B MD group: Family LOA Validity: 06.07.2025 FSC Validity: 02.06.2029 ISO Validity: 31.05.2026 EC Full Quality: 09.07.2025 Design Examination: N/A Shelf life: N/A Codes: AA805R, AD123R, AD125R, AD127R, AD129R, BA713R, BB045T, BB046R, BB073R, BB075R, BB077R, BB084R, BB085R, BB175R, BC004R, BC005R, BC007R, BC011R, BC065R, BC106R,	Rejected for the following: 1. Firm has not applied the products separately as per Board Decision. 2. Firm has not submitted the fee for the family as per SRO 1399(I)/2025 dated 1 st August 2025.

			BC107R, BC110R, BC111R, BC157R, BC165R, BC166R, BC168R, BC173R, BC175R, BC177R, BC178R, BC180R, BC181R, BC186R, BC189R, BC195R, BC211R, BC224R, BC234R, BC242R, BC245R, BC252R, BC253R, BC257R, BC257W, BC259B, BC259R, BC261R, BC263R, BC265B, BC265R, BC267B, BC267R, BC271B, BC271R, BC273R, BC277R, BC279B, BC279R, BC281R, BC283R, BC285R, BC289R, BC294W, BC295W, BC296W, BC298W, BC324R, BC547R, BC584R, BC587R, BC602R, BC606R, BC612R, BC615R, BC616R, BC619R, BC625R, BC627R, BC640R, BC646R, BC861R, BD025R, BD027R, BD029R, BD030R, BD050R, BD151R, BD154R, BD215R, BD220R, BD222R, BD228R, BD230R, BD320R, BD321R, BD330R, BD335R, BD345R, BD510R, BD511R, BD520R, BD535R, BD537R, BD539R, BD540R, BD541R, BD542R, BD543R, BD547R, BD557R, BD561R, BD564R, BD662R, BD665R, BD668R, BD700R, BD760R, BD900R, BF021R, BF047R, BF058R, BF059R, BF063R, BF065R, BF078R,	
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			BF112R, BF118R, BF122R, BF123R, BF136R, BF307R, BF309R, BF311R, BF316R, BF432R, BF465R, BH021R, BH031R, BH032R, BH034R, BH105R, BH108R, BH109R, BH110R, BH111R, BH118R, BH121R, BH141R, BH145R, BH150R, BH167R, BH176R, BH183R, BH202R, BH203R, BH212R, BH229R, BH231R, BH410R, BH424R, BH442R, BH443R, BH447R, BH456R, BH457R, BH614R, BH642R, BH644R, BH646R, BH650R, BH652R, BH814R, BJ008R, BJ011R, BJ012R, BJ021R, BJ022R, BJ023R, BJ024R, BJ025R, BJ032R, BJ033R, BJ043R, BJ044R, BJ045R, BJ047R, BJ048R, BJ055R, BJ062R, BJ080R, BJ090R, BJ091R, BJ100R, BJ104R, BJ123R, BJ130R, BJ131R, BJ132R, BJ300R, BJ313R, BJ314R, BL931R, BL932R, BM005R, BM011R, BM012R, BM013R, BM016R, BM019R, BM020R, BM021R, BM026R, BM030R, BM035R, BM036R, BM037R, BM038R, BM042R, BM046R, BM047R, BM056R, BM057R, BM065R, BM066R, BM067R, BM068R, BM069R, BM077R, BM089R, BM090R, BM096R, BM112R, BM219R, BM247R, BM255R, BM563R, BM564R, BM808R, BM810R, BM920R,	
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			BM922R, BM940P, BN012R, BN020R, BN021R, BN022R, BN023R, BN024R, BN026R, BN034R, BN040R, BN096, BN101R, BN104R, BN114R, BN120R, BN902R, BN903R, BN904R, BT008R, BT019R, BT041R, BT112R, BT114R, BT117R, BT122R, BT126R, BT177R, BT182R, BT184R, BT240R, BT254R, BT256R, BT257R, BT260R, BT261R, BT266R, BT323R, BT326R, BT365R, BT446R, BT513R, BT526R, BT601R, BT602R, BT604R, BT605R, BT621R, BT622R, BT623R, BT624R, BT626R, BT630R, BT633R, BT655R, BT658R, BT672R, BT674R, BT746R, BT758R, BT762R, BT800R, BT818R, BV011R, BV059R, BV066R, BV071R, BV072R, BV076R, BV078R, BV085R, BV086R, BV090R, BV091R, BV094R, BV251R, BV273R, BV585R, BV601R, BV608R, BV650R, BV662R, BV670R, BV817R, BV822R, BV826R, BV827R, BV831R, BV832R, BV840R, BV842R, BV843R, BV849R, BV945R, BV951R, BV952R, BV956R, BV962R, BW080R, BW081R, BW085R, BW086R, BW087R, BW088R, BW092R,	
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			EA010R, EA012R, EA027R, EA030R, EA032R, EA050R, EA052R, EA096R, EA097R, EA099R, EA100R, EA101R, EA116R, EA117R, EA130R, EA131R, EA204R, EA205R, EA355R, EA356R, EA360R, EA362R, EA826R, EA883R, EA903R, EA990R, EB003R, EB062R, EB063R, EB064R, EB065R, EB066R, EB067R, EB068R, EB069R, EB070R, EB168R, EB169R, EB170R, EB171R, EB172R, EB173R, EB174R, EB240R, EB242R, EB246R, EF001R, EF003R, EF051R, EF052R, EF053R, EF054R, EF056R, EL638R, EL639R, EL868R, EL873R, EO164R, FB120R, FB121R, FB122R, FB124R, FB125R, FB126R, FB130R, FB153R, FB154R, FB155R, FB156R, FB400R, FB402R, FB407R, FB408R, FB409R, FB411R, FB415R, FB421R, FB432R, FB434R, FB436R, FB440R, FB441R, FB487R, FB511R, FB517R, FB544R, FB568R, FB593R, FB778R, FB819R, FB890R, FB955R, FC313R, FC412R, FC413R, FD100R, FD101R, FD103R, FD241R, FD242R, FD243R, FD247R, FD251R, FD253R, FD255R, FD259R,	
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			FD284R, FD285R, FD287R, FD561R, FD562R, FD569R, FD611R, FD613R, FD874R, FD875R, FD876R, FD877R, FD884R, FD885R, FD886R, FD887R, FD897R, FE010K, FE011K, FE013K, FE020K, FE021K, FE022K, FE023K, FE024K, FH102R, FH116R, FH197R, FH222R, FH313R, FK171R, FK293R, FK302R, FK358R, FK507R, FK632NR, FK633NR, FK634NR, FK637NR, FL038R, FL044R, FL515R, FL516R, FL583R, FL585R, FL652R, FL654R, FO111R, FO120R, FO127R, FO409R, FO530NR, FO534NR, FO641NR, FO928R, FO930R, FO950R, FO951R, GF860R, GF862R, GF944R, JG504R, JG506R, JG508R, JG513R, JG518R, JG521R, JG522R, JG523R, JG524R, JG525R, JG598, JG600, JG691R, JG703R, JG901, LX159NR, MB246, MB247, MB248, MB285R, OA313R, OA314R, OA332R, OB511, OB792R, OC020R, OC024R, OC100R, OC415R, OF313R, OF314R, OF315R, OF316R, OF317R, OF350R, OF410R, OF420R, OF431R, OF438R, OG002R, OG011R, OG014R, OG040R, OG071R, OG073R, OG085R, OG101R,	
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			OG105R, OG109R, OG112R, OG133R, OG140R, OG145R, OG163R, OG179R, OG181R, OG300R, OG335R, OG345R, OG350R, OG360R, OK035R, OK037R, OK081R, OK082R, OK090R, OK106R, OK108R, OK350R, OK351R, OK372R, OK507R, OK508R, OK521R, OK525R, OK526R, OK924R, OL010R, OL113R, OL114R, OL152R, OL153R, OL155R, OL165R, OL192R, OL195R, OL206R, OL212R, OL214R, OL218R, OL300R, OL301R, OL302R, OL305R, OL319R, OL320R, OL321R, OL322R, OL323R, OL335R, OL405R, OL406R, OL423R, OL427R, OL460R, OL610R, OL611R, OL612R, OL619R, OL621R, OL622R, OL623R, OM116R, OM173R, OM177R, OM178R, OM208R, OM230R, OM314R, OM315R, RT020R, RT040R, RT055P, RT069R, RT071R, RT072R, RT073R, RT081R, RT088R, RT090R, RT092R.	
100.	Chemical House, 6C SKinder Malhi Road, Canal Park Gulberg II, Lahore ELI-00156 Fee. 62000 Challan No 278491762457	Bio-RAD Laboratories, Inc. 4000 Alfred Nobel Drive Hercules CA 94547, USA LOA Valid till: 31-12- 2025(Copy) FSC (USFDA) Valid till: 18-08-2026 (copy)	D-10 Hemoglobin A1C Program D-10 Hemoglobin A1C Program (12000949 D-10) Applied as: Kit	Deferred for the followings: 1. Following codes are not mentioned in CFG 12002716 D-10 Hemoglobin A1c Program Floppy Diskette 12002715 D-10 Hemoglobin A1c Program CD-ROM 2. LOA not submitted. 3. Justification for applying as KIT not provided.

	R&I date: 14-04-2025	ISO Valid till: 20-12-2027 (Copy)	<p>Class C</p> <p>Shelf Life: 12months</p> <p>Code:</p> <p>Pack 220-0110 D-10</p> <p>Hemoglobin A1c-Program</p> <p>Elution Buffer 1</p> <p>220-0111 D-10</p> <p>Hemoglobin A1c Program</p> <p>Elution Buffer 2</p> <p>220-0112 D-10</p> <p>Wash/Diluent Solution</p> <p>12005707 D-10</p> <p>Hemoglobin A1c Program</p> <p>Analytical Cartridge</p> <p>12005706 D-10</p> <p>Hemoglobin A1c Program</p> <p>Calibrator/Diluent Set</p> <p>220-0148 Whole Blood</p> <p>Primer 12002716 D-10</p> <p>Hemoglobin A1c Program</p> <p>Floppy Diskette</p> <p>12002715 D-10</p> <p>Hemoglobin A1c Program</p> <p>CD-ROM 220-0109 D-10</p> <p>Hemoglobin A1c</p> <p>Supplemental</p> <p>Program Reagent Pack</p>	
101.	<p>Name of Importer</p> <p>M/s Mian Scientific Corporation (PVT) Ltd</p> <p>Address of Importer:</p> <p>534-Jinnah Colony Faisalabad, 38030, Pakistan.</p> <p>(ELI-00442)</p> <p>R&I Dated:</p> <p>28 JAN 2021</p> <p>Fee Challan No.:</p> <p>2070371</p> <p>PKR: 50,000/-</p>	<p>Legal Manufacturer:</p> <p>Name:</p> <p>Wuxi BioHerms Bio & Medical Technology CO., Ltd.</p> <p>Address :</p> <p>No.136, Mashan Meiliang Road Binhu, Wuxi 214092, Jiangsu china.</p> <p>LOA Validity:</p> <p>February 28, 2026</p> <p>FSC China Validity:</p> <p>26-04-2025</p>	<p>Name of Medical device</p> <p>BioHermes A1c Chek Pro Glycohemoglobin Analyzer</p> <p>Class: C</p> <p>Shelf life: 5 Year</p> <p>Model:</p> <p>A1c EZ Auto 4,A1c EZ Auto 4W,A1c EZ Auto 4G,A1c Auto 4GW</p>	Approved.
102.	Name of Importer	<p>Legal Manufacturer:</p> <p>Name:</p> <p>Wuxi BioHerms Bio &</p>	<p>Name of Medical device</p> <p>BioHermes A1c Chek Pro</p>	Approved.

	<p>M/s Mian Scientific Corporation (PVT) Ltd Address of Importer: 534-Jinnah Colony Faisalabad, 38030, Pakistan.</p> <p>(ELI-00442)</p> <p>R&I Dated: 28 JAN 2021</p> <p>Fee Challan No.: 2070372 PKR: 50,000/-</p>	<p>Medical Technology CO., Ltd. Address : No.136, Mashan Meiliang Road Binhu, Wuxi 214092, Jiangsu china.</p> <p>LOA Validity: February 28, 2026</p> <p>FSC China Validity: 04-08-2026</p> <p>ISO 13485 validity 10-06-2028</p> <p>CE extension notification.</p>	<p>Glycohemoglobin Test Kit</p> <p>Class: C</p> <p>Shelf life: 24 Month</p> <p>Sizes: 50 tests,100 tests,200 tests</p>	
103.	<p>M YOUSAF & CO 79M GULBERG 111 LAHORE (ELI-00302)</p>	<p>B.J.Z.H.F PANTHER MEDICAL EQUIPMENT CO. LTD FLOOR 3, BUILDING 1, 28 HUOJU STREET, CHANGPING SCIENCE AND TECHNOLOGY PARK, CHINA</p>	<p>CIRCULAR STAPLER</p>	<p>Rejected for the following:</p> <ol style="list-style-type: none"> 1. LOA is not valid. 2. The device name not mentioned in the FSC (Belgium). 3. EC Certificate valid till 26.05.2024. 4. application not submitted.

DEFERRED LOCAL PRODUCT CASES

Agenda Item: Deferred Products of M/s Blue Bird, Islamabad

S#	Importer Name	Name of Medical Device/ Class / Shelf life / Codes / etc	Decision
1.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [936-6L] D.No. 13948 dated 20-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Adhesive Plaster</p> <p>Class: A Model: AP-2000 (1inch, 2 inch, 3 inch, 4 inch) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 9383608032</p>	<p>Approved as recommended by the panel.</p>
2.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [976-7L] D. No. 15347 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp</p>	<p>Medi Plus Mesh Nebulizer (Vibrating Mesh Nebulizer)</p> <p>Class: B Configuration Code: MNB-1540 Capacity: Small Capacity (2-5ml) Medium Capacity (6-10 ml) Large Capacity (>10ml) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 26041804121</p>	<p>Approved as recommended by the panel.</p>

	vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
3.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1010-7L] R & I. 15369 dated 29-05-2025 Approved Sections: Personal Protective Equipment (PPE) Section Ultrasound Gel Section Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) EO (Ethylene Oxide) Sterilization Section Blistering / packing Section of IV Cannula / Cord Clamp Surgical Drapes Section Surgical Swab Section (Packing & Sterilization only) Surgical Gloves Section (Packing & Sterilization only) Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Nasal Aspirator Class: B Code: NA-2501 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 0770729498	Approved as recommended by the panel.
4.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1038-6L] R & I. 15346 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-	Medi Plus Pulse Oximeter Class: A Configurations code: POX-4022 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 306222466598	Approved as recommended by the panel.

	<p>disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
5.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)</p> <p>[1041-6L]</p> <p>R & I. 15306 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Manual Apparatus Dial (Aneroid Dial Gauge)</p> <p>Class: A</p> <p>Configuration code: MDA-3051</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 2888136686</p>	<p>Approved as recommended by the panel.</p>
6.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)</p> <p>[1043-6L]</p> <p>R & I. 15318 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p>	<p>Medi Plus Adult Diaper</p> <p>Class: A</p> <p>Model: AD-1700</p> <p>Sizes: S, M, L, XL, XXL</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 070006597</p>	<p>Approved as recommended by the panel.</p>

	iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
7.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1045-7L] R & I. 15361 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Breast Pump Electric Class: B Configurations code: BPE-5121 (Single Electric Breast Pump) BPED-5120 (Double Electric Breast Pump) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 96820077998	Approved as recommended by the panel.
8.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [988-6L] D. No. 15307 dated 29-05-2025	Medi Plus Band Aid (Adhesive bandage) Class: A Model: BS-2150	Approved as recommended by the panel.

	Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Shelf Life: 5 Years Fee: 6000 Fee Slip No. 409699344	
9.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1036-6L] R & I. 15381 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Spinal Jacket Class: A Configurations code: SJ-1075 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 296562089210	Approved on recommendation of the panel, TLSO (Thoraco-Lumbo-Sacral Orthosis) subject to submission of the fee for the family.
10.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)	Medi Plus P.E Gloves (Polyethylene Gloves)	Deferred for the followings:

	<p>[1006-6L] D. No. 15377 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 7665922774</p>	<p>1. submission the sample of the product.</p> <p>2. submission of documentation issued by reference health regulatory authority or notified body supporting that applied product is medical device.</p>
11.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [999-6L] D. No. 15390 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section</p> <p>ii. Ultrasound Gel Section</p> <p>iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v. EO (Ethylene Oxide) Sterilization Section</p> <p>vi. Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii. Surgical Drapes Section</p> <p>viii. Surgical Swab Section (Packing & Sterilization only)</p> <p>ix. Surgical Gloves Section (Packing & Sterilization only)</p> <p>x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Sole Pad</p> <p>Class: A Configuration code: SP-1250 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 6780981279</p>	<p>Deferred for the followings:</p> <p>1. submission the sample of the product.</p> <p>2. clarification of the type of sole pad applied e.g. Orthopedic insoles / arch supports, Heel pads / cups, Metatarsal pads, Diabetic insoles, Shock-absorbing insoles, Corrective heel lifts etc.</p> <p>3. submission of the fee for the family.</p>

12.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1044-7L] R & I. 15343 dated 29-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders) 	<p>Medi Plus Hot Shaper Belt</p> <p>Class: B Shelf Life: 5 Years Fee: 25000</p> <p>Fee Slip No. 49659126</p>	<p>Deferred for the followings:</p> <ul style="list-style-type: none"> 1. submission the sample of the product. 2. submission of documentation issued by reference health regulatory authority or notified body supporting that applied product is medical device.
13.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [941-6L] D. No. 13953 dated 20-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clam vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) 	<p>Medi Plus Stethoscope</p> <p>Class: A Model: DHS-3330 (Stethoscope Dual Head), DHS-3320 (Stethoscope Single Head) Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3633121355</p>	<p>Approved following on recommendation of the panel;</p> <p>Stethoscope Single Head (DHS-3320)</p>

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
14.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [966-6L] D. No. 15326 dated 29-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders) 	<p>Medi Plus Infrared Forehead Thermometer</p> <p>Class: A Configuration Code: IT-500 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1153572490</p>	<p>Approved as recommended by the panel.</p>
15.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [952-7L] D. No. 13964 dated 20-05-2025</p> <p>Approved Sections:</p> <ul style="list-style-type: none"> i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) 	<p>Medi Plus Non-Woven Fixation Dressing Roll</p> <p>Class: B Code: FDT-1325 Size: 2.5cm, 5cm, 7.5 cm, 10cm, 15cm Shelf Life: 5 Years Fee: 25000 Fee Slip No. 853044245</p>	<p>Approved as recommended by the panel.</p>

	x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
16.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1047-6L] R & I. 15391 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Pregnancy Belt</p> <p>Class: A Configuration code: PB-1215 Sizes: S, M, L, XL, XXL Shelf Life: 5 Years Fee: 6000 Fee Slip No. 14889168800</p>	<p>Approved as recommended by the panel.</p>
17.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [933-6L] D. No. 13945 dated 20-05-2025</p> <p>Approved Sections:</p> <p>i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. Not for auto-disable / disposable syringe v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section</p>	<p>Medi Plus Digital Thermometer</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 47202210</p>	<p>Approved as recommended by the panel.</p>

	viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders.		
18.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [953-7L] D. No. 13965 dated 20-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders	Medi Plus BP Apparatus (Digital) Class: B AS-4031 Shelf Life: 5 Years Fee: 25000 Fee Slip No. 39210554	Approved as recommended by the panel.
19.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1017-6L] R & I. 15332 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp	Medi Plus Crepe Bandage Class: A Configuration Code: CP-2867 Sizes: 3 inch, 4 inch, 6 inch Shelf Life: 5 Years Fee: 6000 Fee Slip No. 03670170000	Approved as recommended by the panel.

	vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)		
20.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1048-6L] R & I. 15375 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Hot and Cold Therapy for Breast Pumping Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 52026373802	Deferred for the followings: 1. submission the sample of the product. 2. submission of documentation issued by reference health regulatory authority or notified body supporting that applied product is medical device.
21.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1007-6L] D. No. 15376 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag	Medi Plus Dignity Sheet Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 0569879768	Approved as recommended by the panel.

	<p>parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>		
22.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097)</p> <p>[1021-6L]</p> <p>R & I. 15323 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p> <p>iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways)</p> <p>iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe)</p> <p>v.EO (Ethylene Oxide) Sterilization Section</p> <p>vi.Blistering / packing Section of IV Cannula / Cord Clamp</p> <p>vii.Surgical Drapes Section</p> <p>viii.Surgical Swab Section (Packing & Sterilization only)</p> <p>ix.Surgical Gloves Section (Packing & Sterilization only)</p> <p>x.Orthopedic Soft Wears Section (soft braces belts slings and binders)</p>	<p>Medi Plus Test Tube</p> <p>Class: A</p> <p>Configurations code:</p> <p>TST-2102 (5ml)</p> <p>TST-2103 (10ml)</p> <p>TST-2104 (15ml)</p> <p>TST-2105 (20 ml)</p> <p>TST-2106 (25ml)</p> <p>TST-2107 (30ml)</p> <p>Shelf Life: 5 Years</p> <p>Fee: 6000</p> <p>Fee Slip No. 9634158179</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. submission the sample of the product. 2. submission of documentation issued by reference health regulatory authority or notified body supporting that applied product is medical device. 3. submission of the fee for the family. 4. uses of the empty glass tube as medical device.
23.	<p>Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097)</p> <p>[1026-7L]</p> <p>R & I. 15353 dated 29-05-2025</p> <p>Approved Sections:</p> <p>i.Personal Protective Equipment (PPE) Section</p> <p>ii.Ultrasound Gel Section</p>	<p>Medi Plus Petri Dishes</p> <p>Class: B</p> <p>Configurations code:</p> <p>PTS-2335</p> <p>PTS-2360</p> <p>PTS-2390</p> <p>PTS-2310</p> <p>PTS-2315</p> <p>Shelf Life: 5 Years</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. submission the sample of the product. 2. submission of documentation issued by reference health regulatory authority or notified body supporting

	iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Fee: 25000 Fee Slip No. 3594557839	that applied product is medical device. 3. Submission of the fee for the family. 4. use of petri dishes as medical device.
24.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [946-6L] D. No. 13958 dated 20-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clam vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders)	Medi Plus Paper Tape Class: A Code: PT-2015 Size: half inch, 1, 2, 3, 4 inch Shelf Life: 5 Years Fee: 6000 Fee Slip No. 400664894192	Approved as recommended by the panel.
25.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [968-6L] D. No. 15331 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section	Medi Plus P.E Tape Class: B Model: PET-2100 Sizes: 1, 2, 3, 4 inches Shelf Life: 5 Years Fee: 25000 Fee Slip No. 33283706297	Approved as recommended by the panel.

	ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders		
26.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1015-7L] R & I. 15370 dated 29-05-2025 Approved Sections: i.Personal Protective Equipment (PPE) Section ii.Ultrasound Gel Section iii.Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv.Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v.EO (Ethylene Oxide) Sterilization Section vi.Blistering / packing Section of IV Cannula / Cord Clamp vii.Surgical Drapes Section viii.Surgical Swab Section (Packing & Sterilization only) ix.Surgical Gloves Section (Packing & Sterilization only) x.Orthopedic Soft Wears Section (soft braces belts slings and binders	Medi Plus Dropper Variant code: D-0.5, D-1.0, D-2.0, D-3.0, D-5.0 with capacities as 0.5ml, 1.0ml, 2.0ml, 3.0ml & 5.0ml. Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 5993301355	Approved as recommended by the panel, subject to verification of the fee.
27.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1029-6L]	Medi Plus BP Bulb Class: A Configuration code:	Approved as recommended by the panel.

	R & I. 15313 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto-disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders)	BB-5020 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 5846127042	
28.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1000-7L] D. No. 15350 dated 29-05-2025 Approved Sections: (As stated above)	Medi Plus Nebulizer Machine Class: B Configurations Code: NM-9026 (Nebulizer machine) NM-9025 (Mini Nebulizer Machine) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 337851399241	Approved as recommended by the panel.
29.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1027-6L] R & I. 15333 dated 29-05-2025 Approved Sections: As above	Medi Plus BP Cuff Class: A Configuration code: CB-5021 (BP Cuff) CB-5020 (BP Cuff with Bladder) Sizes: S, M, L. Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3533197159	Approved as recommended by the panel.
30.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [983-6L] D. No. 15354 dated 29-05-2025 Approved Sections:	Medi Plus Inhaler Spacer (Aerosol Holding Chamber) Class: A Sizes: Small, Medium, Large	Approved as recommended by the panel.

	As above	Shelf Life: 5 Years Fee: 6000 Fee Slip No. 599636956917	
31.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [967-6L] D. No. 15328 dated 29-05-2025 Approved Sections: As above	Medi Plus Air Mattress (Medical Pressure Relief Air Mattress) Class: A Code: AM-2510 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 33136855935	Approved as recommended by the panel.
32.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [980-7L] D. No. 15341 dated 29-05-2025 Approved Sections: As above	Medi Plus Skin Traction Kit Configuration code: ST-1285 Sizes: Adult, Child, Infant Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 175996150588	Approved as recommended by the panel.
33.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [955-7L] D. No. 13967 dated 20-05-2025 Approved Sections: As Above	Medi Plus Non-Woven Tape Class: B Code: NWT-1800 Sizes: 1, 2, 3 & 4 inches Shelf Life: 5 Years Fee: 25000 Fee Slip No. 21469469	Approved as recommended by the panel.
34.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [984-7L] D. No. 15363 dated 29-05-2025 Approved Sections: As Above	Medi Plus Ear Syringe (Ear Irrigation Syringe) Class: B Configuration Code: ES-1020 Sizes: 60ml, 90ml Shelf Life: 5 Years Fee: 25000 Fee Slip No. 6736115842	Approved as recommended by the panel.

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