

DECISIONS OF 90TH MEETING OF MEDICAL DEVICE BOARD
HELD ON 09-05-2025

90th meeting of the Medical Device Board (MDB) was held in the office of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 9th May, 2025. The meeting was chaired by Dr. Muhammad Fakhr-ud-Din Amir, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1	Dr. Muhammad Fakhr-ud-Din Amir, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2	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)
3	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist/ Cardiovascular Surgeon, Lahore.	Member (attended meeting through videolink)
4	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member (attended meeting through videolink)
5	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
6	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member
7	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
8	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9	Mrs. Tazeen S Bukhari, Biomedical Engineer	Co-opted Member (attended meeting through videolink)
10	Hafiz Muhammad Asif Iqbal, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

The meeting commenced with the recitation of the Holy Quran. The Secretary, MDB welcomed all the participants and presented the agenda of the meeting.

REGISTRATION/ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

S#	Name of Applicant	Manufacturer/legal manufacturer	Name of Medical Device	Decision
1.	M/s Gulf Marketing International Rawalpind. ELI-00194 R& I No. 23346 dated 31 Aug 2021) Fee details: Amount paid: PKR 25000 /- Paid Slip/ challan No.22137096: Dated: (30/08/2021)	M/S. Orphee SA 19 Chemin du Champ des Filles, CH-1228 Plan-les-Ouates/Geneva Switzerland Free Sale Certificate valid upto 10/03/2026 issued by SwissMedic ISO 13485 valid upto 07/06/2026. Letter of authorization valid upto 29/03/2028	Orphee Reagents for Mythic 18, 22 and 60. Models / Sizes: Mythic 18-22 Enzymatic Cleaning Solution Mythic 18 Cyanide Free Lytic Solution Mythic 18 Diluent Diluent for Mythic 22 MD Group: Apply as Kit Class-B Declaration of conformity: Issuance date:(10/06/2022) Shelf life: Storage Conditions: 24 Months (Room temperature)	Approved The firm will deposit the differential fee as per revised fee SRO before the issuance of registration certificate.
2.	M/s Gulf Marketing International Rawalpind. ELI-00194 R& I No. 23943 dated 31 Aug 2021) Fee details: Amount paid: PKR 25000 /- Paid Slip/ challan No.775180050: Dated: (30/08/2021)	M/S. Orphee SA 19 Chemin du Champ des Filles, CH-1228 Plan-les-Ouates/Geneva Switzerland Free Sale Certificate valid upto 10/03/2026 issued by SwissMedic ISO 13485 valid upto 07/06/2026. Letter of authorization valid upto 29/03/2028	Orphee Control and Calibrators Models / Sizes: Myt-3D Myt-5D Myt-CAL MD Group: Apply as Kit Class-B Declaration of conformity: Issuance date:(23/05/2022) Shelf life: Myt-3D: 105 days Myt-5D: 105 days Myt-CAL: 45 days	Approved The firm will deposit the differential fee as per revised fee SRO before the issuance of registration certificate.
3.	M/s Gulf Marketing International Rawalpind. ELI-00194	M/S. Orphee SA 19 Chemin du Champ des Filles, CH-1228 Plan-les-	Orphee Only One Models / Sizes: Myt-3D	Approved The firm will deposit the differential fee as per revised

	<p>R& I No. 23345 dated 31 Aug 2021)</p> <p>Fee details: Amount paid: PKR 25000 /- Paid Slip/ challan No.950447388: Dated: (30/08/2021)</p>	<p>Ouates/Geneva Switzerland</p> <p>Free Sale Certificate valid upto 10/03/2026 issued by SwissMedic</p> <p>ISO 13485 valid upto 07/06/2026.</p> <p>Letter of authorization valid upto 29/03/2028</p>	<p>Myt-5D Myt-CAL</p> <p>MD Group: (single)</p> <p>Class-B Declaration of conformity: Issuance date:(14/06/2022)</p> <p>Shelf life: Storage Conditions: 24 Months (Room temperature)</p>	<p>fee SRO before the issuance of registration certificate.</p>
4.	<p>M/s Gulf Marketing International Rawalpind. ELI-00194</p> <p>R& I No. 23943 dated 31 Aug 2021)</p> <p>Fee details: Amount paid: PKR 5000 /- Paid Slip/ challan No. 5643896322: Dated: (30/08/2021)</p>	<p>M/S. Orphee SA 19 Chemin du Champ des Filles, CH-1228 Plan-les-Ouates/Geneva Switzerland</p> <p>Free Sale Certificate valid upto 10/03/2026 issued by SwissMedic</p> <p>ISO 13485 valid upto 07/06/2026.</p> <p>Letter of authorization valid upto 29/03/2028</p>	<p>Orphee In Vitro Medical Device Equipment</p> <p>Models / Sizes: MYTHIC 22AL MYTHIC 60 MYTHIC 18</p> <p>MD Group: (Family)</p> <p>Class-B Declaration of conformity: Issuance date:(23/05/2022)</p> <p>Shelf life: Storage Conditions: 10 Years (Room temperature)</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO before the issuance of registration certificate.</p>
5.	<p>DELTA PLUS (PVT) LTD 08, 2nd floor wall street plaza G-15, Markaz Sector G-15 Islamabad Fee 31000 R& I 11.02.2025</p>	<p>Legal Manufacturer: A1 Globe Sdn. Bhd. A1-2, Block A, Jalan Haruan 5/9, Pusat Komersial Oakland II, 70300 Seremban, Negeri Sembilan, Malaysia</p> <p>LOA non notarized for specific tender.</p> <p>FSC china non notarized valid till 23.7.25</p> <p>ISO 13485 valid till 11.4.25 Expired now</p>	<p>ECG Electrodes</p>	<p>Deferred</p> <ol style="list-style-type: none"> 1. Form7A required 2.DOC required 3.LOA is for specific tender clarification required 4.Copies submitted of LOA, ISO 13485 & FSC original required 5. Fsc of ref country or CE certificate required <p>Shelf life is not mentioned.</p>
6.	<p>DELTA PLUS (PVT) LTD 08, 2nd floor wall street plaza G-15, Markaz Sector G-15 Islamabad Fee 31000 (22932173363) R& I 11.02.2025</p>	<p>Legal Manufacturer: FITONE LATEX PRODUCTS CO., LTD. GUANGDONG No. 5 Tongyi Road,</p>	<p>Natural rubber latex condoms Class B</p>	<p>Deferred</p> <ol style="list-style-type: none"> 1. Form7A required 2.DOC required 3.LOA is for surgical gloves 4.Submitted documents are for surgical latex gloves

		Lingbei Industrial Zone, Suixi, 524338 Zhanjiang, Guangdong, PEOPLE'S REPUBLIC OF CHINA ISO 13485 valid till 11.3.26		
7.	DELTA PLUS (PVT) LTD 08, 2nd floor wall street plaza G-15, Markaz Sector G-15 Islamabad Fee 31000 (22932173363) R& I 11.02.2025	Legal Manufacturer: FITONE LATEX PRODUCTS CO., LTD. GUANGDONG No. 5 Tongyi Road, Lingbei Industrial Zone, Suixi, 524338 Zhanjiang, Guangdong, PEOPLE'S REPUBLIC OF CHINA ISO 13485 valid till 11.3.26 CE PQAS valid till 3-11- 24 with extension letter FSC china valid till 29.7.26 LOA for specific areas and validity not mentioned.	Single use sterile latex surgical gloves Class B	Deferred 1. 1. Form7A required 3.LOA is for specific areas 4.Submitted documents are copies of originals Shelf life is not mentioned.
8.	Sanwa Trading Corporation Office no. G- 88, Pindi Cricket Staadium Double Road, Rawalpindi(ELI-00210 040116837 Fee 31000	Legal Manufacturer: Zhejiang Soudan Medical No.1 Nangong He road , Building 4#, Lingping District, Hangzhou, Zhejiang, China FSC china valid till 12.9.25(non notorised) with name of Disposable biopsy forceps ISO 13485 (non notarized) valid till 11.3.26 LOA valid till 30.5.26	Endoscope bite block (Disposable biopsy forceps) Class B	Deferred Firm has not provided Notorised LOA, ISO, Fsc certificates. Brand name of Endoscope bite block is not present in Fsc and USFDA letter. Shelf life is not mentioned.
9.	Sanwa Trading Corporation Office no. G- 88, Pindi Cricket Staadium Double Road, Rawalpindi(ELI-00210 040116837 Fee 31000	Legal Manufacturer: Zhejiang Soudan Medical No.1 Nangong He road , Building 4#, Lingping District, Hangzhou, Zhejiang, China FSC china valid till 12.9.25(non notorised) ISO 13485 (non notarized) valid till 11.3.26	Disposable guided wire Class B	Deferred Firm has not provided Notorised LOA, ISO, Fsc certificates. Shelf life is not mentioned.

		LOA valid till 30.5.26		
10.	Sanwa Trading Corporation Office no. G-88, Pindi Cricket Staadium Double Road, Rawalpindi(ELI-00210 040116837 Fee 31000	Legal Manufacturer: Zhejiang Soudan Medical No.1 Nangong He road , Building 4#, Lingping District, Hangzhou, Zhejiang, China FSC china valid till 12.9.25(non notorised) ISO 13485 (non notarized) valid till 11.3.26 LOA valid till 30.5.26	Disposable stone extraction basket Class B	Deffered Firm has not provided Notorised LOA, ISO, Fsc certificates. Doc required. USFDA reg letter is not for said product. Shelf life is not mentioned.
11.	Sanwa Trading Corporation Office no. G-88, Pindi Cricket Staadium Double Road, Rawalpindi(ELI-00210 040116837 Fee 31000	Legal Manufacturer: Zhejiang Soudan Medical No.1 Nangong He road , Building 4#, Lingping District, Hangzhou, Zhejiang, China FSC china valid till 12.9.25(non notorised) ISO 13485 (non notarized) valid till 11.3.26 LOA valid till 30.5.26	Disposable biopsy forcep Class B	Deffered Firm has not provided Notorised LOA, ISO, Fsc certificates. Doc required. USFDA reg letter is not for said product Shelf life is not mentioned.
12.	Sanwa Trading Corporation Office no. G-88, Pindi Cricket Staadium Double Road, Rawalpindi(ELI-00210 25111901642 Fee 31000	Legal Manufacturer: Zhejiang Soudan Medical No.1 Nangong He road , Building 4#, Lingping District, Hangzhou, Zhejiang, China FSC china valid till 12.9.25(non notorised) ISO 13485 (non notarized) valid till 11.3.26 LOA valid till 30.5.26	Disposable Eus Needle Class B	Deffered Firm has not provided Notorised LOA, ISO, Fsc certificates. Brand name need clarification as no such name is found in Fsc Doc. Shelf life is not mentioned.
13.	Sanwa Trading Corporation Office no. G-88, Pindi Cricket Staadium Double Road, Rawalpindi(ELI-00210 193502666937 Fee 31000	Legal Manufacturer: Zhejiang Soudan Medical No.1 Nangong He road , Building 4#, Lingping District, Hangzhou, Zhejiang, China FSC china valid till 12.9.25(non notorised) ISO 13485 (non notarized) valid till 11.3.26	Disposable hemostatic clips Class B	Deffered Firm has not provided Notorised LOA, ISO, Fsc certificates. Doc and USFDA certification is provided for some other product. Shelf life is not mentioned.

		LOA valid till 30.5.26								
14.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 923394298</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p> <p>Full Quality Assurance Certificate or Equivalent (Original): NA Submitted on basis of EU FSC</p>	<p>Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)</p> <p>Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 0.20.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 0.20.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.0 0.20.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 0.20.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 0.20.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 0.20.EC .02	R1 48 mL × 2 R2 12 mL × 2									
15.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 55312531</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p>	<p>High Density Lipoprotein Cholesterol (HDL-C) Kit (Enzymatic Method)</p> <p>Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 2.03.EC .01</td><td>R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table>	REF (as per IFU)	Specification (as per FSC)	01.09.0 2.03.EC .01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate		
REF (as per IFU)	Specification (as per FSC)									
01.09.0 2.03.EC .01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									

		Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	<table><tr><td>01.09.0 2.03.EC .02</td><td>R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table>	01.09.0 2.03.EC .02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1					
01.09.0 2.03.EC .02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
			Shelf Life: 18 months							
			Class:B							
16.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 1668763579</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Total Bilirubin (TBIL) Kit(Vanadate Oxidation Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 0.21.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 0.21.EC .03</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table>	REF (as per IFU)	Specification (as per FSC)	01.09.0 0.21.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 0.21.EC .03	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 0.21.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 0.21.EC .03	R1 48 mL × 2 R2 12 mL × 2									
17.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p>	<p>Alanine Aminotransferase (ALT) Kit (Enzymatic Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 0.05.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr></table>	REF (as per IFU)	Specification (as per FSC)	01.09.0 0.05.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate		
REF (as per IFU)	Specification (as per FSC)									
01.09.0 0.05.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									

	20/02/2025 Deposit Slip No: 83172362105	Marketing Authorization Letter (original): Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	<table><tr><td>01.09.0 0.05.EC .03</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> Shelf Life: 18 months Class:B	01.09.0 0.05.EC .03	R1 48 mL × 2 R2 12 mL × 2					
01.09.0 0.05.EC .03	R1 48 mL × 2 R2 12 mL × 2									
18.	Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 58368205383	LEGAL MANUFACTUREUR Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	Aspartate Aminotransferase (AST) Kit (Enzymatic Method) Codes: <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 0.16.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 0.16.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> Shelf Life: 18 months Class:B	REF (as per IFU)	Specification (as per FSC)	01.09.0 0.16.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 0.16.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 0.16.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 0.16.EC .02	R1 48 mL × 2 R2 12 mL × 2									
19.	Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025	LEGAL MANUFACTUREUR Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original):	Urea (UREA) Kit (Urease-GLDH Method) Codes: <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 1.06.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 1.06.EC</td><td>R1 48 mL × 2</td></tr></table> Shelf Life: 18 months Class:B	REF (as per IFU)	Specification (as per FSC)	01.09.0 1.06.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 1.06.EC	R1 48 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 1.06.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 1.06.EC	R1 48 mL × 2									

	Deposit Slip No: 89357770	Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	<table><tr><td>.02</td><td>R2 12 mL × 2</td></tr></table> Shelf Life: 18 months Class:B	.02	R2 12 mL × 2					
.02	R2 12 mL × 2									
20.	Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 056101453	LEGAL MANUFACTUREUR Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	Alkaline Phosphatase (ALP) Kit (Enzymatic Method) Codes: <table><tr><th>REF (as per IFU)</th><th>Specifcation (as per FSC)</th></tr><tr><td>01.09.0 1.06.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 1.06.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> Shelf Life: 18 months Class:B	REF (as per IFU)	Specifcation (as per FSC)	01.09.0 1.06.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 1.06.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specifcation (as per FSC)									
01.09.0 1.06.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 1.06.EC .02	R1 48 mL × 2 R2 12 mL × 2									
21.	Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 056101453	LEGAL MANUFACTUREUR Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11-2028	Albumin (ALB) Kit (Bromocresol Green Method) Codes: <table><tr><th>REF (as per IFU)</th><th>Specifcation (as per FSC)</th></tr><tr><td>01.09.0 0.04.EC .01</td><td>R 30 mL × 6</td></tr><tr><td>01.09.0 0.04.EC .03</td><td>R 60 mL × 2</td></tr></table>	REF (as per IFU)	Specifcation (as per FSC)	01.09.0 0.04.EC .01	R 30 mL × 6	01.09.0 0.04.EC .03	R 60 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specifcation (as per FSC)									
01.09.0 0.04.EC .01	R 30 mL × 6									
01.09.0 0.04.EC .03	R 60 mL × 2									

		FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	Shelf Life: 18 months Class:B							
22.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 3632546296</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Low Density Lipoprotein Cholesterol (LDL-C) Kit (Enzymatic Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specifi cation (as per FSC)</th></tr><tr><td>01.09. 02.00. EC.01</td><td>R1 30 mL × 3 R2 10 mL ×3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr><tr><td>01.09. 02.00. EC.02</td><td>R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table> <p>Shelf Life: 18 months Class:B</p>	REF (as per IFU)	Specifi cation (as per FSC)	01.09. 02.00. EC.01	R1 30 mL × 3 R2 10 mL ×3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	01.09. 02.00. EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specifi cation (as per FSC)									
01.09. 02.00. EC.01	R1 30 mL × 3 R2 10 mL ×3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
01.09. 02.00. EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
23.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original):</p>	<p>Glycated Hemoglobin A1c (HbA1c) Kit (Immunoturbidimetric Method) Codes:</p> <table><tr><th>REF (as per IFU)</th><th>Specifi cation (as per FSC)</th></tr><tr><td>01.09. 06.03. EC.01</td><td>R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2</td></tr></table>	REF (as per IFU)	Specifi cation (as per FSC)	01.09. 06.03. EC.01	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate		
REF (as per IFU)	Specifi cation (as per FSC)									
01.09. 06.03. EC.01	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2									

	Deposit Slip No: 44943347	Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	<table><tr><td></td><td>Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr><tr><td>01.09. 06.03. EC.02</td><td>R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table> Shelf Life: 18 months Class:B		Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	01.09. 06.03. EC.02	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1							
	Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1													
01.09. 06.03. EC.02	R1 15 mL × 2 R2 10 mL × 1 Lyse 50 mL × 2 Calibrator 5 Levels × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1													
24.	Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED Address of Importer House No 323, street No 66, Sector I8/3, Islamabad Fee Amount & Fee Submission Date: Rs. 31,000/- 20/02/2025 Deposit Slip No: 44943347	LEGAL MANUFACTUREUR Zybio Inc. Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China Marketing Authorization Letter (original): Validity Date: 23-11-2028 FSC: China (Original) Issuance Date: 03-11-2026 Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026	Magnesium (Mg) Kit (Xylidyl Blue Method) Codes: <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 C.02.E C.01</td><td>R 30 mL × 6</td></tr><tr><td>01.09.0 C.02.E C.02</td><td>R 60 mL × 2</td></tr><tr><td>01.09.0 C.02.E C.03</td><td>R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1</td></tr><tr><td>01.09.0 C.02.E C.04</td><td>R 60 mL ×2 Calibrator 1 Level× 1.0mL×1</td></tr></table> Shelf Life: 18 months Class:B	REF (as per IFU)	Specification (as per FSC)	01.09.0 C.02.E C.01	R 30 mL × 6	01.09.0 C.02.E C.02	R 60 mL × 2	01.09.0 C.02.E C.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1	01.09.0 C.02.E C.04	R 60 mL ×2 Calibrator 1 Level× 1.0mL×1	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)													
01.09.0 C.02.E C.01	R 30 mL × 6													
01.09.0 C.02.E C.02	R 60 mL × 2													
01.09.0 C.02.E C.03	R 30 mL × 6 Calibrator 1 Level × 1.0 mL × 1													
01.09.0 C.02.E C.04	R 60 mL ×2 Calibrator 1 Level× 1.0mL×1													

25.	<div>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</div> <div>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</div> <div>Fee Amount & Fee Submission Date: Rs. 50,000/-</div> <div>20/02/2025</div> <div>Deposit Slip No: 4635111056</div>	<div>LEGAL MANUFACTUREUR Zybio Inc.</div> <div>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</div> <div>Marketing Authorization Letter (original): Validity Date: 23-11-2028</div> <div>FSC: China (Original) Issuance Date: 03-11-2026</div> <div>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</div>	<div>Hematology Analyzer Models: (as per FSC) Z50 Z52 Shelf Life: 18 months</div> <div>Class:B</div>	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate						
26.	<div>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</div> <div>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</div> <div>Fee Amount & Fee Submission Date: Rs. 31,000/-</div> <div>20/02/2025</div> <div>Deposit Slip No: 71809609647</div>	<div>LEGAL MANUFACTUREUR Zybio Inc.</div> <div>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</div> <div>Marketing Authorization Letter (original): Validity Date: 23-11-2028</div> <div>FSC: China (Original) Issuance Date: 03-11-2026</div> <div>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</div>	<div>Lipase (LPS) Kit (Colorimetric Method)</div> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 B.01.E C.01</td><td>R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr><tr><td>01.09.0 B.01.E C.02</td><td>R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1</td></tr></table>	REF (as per IFU)	Specification (as per FSC)	01.09.0 B.01.E C.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	01.09.0 B.01.E C.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 B.01.E C.01	R1 30 mL × 3 R2 10 mL × 3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									
01.09.0 B.01.E C.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1									

			Shelf Life: 18 months Class:B							
27.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 71809609647</p>	<p>LEGAL MANUFACTURER Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Total Protein (TP) Kit (Biuret Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 0.23.EC .01</td><td>R 30 mL × 6</td></tr><tr><td>01.09.0 0.23.EC .02</td><td>R 60 mL × 2</td></tr></table> <p>Shelf Life: 18 months Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.0 0.23.EC .01	R 30 mL × 6	01.09.0 0.23.EC .02	R 60 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 0.23.EC .01	R 30 mL × 6									
01.09.0 0.23.EC .02	R 60 mL × 2									
28.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 7380613052</p>	<p>LEGAL MANUFACTURER Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 0.03.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 0.03.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.0 0.03.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 0.03.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 0.03.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 0.03.EC .02	R1 48 mL × 2 R2 12 mL × 2									

29.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 50,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 116164750586</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Hematology Analyzer Models: (as per FSC)</p> <p>1. Z3 2. Z31 3. Z30 4. Z3 CRP 5. Z30 CRP 6. Z31 CRP</p> <p>Shelf Life: 18 months</p> <p>Class:B</p>	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate						
30.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 51681194097</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Triglyceride (TG) Kit (Enzymatic Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specific ation (as per FSC)</th></tr><tr><td>01.09.0 2.02.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 2.02.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specific ation (as per FSC)	01.09.0 2.02.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 2.02.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specific ation (as per FSC)									
01.09.0 2.02.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 2.02.EC .02	R1 48 mL × 2 R2 12 mL × 2									
31.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p>	<p>C-Reactive Protein Kit (Immunoturbidimetric Method)</p>	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate						

<div>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</div> <div>Fee Amount & Fee Submission Date: Rs. 62,000/-</div> <div>20/02/2025</div> <div>Deposit Slip No: 699990640</div>	<div>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</div> <div>Marketing Authorization Letter (original): Validity Date: 23-11- 2028</div> <div>FSC: China (Original) Issuance Date: 03-11-2026</div> <div>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11- 2026</div>	REF (as per IFU)	Specifica tion (as per FSC)
		301100 1	25T : R1 0.4mLx2 5, R2 1.5mLx1
		301100 2	100T: R1 0.4mLx1 00, R2 3.0mLx2
		301100 3	25T : R1 0.4mLx2 5, R2 1.5mLx1 (includin g Cal 6 levels x1 x 0.5mL, Con 2 levels x1x0.5m L)
		301100 4	25T: R1 0.4mLx2 5, R2 1.5mLx1 (includin g Con 2 levels x1x0.5m L)
		301100 5	100T: R1 0.4mLx1 00, R2 3mLx2 (includin g Cal 6 levels x1x1.0m L, Con 2 levels x1x1.0m L)
		301100 6	100T: R1 0.4mLx1 00, R2 3mLx2(i ncluding Control 2 levels x1x1.0m L)

			Shelf Life: 18 months Class:C							
32.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 51681194097</p>	<p>LEGAL MANUFACTURER Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Lactate Dehydrogenase (LDH) Kit (Rate Method))</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 4.06.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 4.06.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.0 4.06.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 4.06.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 4.06.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 4.06.EC .02	R1 48 mL × 2 R2 12 mL × 2									
33.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 48737124</p>	<p>LEGAL MANUFACTURER Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Total Cholesterol (CHOL) Kit (Enzymatic Method)</p> <table><tr><th>REF (as per IFU)</th><th>Specification (as per FSC)</th></tr><tr><td>01.09.0 2.10.EC .01</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>01.09.0 2.10.EC .02</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months Class:B</p>	REF (as per IFU)	Specification (as per FSC)	01.09.0 2.10.EC .01	R1 30 mL × 3 R2 7.5 mL × 3	01.09.0 2.10.EC .02	R1 48 mL × 2 R2 12 mL × 2	Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate
REF (as per IFU)	Specification (as per FSC)									
01.09.0 2.10.EC .01	R1 30 mL × 3 R2 7.5 mL × 3									
01.09.0 2.10.EC .02	R1 48 mL × 2 R2 12 mL × 2									

34.	<p>Li zongyang ZYBIO MEDICAL PAKISTAN (SMC-PRIVATE) LIMITED</p> <p>Address of Importer House No 323, street No 66, Sector I8/3, Islamabad</p> <p>Fee Amount & Fee Submission Date: Rs. 31,000/-</p> <p>20/02/2025</p> <p>Deposit Slip No: 0044365032</p>	<p>LEGAL MANUFACTUREUR Zybio Inc.</p> <p>Company Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China</p> <p>Marketing Authorization Letter (original): Validity Date: 23-11-2028</p> <p>FSC: China (Original) Issuance Date: 03-11-2026</p> <p>Production Quality Management System Certificate (ISO 13485) (Original) Validity Date: 29-11-2026</p>	<p>Glucose (GLU) Kit (Hexokinase Method))</p> <table><tr><th>REF (as per IFU)</th><th>Specifica tion (as per FSC)</th></tr><tr><td>108020 1</td><td>R1 30 mL × 1 R2 7.5 mL × 1</td></tr><tr><td>108020 2</td><td>R1 30 mL × 3 R2 7.5 mL × 3</td></tr><tr><td>108020 3</td><td>R1 48 mL × 2 R2 12 mL × 2</td></tr></table> <p>Shelf Life: 18 months</p> <p>Class:B</p>	REF (as per IFU)	Specifica tion (as per FSC)	108020 1	R1 30 mL × 1 R2 7.5 mL × 1	108020 2	R1 30 mL × 3 R2 7.5 mL × 3	108020 3	R1 48 mL × 2 R2 12 mL × 2	<p>Deferred for the submission of LOA with said brand name. EU Fsc or CE certificate</p>
REF (as per IFU)	Specifica tion (as per FSC)											
108020 1	R1 30 mL × 1 R2 7.5 mL × 1											
108020 2	R1 30 mL × 3 R2 7.5 mL × 3											
108020 3	R1 48 mL × 2 R2 12 mL × 2											
35.	<p>M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi</p> <p>ELI-00944</p> <p>R&I details 27/01/2025</p> <p>Fee Challan No:7849801972</p>	<p>Legal Manufacturer: Legal Manufacturer:</p> <p>Ningbo Great Mountain Medical Instrument Co., Ltd.</p> <p>Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China.</p> <p>FSC: China Date of Issuance: 11-10-2024. Validity 2 years.</p> <p>LOA: Validity: 7/03/2027</p> <p>EC Certificate: Validity: 26/05/2024</p> <p>ISO 13485: Validity: 29/12/2025</p>	<p>Ideal Med Nebulizer Mask</p> <p>Nebulizer Mask</p> <p>Shelf Life: 5 Year</p> <p>Class: B</p>	<p>Approved.</p> <p>The firm will submit the cosdes/sizes as per FSC before the issuance of registration letter.</p>								
36.	<p>M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi</p> <p>ELI-00944</p>	<p>Legal Manufacturer: Legal Manufacturer:</p> <p>Ningbo Great Mountain Medical Instrument Co., Ltd.</p>	<p>Respiratory Filters</p> <p>Shelf Life: 5 Year</p> <p>Class: B</p>	<p>Deferred for the submission of brand name and codes.</p>								

	R&I details 27/01/2025 Fee Challan No:7849801972	Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China. FSC: China Date of Issuance: 11-10- 2024. Validity 2 years. LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025		
37.	M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi ELI-00944 R&I details 27/01/2025 Fee Challan No:653549233730	Legal Manufacturer: Legal Manufacturer: Ningbo Great Mountain Medical Instrument Co., Ltd. Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China. FSC: China Date of Issuance: 11-10- 2024. Validity 2 years. LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025	Suction connecting tube with yankauer Shelf Life: 5 Year Class: B	Approved. The firm will submit the Brand name and cosdes/ sizes as per FSC before the issuance of registration letter.
38.	M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi ELI-00944 R&I details 27/01/2025 Fee Challan No:653549233730	Legal Manufacturer: Legal Manufacturer: Ningbo Great Mountain Medical Instrument Co., Ltd. Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China. FSC: China Date of Issuance: 11-10- 2024. Validity 2 years.	Nasal Oxygen Cannula Shelf Life: 5 Year Class: B	Approved. The firm will submit the Brand name and cosdes/ sizes as per FSC before the issuance of registration letter.

		LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025		
39.	M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi ELI-00944 R&I details 27/01/2025 Fee Challan No:37115459	Legal Manufacturer: Legal Manufacturer: Ningbo Great Mountain Medical Instrument Co., Ltd. Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China. FSC: China Date of Issuance: 11-10-2024. Validity 2 years. LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025	Oxygen Mask Shelf Life: 5 Year Class: B	Approved. The firm will submit the Brand name and cosdes/ sizes as per FSC before the issuance of registration letter.
40.	M/s Ideal Distributor, House No.E-64, Block-E, Near Jamia Masjid Aqsa, Satellite Town, Rawalpindi ELI-00944 R&I details 27/01/2025 Fee Challan No:37115459	Legal Manufacturer: Legal Manufacturer: Ningbo Great Mountain Medical Instrument Co., Ltd. Address: No. 309 Xigu Road, Xiangshan County, 315700 Ningbo City, Zhejiang Province, China. FSC: China Date of Issuance: 11-10-2024. Validity 2 years. LOA: Validity: 7/03/2027 EC Certificate: Validity: 26/05/2024 ISO 13485: Validity: 29/12/2025	Respiratory Circuit Shelf Life: 5 Year Class: B	Approved. The firm will submit the Brand name and cosdes/ sizes as per FSC before the issuance of registration letter.

41.	M/s OPTISURG, Address: 17/ C-1, VALENCIA TOWN, LAHORE ELI-000305 R&I details: 24-02-2025 31000/-	Legal Manufacturer: SHANGHAI MEDIWORKS PRECISION INSTRUMENTS CO., LTD. NO.7, MINGPU PHASE II, NO. 3279 SANLU ROAD, MINHANG DISTRICT, 201100, SHANGHAI, CHINA LOA Validity: 21-10-2026 FSC: Country of origin Validity: 2026-04-18 FSC: FSC of Reference country USFDA valid till 5-08-26 ISO 13485: Validity: 01/03/2026 EC Certificate: Validity: 26/05/2024	Applanation Tonometer (Model: T170) Ophthalmic Tonometer, Manual Shelf Life: 3 Year Class B	Approved
42.	M/s OPTISURG, Address: 17/ C-1, VALENCIA TOWN, LAHORE ELI-000305 R&I details: 24-02-2025 31000/-	Legal Manufacturer: SHANGHAI MEDIWORKS PRECISION INSTRUMENTS CO., LTD. NO.7, MINGPU PHASE II, NO. 3279 SANLU ROAD, MINHANG DISTRICT, 201100, SHANGHAI, CHINA LOA Validity: 21-10-2026 FSC: Country of origin Validity: 2026-04-18 FSC: FSC of Reference country USFDA valid till 5-08-26 ISO 13485: Validity: 01/03/2026 EC Certificate: Validity: 26/05/2024	Vision Screener (Models: V100 & V101) Vision / Eye Movement Analysis System Shelf Life: 8 Year Class B	Approved. The firm will submit fee as per revised SRO for System.

43.	M/s OPTISURG, Address: 17/ C-1, VALENCIA TOWN, LAHORE ELI-000305 R&I details: 24-02-2025 31000/-	Legal Manufacturer: OERTLI INSTRUMENTS AG, Address: HAFNER WISENSTRASSE 4, 9442 BERNECK, SWITZERLAND FSC: Switzerland. Date of expiry: 21-07- 2026. LOA Validity: 31-12-2025 ISO 13485: Validity: 18/10/2026 FQAS Certificate: Validity: 14/12/2027	1/A HANDPIECE, COAXIAL, REUSABLE 1/A HANDPIECE, COAXIAL, REUSABLE Shelf Life: N/A Class B	Approved
44.	Name OPTIMUS ENTREPOT Address of Importer House No. 84, H/3-Block, Wapda TOWN, LAHORE ELI-00125 R&I Dated: 22/11/2025 Fee Challan No.: 58887362998 PKR: 31000/-	Legal Manufacturer: Name: Atakan dede- Miray Medikal Address: Çalı mah. 14.(410)sk. 14/B Nilüfer/Bursa, TÜRKİYE	OCUDEKA DECALINE (7ML) Temporary intraocular tamponade Model:: MRY-R4V Shelf Life: 3 years Class: B MD group: Family LOA Validity:31-12- 2026 FSC Validity: Date of issue: 29-04- 2024	Approved
45.	Raffay Associates Office # 4, 2nd Floor Ahmad Plaza Range Road Rawalpindi. ELI-00021 5983-P 62,000/-	Legal Manufacturer: ELLA-CS, s.r.o Milady Horakove 504/45 Trebes 500 06 Hradec Kralove Czech Republic. Original FSC: Czech Republic. Date of Issuance: 15-01- 2025. LOA issuance 31-01-2025 valid for 3 years ISO 13485 validity 20-02- 2026 EU QMS certificate MDR validity 30-11-2026 EU Technical assessment documentation certificate validity 21-08-2029	ELLA-BD Stent Biliary THP Polymer-metal biliary stent, bio-absorbable Class-D Shelf Life: 3 years Codes: 019-15-08-030 019-15-08-040 019-15-08-050 019-15-08-060 019-15-08-070 019-15-08-080 019-10-08-030 019-10-08-040 019-10-08-050	Approved

			019-10-08-060 019-10-08-070 019-10-08-080	
46.	Total Technologies Pvt. Ltd, 696-J-2, M.A. Johar Town, Lahore, Pakistan. ELI-00129 5985-P 62,000/-	<u>Legal Manufacturer:</u> M/s Terumo Corporation, 44-1, 2-Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. <u>Manufacturing facility:</u> Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture, 418-0015, Japan. FSC: Japan issuance 04- 07-2023 (copy) LOA validity 31-03-2026 ISO 13485 validity 29-08- 2026 CE validity 26-05-2024	TERUFUSION (Infusion Syringe Pump Type SS3) Class-C Life time: 6 Year Codes as per FSC: TE*SS835N01 TE*SS835N02 TE*SS835N03 TE*SS835N05 TE*SS835N07	Approved.
47.	Vertex Medical Pvt Ltd, 401- 402, Block-F, Johar Town, Lahore - Pakistan. ELI-00150 5695-P 31,000/-	<u>Legal Manufacturer:</u> Dragerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lubeck, Germany. FSC: Germany. Date of Issuance: 22-04- 2024. LOA validity 31-12-2025 ISO 13485 validity 13-01- 2027 EU QMS certificate (MDR) validity 17-03- 2025	Drager Vamos / Vamos Plus Class-B Shelf Life: N/A Article Number: 6873350	Approved
48.	Vertex Medical Pvt Ltd, 401- 402, Block-F, Johar Town, Lahore - Pakistan. ELI-00150 1417-P 6,000/-	<u>Legal Manufacturer:</u> Dragerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lubeck, Germany. FSC: Germany. Date of Issuance: 22-04- 2024. LOA validity 31-12-2025 ISO 13485 validity 13-01- 2027 EU QMS certificate (MDR) validity 17-03- 2025	Drager Polaris 100/200 Surgical Light Class-A Service Life: 12 years Article Number: G16980	Approved. The firm is advised to apply separately for Polaris 600
49.	Fresenius Medical Care Pakistan Pvt. Ltd, TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore.	<u>Legal Manufacturer:</u> Nipro Corporation 3-26, Senriokashinmachi, Settsu, Osaka, 566-8510, Japan.	Fistula Needle AVF Needle Class-B Shelf Life: 5 Years	Approved The firm will provide the Brand name.

	<p>ELI-00315 5714-P 31,000/-</p>	<p>FSC: Belgium. Date of Issuance: 25-11-2024. LOA validity 23-09-2029 ISO 13485 validity 30-06-2027 CE validity 26-05-2024 with Extension notification letter.</p>	<p>Codes: F00012655 F00012656 F00012657 F00012658 F00012663 F00012665 F00012666 F00012667 F00012668 F00012691</p>	
50.	<p>Fresenius Medical Care Pakistan Pvt. Ltd, TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore. ELI-00315 5713-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Fresenius Medical Care AG Else-Kroner-Str. 1 61352 Bad Homburg, Germany. Manufacturing Site: Nova Med GmbH Antalya Serbest bolgesi Merkez Subesi No: 16, Liman Serbest Bolgesi Mahallesi 07070 Antalya, Turkey. Original FSC: Germany. Date of Issuance: 12-01-2024. LOA issuance 18-10-2023 valid for 3 years. ISO 13485 validity 04-04-2025 EU QMS certificate (MDR) validity 18-06-2025</p>	<p>SN-Set ONLINEplus 5008-R (Hemodialysis tubing sets 5008) Class-B Shelf Life: 2 Years Code: F00000386</p>	Approved
51.	<p>Cardiac Care, 848-C, Shadman-1, Lahore-54610, Pakistan. ELI-00070</p>	<p><u>Legal Manufacturer:</u> HSINER Co., Ltd 312, Jhongshan Rd., Shengang Dist, Taichung City 426, Taiwan. FSC: Germany Date of Issuance: 14-11-2019.</p>	<p>Oxygen Mask and Accessories Oxygen delivery mask Class-B Shelf Life: 3 Years Codes as per FSC</p>	<p>The board has already decided the application so disposed of. The firm may apply afresh as per MDR 2017.</p>
52.	<p>Cardiac Care, 848-C, Shadman-1, Lahore-54610, Pakistan. ELI-00070</p>	<p><u>Legal Manufacturer:</u> HSINER Co., Ltd 312, Jhongshan Rd., Shengang Dist, Taichung City 426, Taiwan. FSC: Germany Date of Issuance: 14-11-2019.</p>	<p>HME and HMEF Humidifiers Heat / Moisture Exchange Class-B Shelf Life: 3 Years Codes as per FSC</p>	<p>The board has already decided the application so disposed of. The firm may apply afresh as per MDR 2017.</p>
53.	<p>Cardiac Care, 848-C, Shadman-1, Lahore-54610, Pakistan. ELI-00070</p>	<p><u>Legal Manufacturer:</u> HSINER Co., Ltd 312, Jhongshan Rd., Shengang Dist, Taichung City 426, Taiwan.</p>	<p>CPAP/VPAP MASK Positive airway pressure mask. Class-B</p>	<p>The board has already decided the application so disposed of. The firm may apply afresh as per MDR 2017.</p>

		FSC: Germany Date of Issuance: 14-11-2019.	Shelf Life: 3 Years Codes as per FSC	
54.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 31,000/- 5737-P	<u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate validity 21-04-2027	Unitron (Stride V-PR) Hearing Aids Class-B Service Life: 5 Years Models: Stride V9-PR 050-6830-P6 Stride V7-PR 050-6829-P6 Stride V5-PR 050-6828-P6 Stride V3-PR 050-6827-P6 Stride V1-PR 050-6826-P6	Approved The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.
55.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5736-P 31,000/-	<u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026	Unitron (Moxi V-RS) Hearing Aids Class-B Service Life: 5 Years Models: Moxi V9-RS Left 050-6548-P6 Moxi V9-RS Right 050-6549-P6 Moxi V7-RS Left 050-6546-P6 Moxi V7-RS Right 050-6547-P6 Moxi V5-RS Left 050-6544-P6 Moxi V5-RS Right 050-6545-P6 Moxi V3-RS Left 050-6542-P6 Moxi V3-RS Right 050-6543-P6 Moxi V1-RS Left 050-6540-P6 Moxi V1-RS Right	Approved The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.

		EU QMS certificate validity 21-04-2027	050-6541-P6	
56.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06-2023 LOA issuance 15-11-2024 IO 13485 validity 14-04-2026 EU QMS certificate validity 21-04-2027</p>	<p>Unitron (Moxi B-R) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Moxi B9-312 050-6404-P6 Moxi B7-312 050-6403-P6 Moxi B5-312 050-6402-P6 Moxi B3-312 050-6401-P6 Moxi B1-312 050-6461-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>
57.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5739-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06-2023 LOA issuance 15-11-2024 IO 13485 validity 14-04-2026</p>	<p>Unitron (Stride B-UP) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Stride B9-UP 050-6444-P6 Stride B7-UP 050-6443-P6 Stride B5-UP 050-6442-P6 Stride B3-UP 050-6441-P6 Stride B1-UP 050-6449-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>

		EU QMS certificate validity 21-04-2027		
58.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5738-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate validity 21-04-2027</p>	<p>Unitron (Moxi B-R) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Moxi B9-R 050-6410-P6 Moxi B7-R 050-6409-P6 Moxi B5-R 050-6408-P6 Moxi B3-R 050-6407-P6 Moxi B1-R 050-6462-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>
59.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5743-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate</p>	<p>Unitron (Moxi V-RT) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Moxi V9-RT 050-6521-P6 Moxi V7-RT 050-6520-P6 Moxi V5-RT 050-6519-P6 Moxi V3-RT 050-6518-P6 Moxi V1-RT 050-6517-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>

		validity 21-04-2027		
60.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5742-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate validity 21-04-2027</p>	<p>Unitron (Moxi V-312) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Moxi V9-312 050-6824-P6 Moxi V7-312 050-6823-P6 Moxi V5-312 050-6822-P6 Moxi V3-312 050-6821-P6 Moxi V1-312 050-6820-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>
61.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5745-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate validity 21-04-2027</p>	<p>Unitron (Moxi B-RT) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Moxi B9-RT 050-6416-P6 Moxi B7-RT 050-6415-P6 Moxi B5-RT 050-6414-P6 Moxi B3-RT 050-6413-P6 Moxi B1-RT 050-6463-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>

62.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5744-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate validity 21-04-2027</p>	<p>Unitron (Moxi V-R) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Moxi V9-R 050-6514-P6 Moxi V7-R 050-6513-P6 Moxi V5-R 050-6512-P6 Moxi V3-R 050-6511-P6 Moxi V1-R 050-6510-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>
63.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5741-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing Sites:</u> Sonova Operations Center Vietnam Co., Ltd. No. 29A VSIP Street 8 Vietnam Singapore Industrial Park Thuan An Town, Binh Duong Province Vietnam. and Sonova Hearing (Suzhou) Co., Ltd. No. 78 Qi Ming Road Comprehensive Bonded Zone, Suzhou Industrial Park Jiangsu Province, P.R. China</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023 LOA issuance 15-11-2024 IO 13485 validity 14-04- 2026 EU QMS certificate validity 21-04-2027</p>	<p>Unitron (Stride B-PR) Hearing Aids</p> <p>Class-B</p> <p>Service Life: 5 Years</p> <p>Models: Stride B9-PR 050-6439-P6 Stride B7-PR 050-6438-P6 Stride B5-PR 050-6437-P6 Stride B3-PR 050-6438-P6 Stride B1-PR 050-6448-P6</p>	<p>Approved</p> <p>The firm will deposit the differential fee as per revised fee SRO for Family before the issuance of registration certificate.</p>

64.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5721-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing site:</u> Sivantos (Suzhou) Co., Ltd. No. 120 Su Tong Road, China-Singapore Suzhou Industrial Park, Jiangsu Province 215021 Suzhou, People republic of China.</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023. LOA issuance 22-03-2024 ISO 13485 validity 30-11- 2025 CE certificate validity 26- 05-2024 with extension notification letter.</p>	<p>Rexton Sterling (In the ear air conduction hearing aid)</p> <p>Class-B</p> <p>Service life: 5 years.</p> <p>Models/codes: Sterling 80 8C Sterling 60 8C Sterling 40 8C Sterling 30 8C Sterling 20 8C</p>	<p>Approved In the ear (ITE) having codes Sterling 80 8C Sterling 60 8C Sterling 40 8C Sterling 30 8C Sterling 20 8C subject to submission of differential fee of 19,000/- as per the revised SRO for Family.</p>
65.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5719-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore.</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023. LOA issuance 24-09-2024 ISO 13485 validity 30-11- 2025 CE certificate validity 26- 05-2024 with extension notification letter.</p>	<p>Rexton Arena (Behind the ear (BTE) Hearing aid)</p> <p>Class-B</p> <p>Service life: 5 years</p> <p>Models: Arena HP3 Arena P3 Arena P1</p>	<p>Approved Arena HP3 Arena P3 The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter.</p> <p>The firm will apply separately for P1.</p>
66.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5720-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore.</p> <p>Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023. LOA issuance 24-09-2024 ISO 13485 validity 30-11-</p>	<p>Rexton Targa (Behind the ear (BTE) Hearing aid)</p> <p>Class-B</p> <p>Service life: 5 years</p> <p>Models: Targa HP5 Targa HP 5A Targa P5 Targa P 5A Targa S5 Targa S 5A</p>	<p>Approved Targa HP5 Targa HP 5A</p> <p>The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter.</p> <p>The firm will apply separately for Targa P5 Targa P 5A and Targa S5 Targa S 5A.</p>

		2025 CE certificate validity 26-05-2024 with extension notification letter.		
67.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5729-P 31,000/-	<u>Legal Manufacturer:</u> Sivantos GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore. Original FSC: Berlin, Germany. Date of Issuance: 02-06- 2023. LOA issuance 24-09-2024 ISO 13485 validity 30-11- 2025 CE certificate validity 26- 05-2024 with extension notification letter.	Rexton inoX (In the ear (ITE) Hearing aid) Class-B Service life: 5 years Models: inoX ITC 5 inoX ITC 5A inoX CIC 5 inoX CIC 5A inoX ITC 10 E1 inoX CIC 10 E1	Approved inoX ITC 5 and inoX ITC 5A. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter.
68.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5725-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lyngby Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11- 2025 EU QMS certificate (MDR) validity 17-02- 2025	Rexton BiCore B-Li M Rugged (Behind the Ear (BTE) Hearing aid) Class-B Service life: 5 years Models: BiCore B-Li M Rugged 80 BiCore B-Li M Rugged 60 BiCore B-Li M Rugged 40 BiCore B-Li M Rugged SDemo	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.
69.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5726-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lyngby Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11- 2025 EU QMS certificate (MDR) validity 17-02- 2025	Rexton BiCore SR (Receiver in the Canal (RIC) Hearing aid) Class-B Service life: 5 years Models: BiCore SR 80 BiCore SR 60 BiCore SR 40 BiCore SR 30 BiCore SR 20 BiCore SR SDemo	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.

70.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5727-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lyngby Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR) validity 17-02-2025	Rexton Reach iX-CIC Li (In the Ear (ITE) Hearing aid) Class-B Service life: 5 years Models: Reach iX-CIC Li 80 Reach iX-CIC Li 60 Reach iX-CIC Li 40 Reach iX-CIC Li SDemo	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.
71.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5723-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lyngby Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR) validity 17-02-2025	Rexton ReCharge B-Li P (Behind the Ear (BTE) Hearing aid) Class-B Service life: 5 years Models: ReCharge B-Li P 30 ReCharge B-Li P 20 ReCharge B-Li P 10 ReCharge B-Li P 5	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.
72.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5724-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lyngby Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR) validity 17-02-2025	Rexton ReCharge R-Li (Receiver in the Canal (RIC) Hearing aid) Class-B Service life: 5 years Models: ReCharge R-Li 30 ReCharge R-Li 20 ReCharge R-Li 10 ReCharge R-Li 5 ReCharge R-Li Sdemo	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.
73.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5728-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lyngby Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR) validity 17-02-2025	Rexton Reach R-Li (Receiver in the Canal (RIC) Hearing aid) Class-B Service life: 5 years Models: Reach R-Li 80 Reach R-Li 60 Reach R-Li 40 Reach R-Li Sdemo	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.

74.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5722-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevvej 6 DK 3540 Lynge Denmark. Original FSC: Denmark. Validity: 17-02-2025 LOA validity 30-09-2028 ISO 13485 validity 30-11-2025 EU QMS certificate (MDR) validity 17-02-2025	Rexton ReCharge B-Li HP (Behind the Ear (BTE) Hearing aid) Class-B Service life: 5 years Models: ReCharge B-Li HP 30 ReCharge B-Li HP 20 ReCharge B-Li HP 10 ReCharge B-Li HP 5	Approved. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid FSC.
75.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5783-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevvej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028 ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Signia Active (In the Ear (ITE) Hearing) Class-B Service life: 5 years Model: Active Pro	Approved The firm will submit valid FSC.
76.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5784-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevvej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028 ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Signia Intuis 4 (Behind the Ear (BTE) Hearing aid) Class-B Service life: 5 years Models: Intuis SP 4.2, Intuis SP 4.1, Intuis SP 4.0, Intuis Intuis P 4.2, Intuis P 4.1, Intuis P 4.0.	Approved Intuis SP. The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration and valid FSC.
77.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5782-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevvej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028 ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Signia Insio IX (In the Ear (ITE) Hearing aid) Class-B Service life: 5 years Models: Insio 7IX CIC Insio 5IX CIC Insio 3IX CIC Insio 2IX CIC Insio 1IX CIC Insio 7IX IIC Insio 5IX IIC	Approved Complete in canal (CIC). The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration The firm is advised to submit application form and fee for the IIC hearing aid as per revised SRO for family.

			Insio 3IX IIC Insio 2IX IIC Insio 1IX IIC	
78.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5781-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028 ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Signia Styletto IX (Receiver in the Canal (RIC) Hearing aid) Class-B Service life: 5 years Models: Styletto 7IX Styletto 5IX Styletto 3IX Styletto sDemo DIX	Approved The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration and valid FSC.
79.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5780-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028 ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Signia Pure C & G IX Receiver in the Canal (RIC) Hearing aid Class-B Service life: 5 years Models: Pure C & G 7IX Pure C & G 5IX Pure C & G 3IX Pure C & G 2IX Pure C & G 1IX Pure C & G sDemo DIX	Approved The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration and valid FSC.
80.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5779-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028 ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Signic Silk C & G IX (In the ear Hearing aid) Class-B Service life: 5 years Models: Silk C & G 7IX Silk C & G 5IX Silk C & G 3IX Silk C & G 2IX Silk C & G 1IX Silk C & G sDemo DIX	Approved The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration and valid FSC.
81.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5778-P 31,000/-	<u>Legal Manufacturer:</u> WSAUD A/S Nymollevej 6 DK 3540 Lynge Denmark. FSC: Denmark Validity: 10-01-2025 LOA validity 30-06-2028	Signia Motion (Behind the ear (BTE) Hearing aid) Class-B Service life: 5 years	Approved Motion C&G SP 7IX Motion C&G SP 5IX Motion C&G SP 3IX Motion C&G SP 2IX Motion C&G SP 1IX The firm will submit

		ISO 13485 validity 17-02-2026 EU QMS certificate (MDR) validity 17-02-2025	Models: Motion C&G SP 7IX Motion C&G SP 5IX Motion C&G SP 3IX Motion C&G SP 2IX Motion C&G SP 1IX Motion C&G SP sDemo DIX Motion C&G P 7IX Motion C&G P 5IX Motion C&G P 3IX Motion C&G P 2IX Motion C&G P 1IX Motion C&G P sDemo DIX	differential fee of 19,000/- as per revised SRO for Family before the issuance of registration and valid FSC. The firm is advised to submit application form and fee for Motion C&G SP sDemo DIX, Motion C&G P 7IX, Motion C&G P 5IX, Motion C&G P 3IX, Motion C&G P 2IX, Motion C&G P 1IX and Motion C&G P sDemo DIX as per revised SRO.
82.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5772-P 31,000/-	<u>Legal Manufacturer:</u> Signia GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore. Original FSC: Germany. Date of Issuance: 13-06-2023 LOA validity 30-06-2028 ISO 13485 validity 17-02-2025 CE validity 26-05-2024	Signia Fast P (Behind the ear (BTE) Hearing aid) Class-B Service life: 5 years Art No: 10936803	Approved. The firm is advised to submit valid ISO 13485 certificate duly notarized before the issuance of registration letter.
83.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5773-P 31,000/-	<u>Legal Manufacturer:</u> Signia GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore. Original FSC: Germany. Date of Issuance: 13-06-2023 LOA validity 30-06-2028 ISO 13485 validity 17-02-2025 CE validity 26-05-2024	Signia Fun (Behind the ear (BTE) Hearing aid) Class-B Service life: 5 years Art No: Fun P (10936806, 10936808, 10936807)	Approved The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid ISO 13485 certificate.
84.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011	<u>Legal Manufacturer:</u> Signia GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai	Signia Intuis 3 (Inside the ear Hearing aid) Class-B	Approved.

	5774-P 31,000/-	Seng Street, #08-08 Singapore 539775 Singapore. Original FSC: Germany. Date of Issuance: 13-06-2023 LOA validity 30-06-2028 ISO 13485 validity 17-02-2025 CE validity 26-05-2024	Service life: 5 years Art No: Intuis 3 Custom 10946784	
85.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5775-P 31,000/-	<u>Legal Manufacturer:</u> Signia GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore. Original FSC: Germany. Date of Issuance: 13-06-2023 LOA validity 30-06-2028 ISO 13485 validity 17-02-2025 CE validity 26-05-2024	Signia Run (Behind the ear (BTE) Hearing aid) Class-B Service life: 5 years Art No: Run SP (10937288, 10937289, 10937290)	Approved The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid ISO 13485 certificate.
86.	Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore. ELI-01011 5776-P 31,000/-	<u>Legal Manufacturer:</u> Signia GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany. <u>Manufacturing site:</u> Sivantos (Suzhou) Co., Ltd. No. 120 Su Tong Road, China-Singapore Suzhou Industrial Park, Jiangsu Province 215021 Suzhou, People republic of China. Original FSC: Germany. Date of Issuance: 13-06-2023 LOA validity 30-06-2028 ISO 13485 validity 17-02-2025 CE validity 26-05-2024	Signia Insio (In-the-ear air conduction Hearing aid) Class-B Service life: 5 years Models/Article no: Insio 7Nx ITE Insio 5Nx ITE Insio 3Nx ITE Insio 2Nx ITE Insio 7Nx ITC Insio 5Nx ITC Insio 3Nx ITC Insio 2Nx ITC Insio 7Nx CIC Insio 5Nx CIC Insio 3Nx CIC Insio 2Nx CIC Insio 7Nx IIC Insio 5Nx IIC Insio 3Nx IIC Insio 2Nx IIC	Approved Insio 7Nx ITE Insio 5Nx ITE Insio 3Nx ITE Insio 2Nx ITE The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid ISO 13485 certificate. The firm is advised to submit form and fee for Insio 7Nx ITC Insio 5Nx ITC Insio 3Nx ITC Insio 2Nx ITC, Insio 7Nx CIC Insio 5Nx CIC Insio 3Nx CIC Insio 2Nx CIC and Insio 7Nx IIC Insio 5Nx IIC Insio 3Nx IIC Insio 2Nx IIC as per the revised SRO for family.

87.	<p>Audio Medics, 30-A, Shan Centre, Near Honda Fort Queens Road, Abid Market, Lahore.</p> <p>ELI-01011 5777-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Signia GmbH Henri-Dunant-Strasse 100 91058 Erlangen Germany.</p> <p><u>Manufacturing site:</u> Sivantos Pte. Ltd. 18 Tai Seng Street, #08-08 Singapore 539775 Singapore.</p> <p>Original FSC: Germany. Date of Issuance: 13-06- 2023 LOA validity 30-06-2028 ISO 13485 validity 17-02- 2025 CE validity 26-05-2024</p>	<p>Signia Silk X (In-the-ear Hearing aid)</p> <p>Class-B</p> <p>Service life: 5 years</p> <p>Models/Article no: Silk 7X Silk 5X Silk 3X Silk 2X Silk 1X</p>	<p>Approved.</p> <p>The firm will submit differential fee of 19,000/- as per revised SRO for Family before the issuance of registration letter and valid ISO 13485 certificate.</p>
88.	<p>Scientific Technical Corporation (Pvt) Ltd, LG- 2,3,4 & 6 Queens Center Queens Road, Lahore.</p> <p>ELI-00995 1403-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA.</p> <p>Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08- 2024</p>	<p>HTI Alkaline Phosphatase Reagent Set</p> <p>Class-A</p> <p>Shelf Life: 18 Months</p>	<p>Deferred for the provision of following:</p> <p>Valid and attested FSC.</p> <p>Notarized ISO 13485 certificate.</p> <p>Revised Form and Fee since the device falls in Class-B</p> <p>Original fee challan.</p>
89.	<p>Scientific Technical Corporation (Pvt) Ltd, LG- 2,3,4 & 6 Queens Center Queens Road, Lahore.</p> <p>ELI-00995 1404-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA.</p> <p>Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08- 2024</p>	<p>HTI Uric Acid Reagent Set</p> <p>Class-A</p> <p>Shelf Life: 18 Months</p>	<p>Deferred for the provision of following:</p> <p>Valid and attested FSC.</p> <p>Notarized ISO 13485 certificate.</p> <p>Revised Form and Fee since the device falls in Class-B</p> <p>Original fee challan.</p>
90.	<p>Scientific Technical Corporation (Pvt) Ltd, LG- 2,3,4 & 6 Queens Center Queens Road, Lahore.</p> <p>ELI-00995 1405-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA.</p> <p>Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08- 2024</p>	<p>HTI Glucose Oxidase Reagent Set</p> <p>Class-A</p> <p>Shelf Life: 18 Months</p>	<p>Deferred for the provision of following:</p> <p>Valid and attested FSC.</p> <p>Notarized ISO 13485 certificate.</p> <p>Revised Form and Fee since the device falls in Class-B</p> <p>Original fee challan.</p>
91.	<p>Scientific Technical Corporation (Pvt) Ltd, LG- 2,3,4 & 6 Queens Center Queens Road, Lahore.</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763</p>	<p>HTI Albumin Reagent Set</p> <p>Class-A</p>	<p>Deferred for the provision of following:</p> <p>Valid and attested FSC.</p>

	<p>ELI-00995 1406-P 6,000/-</p>	<p>USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024</p>	<p>Shelf Life: 36 Months</p>	<p>Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.</p>
92.	<p>Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1407-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024</p>	<p>HTI Triglyceride Reagent Set Class-A Shelf Life: 24 Months</p>	<p>Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.</p>
93.	<p>Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1408-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024</p>	<p>HTI Aspartate Aminotransferase (AST or SGOT) Reagent Set Class-A Shelf Life: 18 Months</p>	<p>Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.</p>
94.	<p>Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1409-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024</p>	<p>HTI Calcium Reagent Set Class-A Shelf Life: 36 Months</p>	<p>Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.</p>
95.	<p>Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1410-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024</p>	<p>HTI Cholesterol Reagent Set Class-A Shelf Life: 18 Months</p>	<p>Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.</p>

96.	Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1411-P 6,000/-	<u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024	HTI Amylase Reagent Set Class-A Shelf Life: 18 Months	Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.
97.	Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1412-P 6,000/-	<u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024	HTI Bilirubin Total Reagent Set * Bilirubin Total (Auto) Reagent Set *Bilirubin Total (Semi-Auto) Reagent Set Class-A Shelf Life: 36 Months	Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.
98.	Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1413-P 6,000/-	<u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024	HTI Urea Nitrogen (BUN) Reagent Set Class-A Shelf Life: 18 Months	Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.
99.	Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1414-P 6,000/-	<u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024	HTI Alanine Aminotransferase (ALT or SGPT) Reagent Set Class-A Shelf Life: 18 Months	Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.
100.	Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore. ELI-00995 1415-P 6,000/-	<u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA. Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024	HTI Total Protein Reagent Set Class-A Shelf Life: 36 Months	Deferred for the provision of following: Valid and attested FSC. Notarized ISO 13485 certificate. Revised Form and Fee since the device falls in Class-B Original fee challan.

101.	<p>Scientific Technical Corporation (Pvt) Ltd, LG-2,3,4 & 6 Queens Center Queens Road, Lahore.</p> <p>ELI-00995 1416-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> High Technology, Inc. Alice Agnew Dr. North Attleboro, MA 02763 USA.</p> <p>Original FSC: USA. Validity: 18-04-2025. LOA issuance August 2023 valid for 3 years ISO 13485 validity 02-08-2024</p>	<p>HTI Creatinine Reagent Set</p> <p>Class-A</p> <p>Shelf Life: 36 Months</p>	<p>Deferred for the provision of following:</p> <p>Valid and attested FSC.</p> <p>Notarized ISO 13485 certificate.</p> <p>Revised Form and Fee since the device falls in Class-B</p> <p>Original fee challan.</p>
102.	<p>TRADING360 Office # 1, 1st Floor, Bint-e-Zaman mall, Murree Road, Rawalpindi.</p> <p>ELI-01327 1420-P 6000/-</p>	<p><u>Legal Manufacturer:</u> JIANGSU WEBEST MEDICAL PRODUCT CO. LTD. No. 5, Yingchun Road, Industrial Park, Xuyi, Jiangsu, China.</p> <p>Original FSC: China Validity: 30-06-2025. LOA validity 30-12-2026 ISO 13485 validity 31-05-2026 CE with extension notification</p>	<p>WEBEST Extension Tube</p> <p>Class-A</p> <p>Shelf Life: 5 Year</p> <p>Codes: LIG-01, LIG-02, LIG-03, LIG-04, LIG-05, LIG-06 Length of the tube: 100mm, 300mm, 600mm, 900mm, 1200mm, 1500mm, 2000mm</p>	<p>Deferred for the provision of following:</p> <p>Revised Form and Fee since the device falls in Class-B and fee for Family as per revised SRO.</p>
103.	<p>M. Yousaf & Co, 79 M Block Gulberg III Lahore.</p> <p>ELI-00302 1423-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Sterilance Medicl (SUZHOU) Inc. No. 168, Putuoshan Road, New District 215153, SUZHOU, Jiangsu, P.R. China.</p> <p>Original FSC: China. Validity: 07-06-2026. LOA validity 08-10-2029 ISO 13485 validity 01-12-2025 EU QMS certificate (MDR) validity 23-11-2027</p>	<p>SKYMAX Disposable Surgical Blade, carbon steel</p> <p>Class-A</p> <p>Shelf Life: 5 years</p> <p>Codes/sizes as per FSC: 9, 10, 10A, 11, 12, 12B, 12D, 13, 14, 15, 15C, 16, 17 18, 19, 20, 21, 22, 22A, 23, 24, 25, 26, 27, 34, 36, 60, 70, PM40</p>	<p>Deferred for the submission of relevant form completely filled.</p> <p>Apply separately for Stainless steel type.</p>
104.	<p>Global Health Care Midway Commercial Plaza No. 20, back side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi.</p> <p>ELI-00086 5701-P 31,000/-</p>	<p><u>Legal Manufacturer:</u> Shenzhen Enmind Medical Instrument Co., Ltd, 2nd Floor, Block 2#, No. 14 Zhongxing Road, Xiuxin Community, Kengzi Street Pingshan district, Shenzhen, 518122 China.</p> <p>FSC: China Validity: 18-07-2026.</p>	<p>Disposable Trocar Disposable Trocar</p> <p>Class-B</p> <p>Shelf Life: 3 Years</p> <p>Codes as per FSC</p>	<p>Approved Bladed trocars.</p> <p>The firm will submit fee as per revised SRO for Family before the issuance of registration letter.</p> <p>The firm is advised to apply separately for Optical Bladeless trocars.</p>

		LOA validity 30-12-2026 ISO 13485 validity 22-01-2026 CE with extension notification letter		
105.	Global Health Care Midway Commercial Plaza No. 20, back side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086 1424-P 5,000/-	<u>Legal Manufacturer:</u> Shenzhen Xilaiheng Medical Electronics CO., LTD 10/F, YiFang Building, No. 315, ShuangMing Road, DongZhou Community, GuangMing Street, GuangMing District, Shenzhen, China. FSC: China. Validity: 19-05-2025. LOA validity 24-09-2029	Semi-automatic Electrolyte Analyzer Semi-automatic Electrolyte Analyzer Class-A Shelf Life: N/A Model: M-900	Approved The firm will submit fee as per revised SRO before the issuance of registration letter and original LOA and FSC.
106.	Mediland Pakistan Private Limited, Office No. B-09 2nd Floor, Masood Arcade IJP Road near Saidpur Road Rawalpindi. ELI-00202 5706-P 31,000/-	<u>Legal Manufacturer:</u> Getinge Disinfection AB Ljungadalsgatan 11 SE- 352 46 Vaxjo Sweden. Original FSC: Sweden. Date of Issuance: 17-06- 2024. LOA validity 31-10-2025 ISO 13485 validity 29-03- 2026 EU QMS certificate (MDR) validity 17-05- 2026	Getinge Poladus H ₂ O ₂ Sterilant Class-B Shelf Life: 12 Months	Approved The firm will submit fee as per revised SRO for family before the issuance of registration certificate
107.	Mediland Pakistan Private Limited, Office No. B-09 2nd Floor, Masood Arcade IJP Road near Saidpur Road Rawalpindi. ELI-00202 5707-P 31,000/-	<u>Legal Manufacturer:</u> Getinge Disinfection AB Ljungadalsgatan 11 SE- 352 46 Vaxjo Sweden. Original FSC: Sweden. Date of Issuance: 17-06- 2024. LOA validity 31-10-2025 ISO 13485 validity 29-03- 2026 EU QMS certificate (MDR) validity 17-05- 2026	Getinge Stericool Sterilant Agent Class-B Shelf Life: 12 Months	Approved The firm will submit fee as per revised SRO for family before the issuance of registration certificate
108.	Medical Equipment & Systems, 60/61 F.C.C Syed Maratib Ali Road Gulberg IV, Lahore, 54000, Pakistan. ELI-00554 5710-P	<u>Legal Manufacturer:</u> Fresenius Kabi AG Else-Kroner-Str. 1 61352 Bad Homburg Germany. Original FSC: Germany. Date of Issuance: 07-11- 2023.	CONOX 2D Anesthesia Monitor Class-B Shelf Life: 2 Year Code:	Approved. The firm is advised to submit separate application for Sensors.

	31,000/-	LOA validity 30-12-2025 ISO 13485 validity 31-03-2025 EU QMS certificate (MDR) validity 09-03-2026	Z029300	
109.	Life Care Diagnostics Solution, House No. 10, 1st Floor Near Dar Ul Aloom Jamia Masjid, 22No Chungi Opposite Mian CNG Rawalpindi. ELI-01286 5709-P 31,000/-	Legal Manufacturer: Aehealth Limited, Floor 11, Building 1B, BTR Technology Park, longtian Street, Pingshan District Shenzhen, P.R. China. Original FSC: China. Date of Issuance: 03-12-2024. LOA validity 26-11-2026	Lamuno-X (Fluorescence Immunoassay Analyzer) AEHEALTH Medical Devices (Cluster) Class-B Shelf Life: N/A	Deferred for clarification of product applied and class of medical device.
110.	Defence Resource Group, 309, 3rd Floor, Divine Mega II, New Airport Road, Lahore. ELI-01319 1421-P 6,000/-	Legal Manufacturer: A1 Globe SDN. BHD. A1-2, Block A, Jalan Haruan 5/9, Psurat Komersial Oakland, 70300 Seremben, Negeri Sembilan, Malaysia. FSC: Malaysia. Validity: 19-06-2027. LOA validity 15-07-2029 ISO 13485 validity 20-11-2025 EC Declaration of Conformity by manufacturer.	A1 Globe Latex Examination Gloves Class-a Shelf Life: 3 Years Sizes: XS, S, M, L, XL	Deferred since the same brand name from the same legal manufacturer is applied by M/s Delta Plus, Islamabad. The board decided for personal hearing of both the firms and directed to present current notarized LoA
111.	Verizon, 60-D, FCC Zahoor elahi Road, Gulberg IV, Lahore, Punjab, Pakistan. ELI-00087 7206-P 62,000/-	Legal Manufacturer: Beijing LidaKang Technology Co., Ltd No. 19 Dongying Road, Zhaofeng Industrial Zone, Zhaoquanying Town, Shunyi District, 101300 Beijing, China. Original FSC: China. Date of Validity: 15-03-2025. LOA issuance 11-10-2024 ISO 13485 validity 12-12-2025 CE certificate with extension notification validity 26-05-2024 DEC validity 26-05-2024	Hip Prosthesis Hip Prosthesis Class-D Shelf Life: 5 Years Codes as per FSC	Approved RLH Cementless femoral stem, RML cementless femoral stem The firm will submit fee as per revised SRO for System before the issuance of registration letter.
112.	Vital Care 9-S-1C, Sikander Malhi road, Canal Park, Gulberg-II,	Legal Manufacturer: Via Selciatella, 40-04011aprillia (Lt)- Italy	LED SPA Electro Surgery Unit	Approved

	Lahore. ELI-01049 5982-P 100,000/-	Via Marco Tullio Cicerone, 138-03100 Frosinone (Fr) Italy. Original FSC: Italy. Date of Issuance: 24-05-2024. LOA validity 31-12-2028 ISO 13485 validity 19-07-2025 EU QMS certificate (MDR) validity 21-09-2027	Class-C Shelf Life: 5 Year Models: Surtron 50 Surtron 80 Surtron 120 Surtron 160 Surtron 200	
113.	Opti Med, 37 A Main Gulberg III, Lahore, 54000, Pakistan. ELI-00501 5957-P 62,000/-	<u>Legal Manufacturer:</u> Anadolu Optomekanik Teknolojileri Sanayi Ticaret Anonim Sirketi Ahmet turan gazi Mah. OSB 5 Cad. No:10 Kapi No:- Merkez, Sivas/Turkiye. Original FSC: Turkiye. Date of Issuance: 24-10-2022 valid for 3 years LOA validity 30-10-2026 ISO 13485 validity 19-12-2026 CE certificate with extension notification letter validity 27-05-2024	IOLSTAR Foldable Hydrophobic Intraocular Lens Class-C Shelf Life: 5 Years Models: SP6125 SP6130	Approved The firm will submit fee as per revised SRO for family before the issuance of registration letter.
114.	Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road Rawalpindi. ELI-01172 5990-P 62,000/-	<u>Legal Manufacturer:</u> Exmoor Plastics Ltd Lisieux Way, Taunton, Somerset, TA1 2LB, UK. FSC: United Kingdom Validity: 31-12-2029. ISO 13485 validity 18-08-2025 CE certificate validity 26-05-2024	Aural Ventilation Tubes Aural Ventilation Tubes Class-C Shelf Life: 3 Year Models with article no: Shepards Drain with wire 1.14 mm (E101) Shepards Drain with wire 0.97 mm (E103) Shepards Drain without wire 1.41 mm (E102) Shepards Drain without wire 0.97 mm (E104)	Deferred for the provision of following: Credentials are not as per format given in 3 rd MDB meeting. LOA is missing between the importer and the legal manufacturer. FSC is copy and without attestation. ISO 13485 and FQA are without notarization. The firm applied both with wire and without wire tubes, differential fee is required as per revised SRO.
115.	Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road Rawalpindi. ELI-01172	<u>Legal Manufacturer:</u> Exmoor Plastics Ltd Lisieux Way, Taunton, Somerset, TA1 2LB, UK.	Nasal Splint Airway Nasal Splint Class-C	Deferred for the provision of following: Application required on Form-6A.

	5991-P 6,000/-	FSC: United Kingdom Validity: 31-12-2029. ISO 13485 validity 18-08-2025 CE certificate validity 26-05-2024	Shelf Life: 3 Years Models with version: Shah Nasal Splint L (N7, N8, N9)	Credentials are not as per format given in 3 rd MDB meeting. LOA is missing between the importer and the legal manufacturer. FSC is copy and without attestation. ISO 13485 and FQA are without notarization. The firm applied both with wire and without wire tubes, differential fee is required as per revised SRO.
116.	Allied Business System, Office No. B-305, 1st Floor B-Block Chandni Chowk Satellite Town, Rawalpindi. ELI-01118 5940-P 62,000/-	<u>Legal Manufacturer:</u> Beijing Wantai Biological Pharmacy Enterprise Co., Ltd No. 31 Kexueyuan Road Changping District Beijing P.R. China.	HbsAg Elisa Kit Wantai 1X96 Tests Class-C Shelf Life: 18-24 Month	Deferred for the provision of following: Original and valid LOA. Valid and notarized ISO 13485. Original, valid and attested FSC in the country of origin. Original, valid and attested FSC of reference country or notarized and valid CE certificate. stability studies and technical data of the subject device.
117.	Allied Business System, Office No. B-305, 1st Floor B-Block Chandni Chowk Satellite Town, Rawalpindi. ELI-01118 5941-P 62,000/-	<u>Legal Manufacturer:</u> Beijing Wantai Biological Pharmacy Enterprise Co., Ltd No. 31 Kexueyuan Road Changping District Beijing P.R. China.	HCV Elisa Kit Wantai 1X96 Tests Class-C Shelf Life: 18-24 Month	Deferred for the provision of following: Original and valid LOA. Valid and notarized ISO 13485. Original, valid and attested FSC in the country of origin. Original, valid and attested FSC of reference country or notarized and valid CE certificate. stability studies and technical data of the subject device. Clarification of Class of medical device.
118.	ASTO Life Science Pvt Ltd, Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt. ELI-00103 1513-P 6,000/-	<u>Legal Manufacturer:</u> Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland, 21152 USA. FSC: USA. Validity: 24-10-2025. LOA issuance 13-09-2024 ISO 13485 validity 10-10-2027	BD BACTEC TM FX 40 (CAT# 442296) & BD BACTEC TM FX 40 System Software (CAT#442391) Blood Culture instrument and System Software Class-A Shelf Life: N/A	Approved instrument. The firm is advised to submit fee and application for software.

119.	ASTO Life Science Pvt Ltd, Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt. ELI-00103 1514-P 6,000/-	<u>Legal Manufacturer:</u> Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland, 21152 USA. FSC: USA. Validity: 24-10-2025. LOA issuance 13-09-2024 ISO 13485 validity 10-10- 2027 Class-A Shelf Life: N/A	BD BACTEC TM FX TOP (CAT# 441385) BD BACTEC TM FX Bottom (CAT#441386) BD BACTEC TM Digital Thermometer (CAT#441370) & BD BACTEC TM FX System Software (CAT#441398) Blood Culture instrument and System Software Class-A Shelf Life: N/A	Approved instrument The firm will submit fee as per revised SRO for Family for Family for Top and bottom type before the issuance of registration letter. The firm is advised to submit fee and application for digital thermometer and software.
120.	Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 1512-P 6,000/-	<u>Legal Manufacturer:</u> BioMerieux S.A. 376 Chemin de l'Orme 69280 Marcy-l'Etoile - France. <u>Manufacturing sites:</u> BioMérieux SA 3 route de Port Michaud 38390 La Balme les grottes – France and M/s BioMerieux SA 3 Route de Port Michand 38390 La Balme Les Grottes, France (<i>For software</i>) FSC: France. Date of Issuance: 10-06- 2024 LOA validity 31-03-2025	VIDAS® KUBE CLINICAL Class-A Shelf Life: N/A Codes: KUBE clinical (423912) VIDAS KUBE V1.0 Software Clinic (424350)	Approved The firm will submit fee as per revised SRO for System before the issuance of registration letter.
121.	Genome Pharma, House No. 166-A, Street No. 09, Chaklala Scheme III, Rawalpindi. ELI-00267 7168-P 31,000/-	<u>Legal Manufacturer:</u> MedGyn Product Inc 800 Pasquinelli drive, Westmont, Illinois, USA. FSC: USA Date of Validity: 01-12- 2026. LOA validity 06-02-2030 ISO 13485 validity 04-03- 2027	MedGyn Pessary Cerclage Class-B Shelf Life: 10 Years Codes: Without drain 050191, 050192, 050193, 050194, 050195, 050196, With drain 050210, 050211, 050212, 050213, 050214, 050215	Approved The firm will submit fee as per revised SRO for Family before the issuance of registration letter.
122.	Zafaryab Traders, 134, First Floor, Eden Center, Jail Road, Lahore.	<u>Legal Manufacturer:</u> Medster Tibbi Cihaz Ve Saglik Hizmetleri Ltd. Sti Malikoy Baskent OSB	SafeCheck (Chemical Indicators, Sterilization Tape, Bowie Disk Test Packs,	Approved Chemical Indicator Steam Type 4, Steam Adhesive type 4, Steam dual type 4 Steam dual adhesive

	ELI-00505 1539-P 6,000/-	Mahalleesi 19.Cadde No:51 Temelli Sincan- ANKARA, Turkiye. Original FSC: Turkiye. Date of Issuance: 01-01- 2023 valid for 3 years LOA validity 31-12-2025 ISO 13485 validity 27-05- 2025	Washing Disinfector Cleaning Autoclave Tapes & Sterilization Control Strips) Class-A Shelf Life: 5 Years	type 4 (40.200, 40.110, 40.200, 40.210) The firm will submit fee as per revised SRO for Family before the issuance of registration letter. The firm is advised to submit application for other product as per their grouping in Family.
123.	Zafaryab Traders, 134, First Floor, Eden Center, Jail Road, Lahore. ELI-00505	Legal Manufacturer: Medster Tibbi Cihaz Ve Saglik Hizmetleri Ltd. Sti Malikoy Baskent OSB Mahalleesi 19.Cadde No:51 Temelli Sincan- ANKARA, Turkiye. Original FSC: Turkiye. Date of Issuance: 10-03- 2023 valid for 3 years LOA validity 31-12-2025 ISO 13485 validity 27-05- 2025	SafeCheck (Sterilization Reels, Sterilization Pouches Gusseted Sterilization Reel, Flat Sterilization Reel, Tyvek® Sterilization Reel, Gusseted Sterilization Pouch, Flat Sterilization Pouch, Self-Seal Sterilization Pouch, Tyvek(R) Sterilization Pouch) Class-A Shelf Life: 5 Years	Approved Gusseted Sterilization reel. The firm is advised to submit separate fee and application for other types.
124.	Bioactive Diagnostic Systems, Flat No. 3/C-Bfirst Floor Chouburji Center Multan Road, Lahore. ELI-01037 1545-P 6,000/-	Legal Manufacturer: Pishtaz Teb Zaman No. 1, 3rd Yas Street Golha Blvd, Shahrak-e-Golestan, Tehran, Iran. FSC: Iran. Date of Issuance: 08-03- 2022.	Anti CCp Elisa Diagnostic Kit Class-A Shelf Life: N/A	Deferred for the provision of following: The subject device falls in Class-B so submit the application on Form-7A with all the required legal documents in original and technical data as per the requirements of application form. The stability data given is of Guidewire. Submit the stability studies of the subject device.
125.	Shahid Surgical Peshawar Basement Abdul Market, Shop No,14. Namak Mandi, Peshawar Pakistan. ELI No. 00492 Fee 31000/=	Legal Manufacturer: SUZHOU NEW AREA MINGJI MACROMOLECULE APPRATUS CO., LTD, Located at Address's 1, KANGJIAN ROAD, MUDU TOWN WUZHONG DISTRICT, SUZHOU 215101 CHINA.	GREAT MED IRRIGATION SET Class-B Shelf life: 3 Years Sizes: F8, F10, F12, F14, F16, F18, F20	Approved

		FSC Valid till: 21/03/2026 EC Validity: Expired in 25-05-2024, CE confirmation letter is attached for further validity.31/12/2028 ISO Valid till: 25/6/2025 LOA Valid till: 05/3/2030		
126.	Shahid Surgical Peshawar Basement Abdul Market, Shop No,14. Namak Mandi, Peshawar Pakistan. ELI No. 00492 Fee 31000/=	<u>Legal Manufacturer:</u> SUZHOU NEW AREA MINGJI MACROMOLECULE APPRATUS CO., LTD, Located at Address's 1, KANGJIAN ROAD, MUDU TOWN WUZHONG DISTRICT, SUZHOU 215101 CHINA. FSC Valid till: 21/03/2026 EC Validity: Expired in 25-05-2024, CE confirmation letter is attached for further validity.31/12/2028 ISO Valid till: 25/6/2025 LOA Valid till: 05/3/2030	GREAT MED Disposable Esophageal Stomach Cannula Class-B Shelf life: 3 Years Sizes: F8, F10, F12, F14, F16, F18, F20	Approved
127.	M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863) Fee details: Amount paid: PKR 31030/- Paid Slip / challan No.: 24573413601	<u>(Legal Manufacturer)</u> TIANCHANG HENGSHENG MEDICAL DEVICES CO., LTD., Address: Qinlan Industrial Park, Tianchang City, Anhui Province, China Free Sale Certificate Validity: (22/11/2025) ISO 13485 certificate validity: (11/04/2026) EC certificate Validity: (26/05/2024) Letter of authorization: Validity: (16/11/2028)	Mediclean Latex surgical gloves(Powdered) Models / Sizes: (6.0/6.5/7/7.5/8/8.5/9) Class-B Shelf life: 60 Months	Approved
128.	M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)	<u>(Legal Manufacturer)</u>	Sure-Guard IV Cannula (Pen type)	Approved

	<p>Fee details: Amount paid: PKR 25000/- Paid Slip / challan No.: 98710387</p>	<p>JIANGXI FENGLIN MEDICAL APPLIANCE CO., LTD Address: Fulin Road, Fuzhou City, 344100, Jiangxi, P.R, China.</p> <p>Free Sale Certificate Validity: (29/07/2025)</p> <p>ISO 13485 certificate validity: (12/11/2026)</p> <p>EC certificate Validity: (27/05/2024)</p> <p>Letter of authorization: Validity: (07/12/2026)</p>	<p>Models / Sizes: (16G/18G/20G/22G/24 G)</p> <p>Class-B</p> <p>Shelf life: 60 Months</p>	
129.	<p>M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)</p> <p>Fee details: Amount paid: PKR 25000/- Paid Slip / challan No.: 4385399362</p>	<p>(Legal Manufacturer) JIANGXI FENGLIN MEDICAL APPLIANCE CO., LTD Address: Fulin Road, Fuzhou City, 344100, Jiangxi, P.R, China.</p> <p>Free Sale Certificate Validity: (29/07/2025)</p> <p>ISO 13485 certificate validity: (12/11/2026)</p> <p>EC certificate Validity: (27/05/2024)</p> <p>Letter of authorization: Validity: (07/12/2026)</p>	<p>Sure-Guard IV Cannula (WITHOUT INJECTION PORT)</p> <p>Models / Sizes: (16G/18G/20G/22G/24 G)</p> <p>Class-B</p> <p>Shelf life: 60 Months</p>	Approved
130.	<p>M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)</p> <p>Fee details: Amount paid: PKR 62000/- Paid Slip / challan No.: 873067263741</p>	<p>(Legal Manufacturer) M/s Biostandard Co., Ltd: #501, 20, Hoseo ro 79 beon gil, Baebang eup, Asan si, Chungcheongnam do, 31499, Republic of Korea</p> <p>Free Sale Certificate Validity: (05/11/2026)</p> <p>ISO 13485 certificate validity: (14/02/2027)</p> <p>Letter of authorization: Validity: (03/2035)</p>	<p>MELINE VOLUME LIDOCAINE</p> <p>Models / sizes: MVL-3E</p> <p>Class-C</p> <p>Shelf life: 24 months</p>	Approved
131.	<p>M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)</p>	<p>(Legal Manufacturer) Name:</p>	<p>MELINE DEEP LIDOCAINE</p>	Approved

	Fee details: Amount paid: PKR 62000/- Paid Slip / challan No.: 017947506	M/s Biostandard Co., Ltd., #501, 20, Hoseo ro 79 beon gil, Baebang eup, Asan si, Chungcheongnam do, 31499, Republic of Korea Free Sale Certificate Validity: (05/11/2026) ISO 13485 certificate validity: (14/02/2027) Letter of authorization: Validity: (03/2035)	Models / Sizes: MDL-2E Class-C Shelf life: 24 Months	
132.	M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863) Fee details: Amount paid: PKR 62000/- Paid Slip / challan No.: 7785299964	(Legal Manufacturer) M/s Biostandard Co., Ltd: #501, 20, Hoseo ro 79 beon gil, Baebang eup, Asan si, Chungcheongnam do, 31499, Republic of Korea Free Sale Certificate Validity: (05/11/2026) ISO 13485 certificate validity: (14/02/2027) Letter of authorization: Validity: (03/2035)	MELINE CLASSIC LIDOCAINE Models / Sizes: MCL-1E Class-C Shelf life: 24 Months	Approved
133.	M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863) Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 931135191	(Legal Manufacturer) M/s Haiyan Kangyuan Medical Instrument Co., Ltd. Address: Songpodong Road, Shendang Town, Haiyan, 314311 Zhejiang, P.R. China Free Sale Certificate Validity: (24/09/2025) ISO 13485 certificate validity: (25/08/2026) EU QMS Certificate MDR Validity: (01/02/2028) Letter of authorization: Validity: (03/2035)	SURE-GUARD ETT (CUFFED) Models / Sizes: Size: ID2.0, ID2.5, ID3.0, ID3.5, ID4.0, ID4.5, ID5.0, ID5.5, ID6.0, ID6.5, ID7.0, ID7.5, ID8.0, ID8.5, ID9.0, ID9.5, ID10.0 Class-B Shelf life: 60 Months	Approved
134.	Applicant: M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)	(Legal Manufacturer) M/s Haiyan Kangyuan Medical Instrument Co., Ltd.	SURE-GUARD ETT (UNCUFFED) Models / Sizes:	Approved

	Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 1520465538	Address: Songpodong Road, Shendang Town, Haiyan, 314311 Zhejiang, P.R. China Free Sale Certificate Validity: (24/09/2025) ISO 13485 certificate validity: (25/08/2026) EU QMS Certificate MDR Validity: (01/02/2028) Letter of authorization: Validity: (03/2035)	Size: ID2.0, ID2.5, ID3.0, ID3.5, ID4.0, ID4.5, ID5.0, ID5.5, ID6.0, ID6.5, ID7.0, ID7.5, ID8.0, ID8.5, ID9.0, ID9.5, ID10.0 Class-B Shelf life: 60 Months	
135.	M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863) Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 65409544405	(Legal Manufacturer) M/s Haiyan Kangyuan Medical Instrument Co., Ltd. Address: Songpodong Road, Shendang Town, Haiyan, 314311 Zhejiang, P.R. China Free Sale Certificate Validity: (24/09/2025) ISO 13485 certificate validity: (25/08/2026) EU QMS Certificate MDR Validity: (01/02/2028) Letter of authorization: Validity: (03/2035)	Sure-Guard Silicone Foley Catheter with Temperature Probe (Single Use) Models / Sizes: THREE CAVITY TYPE SIZES: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr 16Fr, 18Fr, 20Fr, 22Fr, 24Fr FOUR CAVITY TYPE SIZES: 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr Class-B Shelf life: 60 Months	Approved THREE CAVITY TYPE
136.	M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863) Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 08340514	(Legal Manufacturer) M/s Haiyan Kangyuan Medical Instrument Co., Ltd. Address: Songpodong Road, Shendang Town, Haiyan, 314311 Zhejiang, P.R. China Free Sale Certificate Validity: (24/09/2025) ISO 13485 certificate validity: (25/08/2026) EU QMS Certificate MDR	Sure-Guard Latex Foley Catheter (Single Use) Models / Sizes: SIZES: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr MODELS: 2 Way Standard, 2 Way Female, 2 Way Children,	Approved 2 Way type. The firm will submit fee as per revised SRO for family before the issuance of registration letter.

		<p>Validity: (01/02/2028)</p> <p>Letter of authorization: Validity: (03/2035)</p>	<p>(3 Way Standard) 、 (3 Way Female) 、 (3 Way Children) 、 (2 Way Suprapubic) 、 (3 Way Suprapubic) 、 (2 Way Longitudinal Grooves) 、 (3 Way Longitudinal Grooves) 、 (Single Way Standard) 、 (Single Way Children) 、 (2 Way Half Side Balloon) 、 (3 Way Half Side Balloon) (3 Way Standard Large Balloon Straight Tip) (3 Way Standard Large Balloon Tiemann Tip)</p> <p>Class-B</p> <p>Shelf life: 60 Months</p>	
137.	<p>M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 97990176</p>	<p>(Legal Manufacturer) M/s Haiyan Kangyuan Medical Instrument Co., Ltd. Address: Songpodong Road, Shendang Town, Haiyan, 314311 Zhejiang, P.R. China</p> <p>Free Sale Certificate Validity: (24/09/2025)</p> <p>ISO 13485 certificate validity: (25/08/2026)</p> <p>EU QMS Certificate MDR Validity: (01/02/2028)</p> <p>Letter of authorization: Validity: (03/2035)</p>	<p>Sure-Guard Guedel Airway</p> <p>Class-B</p> <p>Shelf life: 60 Months</p> <p>Codes/sizes: 3cm,3.5cm,4cm,4.5cm, 5cm, 5.5cm,6cm, 7cm, 8cm, 9cm, 10cm, 11cm, 12cm</p>	Approved
138.	<p>M/s AMB HK ENTERPRISES (PVT) LTD. (ELI- 00863)</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 8157535602</p>	<p>(Legal Manufacturer) M/s Anhui Deepblue Medical Technology Co., Ltd. Address: No.777 Jimingshan Road, High-Tech Development Zone230088 Hefei, Anhui, China</p>	<p>SURE-GUARD HCG Pregnancy Test (Colloidal Gold) Strip</p> <p>Class-B</p> <p>Shelf life: 36 Months</p>	Approved

		<p>Free Sale Certificate Validity: (28/10/2026)</p> <p>ISO 13485 certificate validity: (21/06/2027)</p> <p>CE CERTIFICATE Validity: (26/05/2025)</p> <p>Letter of authorization: Validity: (03/2035)</p>		
139.	<p>M/S Diagnostors (Smc Pvt) Ltd Building 32 Lalazar Commercial Market Raiwand Road Thokar Niaz Baig, Lahore (ELI-01174)</p> <p>Fee details: Amount paid: PKR 25000 /- Paid Slip / challan No.6829719293:</p>	<p>(Legal Manufacturer) M/S. Tiangcheng City Anrui Medical Equipments Co., Ltd Watang Team Renhe Industrial District, Tiangcheng City, Anhui Province, China</p> <p>Free Sale Certificate Validity: (15/01/2026)</p> <p>ISO 13485 certificate validity: (19/07/2027)</p> <p>EC certificate Validity: (26/05/2024)</p> <p>Letter of authorization: Validity: (31/03/2029)</p>	<p>D Support Latex Surgical Gloves Models / Sizes: (6,6.5,7,7.5,8,8.5,9)</p> <p>Class-B</p> <p>Shelf life: 5 Years</p>	Approved
140.	<p>M/s CURATIVE SOLUTION located at 290-D, Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-00969,</p> <p>Fee details: Amount paid: PKR 6030/- Paid Slip / challan No.: 7148650979</p>	<p>(Legal Manufacturer) Changzhou Major Medical Products Co., Ltd. Address: No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Tel: +86 519 68020210 Fax: +86 519 68020208 Web: https://cn.czmajor.com/ Free Sale Certificate Date of Issue:11/02/2025 Validity: 2 years (from the Date of Issue)</p> <p>ISO 13485 certificate Date of Issue: 20/09/2023 validity: (19/09/2026)</p> <p>EC certificate Validity: (14/07/2029)</p> <p>Letter of authorization:</p>	<p>CS CURE Adhesive Wound Dressing</p> <p>Models / Sizes: PU TYPE</p> <p>Class-A</p> <p>Shelf life: 3 years</p>	Approved.

		Date of Issue:18/02/2025 Validity: 5 years (from the Date of Issue)		
141.	M/s CURATIVE SOLUTION located at 290-D, Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-00969 Fee details: Amount paid: PKR 6030/- Paid Slip / challan No.: 9210503929 Dated: (21/03/2025)	(Legal Manufacturer) Changzhou Major Medical Products Co., Ltd. Address: No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144 Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Tel: +86 519 68020210 Fax: +86 519 68020208 Web: https://cn.czmajor.com/ Free Sale Certificate Date of Issue:11/02/2025 Validity: 2 years (from the Date of Issue) ISO 13485 certificate Date of Issue: 20/09/2023 validity: (19/09/2026) EC certificate Validity: (14/07/2029) Letter of authorization: Date of Issue:18/02/2025 Validity: 5 years (from the Date of Issue)	CS CURE Medical Tape Models / Sizes: NON-WOVEN TYPE Class-A Shelf life: 5 years	Approved
142.	M/s CURATIVE SOLUTION located at 290-D, Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-00969, Fee details: Amount paid: PKR 6030/- Paid Slip / challan No.: 6705193394	(Legal Manufacturer) M/S. Suzhou Riyuexing Plastic Co., Ltd. Address: No.9, Ximuhe Street, Huashan Road, High and New Zone, 215129 Suzhou, China Tel: 86-512-67365188 Fax: 86-512-67365188 Free Sale Certificate Date of Issue:11/02/2025 Validity: 2 years (from the Date of Issue) ISO 13485 certificate Date of Issue: 26/07/2024 validity: (25/79/2027) EC certificate Validity: (25/07/2029) Letter of authorization: Date of Issue:18/02/2025 Validity: 5 years (from the Date of Issue)	CS CURE Drainage Bottle Equipment Models / Sizes: <i>SINGLE CHAMBER, DOUBLE CHAMBER TRIPLE CHAMBER</i> Class-B Shelf life: 3 years	Approved Single chamber. The firm is advised to submit fee and application form for other two types.

143.	<p>M/s CURATIVE SOLUTION located at 290-D Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-00969,</p> <p>Fee details: Amount paid: PKR 31030/- Paid Slip / challan No.: 4895795203</p>	<p>(Legal Manufacturer) M/S. Shandong Wuzhou Medical Equipment Co., Ltd. Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China Tel: 0530-2135555 Fax: 0533-2135555 Web: http://www.wzhmed.com/</p> <p>Free Sale Certificate Date of Issue: 11/02/2025 Validity: 2 years (from the Date of Issue)</p> <p>ISO 13485 certificate Date of Issue: 05/09/2022 validity: (04/09/2025)</p> <p>EC certificate Validity: (31/12/2028)</p> <p>Letter of authorization: Date of Issue: 18/02/2025 Validity: 5 years (from the Date of Issue)</p>	<p>CS CURE Infusion Set</p> <p>Models / Sizes: With needle, without needle.</p> <p>Class-B</p> <p>Shelf life: 5 years</p>	<p>Approved</p> <p>The firm is advised to submit fee as per revised SRO for family before the issuance of registration letter.</p>
144.	<p>M/s CURATIVE SOLUTION located at 290-D, Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-00969</p> <p>Fee details: Amount paid: PKR 6030/- Paid Slip / challan No.: 297262450870</p>	<p>(Legal Manufacturer) Conod Medical Co., Limited Address: No. 11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Tel: +86 0512-52531238 Fax: +86 0512-52531238 Web: https://conodmedical.com/</p> <p>Free Sale Certificate Date of Issue: 11/02/2025 Validity: 2 years (from the Date of Issue)</p> <p>ISO 13485 certificate Date of Issue: 01/01/2025 validity: (31/12/2027)</p> <p>EC QMS certificate MDR Validity: (16/10/2027)</p> <p>Letter of authorization:</p>	<p>CS CURE Urine Meter</p> <p>Models / Sizes: 2000ml, 2200ml, 2350ml, 2500ml, 2900ml, 3000ml, 3100ml</p> <p>Class-A</p> <p>Shelf life: 5 years</p>	<p>Approved.</p>

		Date of Issue:18/02/2025 Validity: 5 years (from the Date of Issue)		
145.	<p>M/s CURATIVE SOLUTION located at 290-D, Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-0096</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 441205224122 Dated: (21/03/2025)</p>	<p>(Legal Manufacturer) M/S. Bonree Medical Co., Ltd. Address: 1st floor of Building No.2, Building No.4, Longzhu Village Economic Estate, Longzhu Avenue, Nanlang, 528451 Zhongshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA Tel: +86 760 8520 3166 Fax: +86 760 8520 3166 Web: http://www.bonreemed.com/ Free Sale Certificate Date of Issue:11/02/2025 Validity: 2 years (from the Date of Issue)</p> <p>ISO 13485 certificate Date of Issue: 01/12/2023 Validity: (31/07/2025)</p> <p>EC certificate Validity: (31/12/2028)</p> <p>Letter of authorization: Date of Issue:17/02/2025 Validity: 5 years (from the Date of Issue)</p>	<p>CS CURE Yankauer Suction Set</p> <p>Models / Sizes: Type or Sizes 9/32", 1/4",3/16"</p> <p>Class-B</p> <p>Shelf life: 5 years</p>	Approved
146.	<p>M/s CURATIVE SOLUTION located at 290-D, Anghoori Baagh Scheme No. 1, Lahore 09, Pakistan ELI-00969</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: 749331460632</p>	<p>(Legal Manufacturer) Conod Medical Co., Limited Address: No. 11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Tel: +86 0512-52531238 Fax: +86 0512-52531238 Web: https://conodmedical.com/ Free Sale Certificate Date of Issue:11/02/2025 Validity: 2 years (from the Date of Issue)</p> <p>ISO 13485 certificate Date of Issue: 01/01/2025</p>	<p>CS CURE Wound Drainage System</p> <p>Models / Sizes: 100 ML, 200 ML, 400 ML, 500 ML, 600 ML, 800 ML</p> <p>Class-B</p> <p>Shelf life: 5 years</p>	Approved

		<p>validity: (31/12/2027)</p> <p>EC certificate Validity: (16/10/2027)</p> <p>Letter of authorization: Date of Issue:18/02/2025 Validity: 5 years (from the Date of Issue)</p>		
147.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15745 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 070482265107 PKR: 50000/- Dated: 30-07-2024</p>	<p>Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China (country of origin): 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019</p>	<p>Suigly Suicon Surgical Sutures Polyglycolic Acid Surgical Suture with Needle (PGA) USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper Cutting, Non cutting. Needle Curvature: ½ Circle, 3/8 circle, straight & double spatulated. Class: D Shelf life: 05 years</p>	<p>Deferred for the clarification as the the same brand is already registered for M/s Nasir Brothers but the legal manufacturer is different.</p>
148.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15744 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 838593134 PKR: 50000/- Dated: 30-07-2024</p>	<p>Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China (country of origin): 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019</p>	<p>Suicon Surgical Sutures Silk Braided Surgical Suture with needle USP Suture Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting. Needle Curvature: ½ Circle, 3/8 circle, straight. Class: D Shelf life: 05 years</p>	<p>Deferred for the clarification as the the same brand is already registered for M/s Nasir Brothers but the legal manufacturer is different.</p>
149.	<p>M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15747 DRAP (R&I)</p>	<p>Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City,</p>	<p>Suicon Surgical Sutures Suilene Polypropylene Monofilament Surgical Suture with Needle USP Suture</p>	<p>Deferred for the clarification as the the same brand is already registered for M/s Nasir Brothers but the legal manufacturer is different.</p>

	Dated: 18-09-2024 Fee Challan No.: 7798811089 PKR: 50000/- Dated: 09-08-2024	Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China <i>(country of origin):</i> 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019	Size: 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting and non-cutting. Needle Curvature: ½ Circle, 3/8 circle, straight, Double Needle. Class: D Shelf life: 05 years	
150.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 15746 DRAP (R&I) Dated: 18-09-2024 Fee Challan No.: 06434554213 PKR: 50000/- Dated: 09-08-2024	Legal Manufacturer: M/s Shandong Haidike Medical Products Co. Ltd. Manufacturer Address: Tianfu Road, Dongcheng District, Shan County, 274300, Heze City, Shandong Province, China. ISO 13485 Certificate validity: 19-04-2026 EC Certificate validity: 09-04-2024 LOA Validity: 30-12-2027 FSC Validity: China <i>(country of origin):</i> 14-02-2025 FSC (MHRA-UK) Dated 23-02-2019	Suicon Surgical Sutures Suicryl Polyglactin 910 (PGLA) Surgical Suture with Needle USP Suture Size: 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5. Needle Shape: Round Bodied, Straight, Curve, Cutting, Reverse Cutting, Taper cutting. Needle Curvature: ½ Circle, 3/8 circle, straight. Class: D Shelf life: 05 years	Deferred for the clarification as the the same brand is already registered for M/s Nasir Brothers but the legal manufacturer is different.
151.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1493-P 6,000/-	Legal Manufacturer: Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. FSC: China. Validity: 18-04-2026. LOA Validity: 27-12-2027 FSC: FSC of Reference Country Validity: 05-08-2026 OR EC Certificate Validity: 31-12-2028 ISO 13485 Validity: 01-03-2026	Hand-Held Fundus Camera (Models: FC160 & FC161) Ophthalmic Fundus Camera Class-A Shelf Life: 4 Years	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter.

152.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1494-P 6,000/-	<u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. <u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027 <u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028 <u>ISO 13485</u> Validity: 01-03-2026	Corneal Topographer (Model: DEA520) Corneal Topography System Class-A Shelf Life: 8 Years	Approved. The firm will submit fee as per revised SRO for System before the issuance of registration letter.
153.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1495-P 6,000/-	<u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. <u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027 <u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028 <u>ISO 13485</u> Validity: 01-03-2026	Three-Dimensional Analysis Systems for the Anterior Eye Segment (Anterior Segment Analyzer), Model: Scansys TA517. Eye Anterior Segment Analyzer Class-A Service Life: 8 Years	Approved
154.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1496-P 6,000/-	<u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. <u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027	Portable Slit Lamp (Model: S150) Slit Lamp Microscope Class-A Shelf Life: 8 Years	Approved

		<u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028 <u>ISO 13485</u> Validity: 01-03-2026		
155.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1497-P 6,000/-	<u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. <u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027 <u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028 <u>ISO 13485</u> Validity: 01-03-2026	Slit Lamp Microscope (Models: S390L, S360S & S360) Slit Lamp Microscope Class-A Shelf Life: 8 Years	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter.
156.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1498-P 6,000/-	<u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. <u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027 <u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028 <u>ISO 13485</u> Validity: 01-03-2026	Retina Lens (Models: 20D, 78D & 90D) Hand-held Magnifier Class-A Shelf Life: 4 Years	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter.
157.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan.	<u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co.,	Slit Lamp Microscope S290 Slit Lamp Microscope	Approved.

	<p>ELI-00305 1503-P 6,000/-</p>	<p>Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China.</p> <p><u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027</p> <p><u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028</p> <p><u>ISO 13485</u> Validity: 01-03-2026</p>	<p>Class-A</p> <p>Shelf Life: 8 Years</p>	
158.	<p>Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan.</p> <p>ELI-00305 1504-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China.</p> <p><u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027</p> <p><u>FSC:</u> FSC of Reference Country Validity: 05-08-2026 OR <u>EC Certificate</u> Validity: 31-12-2028</p> <p><u>ISO 13485</u> Validity: 01-03-2026</p>	<p>Slit Lamp Microscope (Models: S260 & S260s) Slit Lamp Microscope</p> <p>Class-A</p> <p>Shelf Life: 8 Years</p>	<p>Approved.</p> <p>The firm will submit fee as per revised SRO for Family before the issuance of registration letter.</p>
159.	<p>Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan.</p> <p>ELI-00305 1505-P 6,000/-</p>	<p><u>Legal Manufacturer:</u> Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China.</p> <p><u>FSC:</u> China. Validity: 18-04-2026. <u>LOA</u> Validity: 27-12-2027</p> <p><u>FSC:</u> FSC of Reference Country Validity: 05-08-2026</p>	<p>Automatic Fundus Camera (Model: FC162)</p> <p>Ophthalmic Fundus Camera</p> <p>Class-A</p> <p>Shelf Life: 5 Years</p>	<p>Approved</p>

		OR EC Certificate Validity: 31-12-2028 ISO 13485 Validity: 01-03-2026		
160.	Optisurg, 17-C1, P.E.C.H.S, Valencia Town, Lahore - Pakistan. ELI-00305 1506-P 6,000/-	Legal Manufacturer: Shanghai Mediworks Precision Instruments Co., Ltd. No. 7, Mingpu Phase II, No. 3279 Sanlu Road, Minhang District, 201100, Shanghai, China. FSC: China. Validity: 18-04-2026. LOA Validity: 27-12-2027 FSC: FSC of Reference Country Validity: 05-08-2026 OR EC Certificate Validity: 31-12-2028 ISO 13485 Validity: 01-03-2026	Ophthalmic Surgical Microscope (Model: SM621) Ophthalmic Surgical Microscope Class-A Shelf Life: 8 Years	Approved
161.	Sanwa Trading Corporation, Office No. G-88, Pindi Cricket Stadium, Stadium Road, Rawalpindi. ELI-00210 1478-P 6,000/-	Legal Manufacturer: Soudan Medical No. 1 Nangong He Road, Building 4# Lingping District, Hangzhou, Zhejiang FSC: China. Validity: 12-09-2025.	Sondan Medical Diaflow Regulator Class-A Shelf Life: 3 Years	Deferred for clarification since the form is submitted for Diaflow regulator whereas the rest of documents are submitted of different products including forceps, biopsy needle and endoscopic injection needle, clarification is required that which product is applied in actual.
162.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1515-Ibd 25,000/-	Legal Manufacturer: Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Chemistry Analyzer Class-A Service Life: 10 Years Model: EXC200 EXC220	Approved.
163.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, 	Legal Manufacturer: Zybio Inc No. 45, Shilin Avenue,	ZYBIO Diluent kit	Approved

	Sector I-8/3, Islamabad. ELI-01195 1516-Ibd 6,000/-	Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	Class-A Shelf Life: 24 Months Codes: (20 Lx1 Bucket) (10 Lx1 bucket)	
164.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1517-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Lyse kit Class-A Shelf Life: 24 Months Codes: 250mL/ Bottle 500mL/ Bottle	Approved
165.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1518-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Lyse kit Class-A Shelf Life: 24 Months Model with Specs: (Z5 LD) 500mL x 1	Approved
166.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1519-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Nucleic Acid Isolation System Class-A Shelf Life: 6 Years Model: (EXM3000)	Approved
167.	Zybio Medical Pakistan (SMC-Private) Ltd,	<u>Legal Manufacturer:</u> Zybio Inc	ZYBIO Nucleic Acid Isolation	Approved

	House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1520-Ibd 6,000/-	No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	System Class-A Shelf Life: 6 Years Model: (EXM6000)	
168.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1521-Ibd 6,000/-	Legal Manufacturer: Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Nucleic Acid Extraction Kit (Magnetic Bead Method) for virus Class-A Shelf Life: 12 Months Codes: B-200: 8T/kit B-200: 16T/kit B-200: 20T/kit B-200: 32T/kit T-200: 32T/kit T-200: 96T/kit	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter
169.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1522-Ibd 6,000/-	Legal Manufacturer: Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Nucleic Acid Extraction Kit (Magnetic Bead Method) for RT virus Class-A Shelf Life: 12 Months Codes: RT-B-200: 8T/kit RT-B-200: 16T/kit RT-B-200: 20T/kit RT-B-200: 32T/kit RT-T-200: 32T/kit RT-T-200: 96T/kit	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter
170.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1523-Ibd 6,000/-	Legal Manufacturer: Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026.	ZYBIO Nucleic Acid Extraction Kit (Magnetic Bead Method) for WB Class-A Shelf Life: 12 Months	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter

		LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	Codes: WB-B: 8T/kit WB-B: 16T/kit WB -B: 20T/kit WB -B: 32T/kit WB -T: 32T/kit WB -T: 96T/kit	
171.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1524-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Nucleic Acid Extraction Kit (Magnetic Bead Method) for BF Class-A Shelf Life: 12 Months Codes: BF-B: 8T/kit BF-B: 16T/kit BF -B: 20T/kit BF-B: 32T/kit BF -T: 32T/kit BF -T: 96T/kit	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter
172.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1525-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Nucleic Acid Extraction Kit (Magnetic Bead Method) for FFPE Class-A Shelf Life: 12 Months Codes: FFPE-B: 8T/kit FFPE -B: 16T/kit FFPE -B: 20T/kit FFPE -B: 32T/kit FFPE T: 32T/kit FFPE -T: 96T/kit	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter
173.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1526-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Nucleic Acid Extraction Kit (Magnetic Bead Method) for stool Class-A Shelf Life: 12 Months Codes: S-B: 8T/kit S -B: 16T/kit S -B: 20T/kit S -B: 32T/kit	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter.

			S T: 32T/kit S -T: 96T/kit	
174.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1527-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Blood Culture System Class-A Shelf Life: 5 Years Models: EXB 120 EXB 120S EXP 120P	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter.
175.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1528-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Blood Culture Bottle (Colorimetric Method) - Resin Anaerobic Bottle (AN) Class-A Shelf Life: 12 Months Codes/sizes: 20 Bottles/box 100 bottles/box	Approved
176.	Zybio Medical Pakistan (SMC-Private) Ltd, House No. 323, Street No. 66, Sector I-8/3, Islamabad. ELI-01195 1529-Ibd 6,000/-	<u>Legal Manufacturer:</u> Zybio Inc No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, People's Republic of China. FSC: China. Validity: 03-11-2026. LOA validity 23-11-2029 ISO 13485 29-11-2026 EU Declaration of Conformity	ZYBIO Blood Culture Bottle (Colorimetric Method) - Resin Aerobic Bottle (AE&PE) Class-A Shelf Life: 12 Months Codes/sizes: 20 Bottles/box 100 bottles/box (Resin Aerobic Bottle) 20 Bottles/box 100 bottles/box (Pediatric Resin Bottle)	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter
177.	M/s MA TRADERS Khan G Arked Main Gulbahar Road Back Side Gulbahar Police Station, Peshawar. ELI-00601 Fee Rs: 6,000/ through slip no.	<u>Legal Manufacturer:</u> Shanghai Zhichen Medical Technology Co., Ltd., No. 686 Nanfeng highway, Fengxiang District, Shanghai China. LOA:	PRIMAX (Disposable ECG Electrodes) Class-A Shelf Life :5 years	Approved. The firm will submit fee as per revised SRO for Family before the issuance of registration letter

	387168796257	Validity: 30-June- 2029 FSC: Validity: 12-12-2025 ISO-13485: Validity: 09-04-2026	Models: CM26, CM01, CM02, CM03, CM04, CM05, CM10, CM12, CM14, CM15, CM16, CM17, CM25, CM27, CM29, CM30, CM32, CM34, CM35, CM36;	
178.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. ELI-00183 1508-Ibd 6,000/-	<u>Legal Manufacturer:</u> Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Humeca Mesher Skin Graft Mesher Class-A Shelf Life: 4 Years Code: 6.HM01	Deferred since the subject device is already registered for M/s Medic Ally (Pvt) Ltd 403-Nishtar Block Allama Iqbal Town , Lahore from the same manufacturer with MDIE No. 0000766
179.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. ELI-00183 1509-Ibd 6,000/-	<u>Legal Manufacturer:</u> Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Meek Micrograft Skin Graft Mesher Class-A Shelf Life: 10 Years Codes: 3.MD 3.HD	Deferred since the subject device is already registered for M/s Medic Ally (Pvt) Ltd 403-Nishtar Block Allama Iqbal Town , Lahore from the same manufacturer with MDIE No. 0000817
180.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. ELI-00183 1510-Ibd 6,000/-	<u>Legal Manufacturer:</u> Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Humeca V-carrier Skin graft carrier Class-A Shelf Life: 4 Years Codes as per FSC	Deferred since the subject device is already registered for M/s Medic Ally (Pvt) Ltd 403-Nishtar Block Allama Iqbal Town , Lahore from the same manufacturer with MDIE No. 0000816
181.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. ELI-00183 1511-Ibd 6,000/-	<u>Legal Manufacturer:</u> Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands. Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	MEEK Adhesive Adhesive for skin grafting Class-A Shelf Life: 4 Years Codes: 2.9190	Deferred for the provision of original documents.
182.	Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. ELI-00183	<u>Legal Manufacturer:</u> Humeca BV Oostermaat 5, 7623 CS Borne, The Netherlands. FSC: Netherlands.	Meek Micrograft gauze Sterile woven Gauze Pad Class-A	Deferred for the provision of original documents.

	1507-Ibd 6,000/-	Validity: 31-12-2028. LOA validity 31-12-2027 ISO 13485 validity 01-07-2026	Shelf life: 4 years Codes: 2.2/10, 2.3/10, 2.3/40, 2.4/10, 2.4/40, 2.6/10, 2.6/40, 2.9/10, 2.9/40	
183.	M/s Hashir Surgical Services. 05/06, 2nd Floor, Syed's Tower, University Road, Peshawar. ELI-00075 6215-kpk	<u>Legal Manufacturer:</u> M/s Pentamaster MediQ sdn. Bhd. 749, Persiaran Cassia Selatan 4, Taman Perindustrian Batu Kawan, Bandar Cassia, 14110 Simpang Ampat, Penang, Malaysia. LOA issuance 20-01-2025 valid for 5 years FSC validity 18-02-2027 ISO 13485 validity 21-11- 2025 EU QMS certificate (MDR) validity 07-08- 2028	Kawana™ NS Peripheral (IV Catheter with Wings and Injection Port) Class-B Shelf life: 5 years Sizes: G-14, G-16, G-18, G- 20, G-22	Approved
184.	M/s Hashir Surgical Services. 05/06, 2nd Floor, Syed's Tower, University Road, Peshawar. ELI-00075 6215-kpk	<u>Legal Manufacturer:</u> M/s Pentamaster MediQ sdn. Bhd. 749, Persiaran Cassia Selatan 4, Taman Perindustrian Batu Kawan, Bandar Cassia, 14110 Simpang Ampat, Penang, Malaysia. LOA issuance 20-01-2025 valid for 5 years FSC validity 18-02-2027 ISO 13485 validity 21-11- 2025 EU QMS certificate (MDR) validity 07-08- 2028	Kawana™ NS Peripheral IV Catheter with Wings, Injection Port and Stopper Class-B Shelf life: 5 years Sizes: G-14, G-16, G-18, G- 20, G-22, G-24	Approved
185.	M/s Hashir Surgical Services. 05/06, 2nd Floor, Syed's Tower, University Road, Peshawar. ELI-00075 6215-kpk	M/s Pentamaster MediQ sdn. Bhd. 749, Persiaran Cassia Selatan 4, Taman Perindustrian Batu Kawan, Bandar Cassia, 14110 Simpang Ampat, Penang, Malaysia	Kawana™ Safety Peripheral IV Catheter with Wings and Injection Port Class-B Shelf life: 5 years Sizes: G-14, G-16, G-18, G- 20, G-22, G-24	Approved

186.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 Fee Challan No. 47363288 6224-Kpk 6,000/-	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical Technology Co., Ltd No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 01/03/2030 FSC Validity:	Hematology Analysis Diluent Model: MEK Diluent Class: A Shelf Life: 2 Years Sizes: 1L, 5L, and 20L	Deferred for the provision of following: Original documents Brand name.
187.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 Fee Challan No. 09159423 6226-Kpk 6,000/-	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical Technology Co., Ltd Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 1/03/2030 FSC Validity: 18-09-2026 ISO 13485 validity 20-11- 2026	Hematology Analysis Lytic Agent Model: BCH Lyse Class: A Shelf Life: 2 Years Sizes: 500ml, 1L, 5L, and 20L	Deferred for the provision of following: Original documents Brand name.
188.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 Fee Challan No. 2345846369 6225-P 6,000/-	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical Technology Co., Ltd Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 1/03/2030 FSC Validity: 18-09-2026 ISO 13485 validity 20-11- 2026	Cleaning Solution Model: Rinse Cleaning Solution Class: A Shelf Life: 2 Years Sizes: 500ml, 1L, 1L x 4, 5L, 5L x 2, 5.5L and 20L	Deferred for the provision of following: Original documents Brand name.
189.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 Fee Challan No. 92530528 6,000/- 6222-Kpk	<u>Legal Manufacturer:</u> M/s Zhejiang Bangli Medical Products Co., Ltd Address: No.118, Yuegui South Road, City West New District, 321300 Yongkang City, Zhejiang Province, China LOA Validity: 16/03/2035 FSC Validity: 10-03-2027 ISO 13485 validity 25-11- 2026	Medical Tape Class: A Shelf Life: 5 Years Sizes: As per FSC	Deferred for the provision of following: Original documents Brand name.
190.	M/s Reliable Medical Supply Office No.204, 2 nd Floor,	<u>Legal Manufacturer:</u> M/s Hebei Free Trade	Single-use Container for Human Venous	Deferred for the provision of following:

	<p>Makkah Tower, Namak Mandi, Peshawar</p> <p>ELI-00618</p> <p>Fee Challan No. 38080996 6,000/- 6221-Kpk</p>	<p>Zone Shenghong Medical Devices Co., Ltd.</p> <p>Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone</p> <p>LOA Validity: 02/04/2030 FSC Validity: 03-09-2026 ISO 13485 validity 16-03-2026</p>	<p>Blood Collection Specimen Collection</p> <p>Class: A</p> <p>Shelf Life: 3 Years</p> <p>Sized: As per FSC</p>	<p>Original documents</p> <p>Brand name.</p> <p>Specify the type of tube in this application and submit form and fee for all other types.</p>
191.	<p>Easha Enterprises,</p> <p>2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi.</p> <p>ELI-00203</p> <p>Fee Rs. 100,000/- Submitted</p>	<p><u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt.</p> <p>FSC: Egypt. Date of Validity: 25-03-2026</p> <p>LOA validity: 1st of July 2026</p> <p>CE Design Examination Validity: 26 May 2026</p> <p>CE Certificate Validity: 26-05-2024 (Extension Letter Provided)</p>	<p>EGYSILK</p> <p>Silk silicon coated non-absorbable suture</p> <p>Shelf Life: 5 years</p> <p>Class D</p> <p>Codes/Sizes: List provided</p>	<p>Approved in class-C</p>
192.	<p>Easha Enterprises,</p> <p>2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi.</p> <p>ELI-00203</p> <p>Fee Rs. 100,000/- Submitted</p>	<p><u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt.</p> <p>FSC: Egypt. Date of Validity: 25-03-2026</p> <p>LOA validity: 1st of July 2026</p> <p>CE Design Examination Validity: 26 May 2026</p> <p>CE Certificate Validity:</p>	<p>EGYPROLENE</p> <p>Polypropylene monofilament non-absorbable Suture</p> <p>Shelf Life: 5 years</p> <p>Class D</p> <p>Codes/Sizes: List provided</p>	<p>Approved</p>

		26-05-2024 (Extension Letter Provided)		
193.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	Legal Manufacturer: TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026 LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)	EGYSORB Polyglycolic Acid absorbable surgical suture, PGA Shelf Life: 5 years Class D Codes/Sizes: List provided	Approved
194.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	Legal Manufacturer: TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026 LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)	EGYMONOCRYL Polyglycolide-co-caprolactone (PGACL) absorbable monofilament suture Shelf Life: 5 years Class D Codes/Sizes: List provided	Approved
195.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	Legal Manufacturer: TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026	EGYMESH Knitted Polypropylene Mesh Shelf Life: 5 years Class-C Codes/Sizes: List provided	Approved

		LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)		
196.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	<u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026 LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)	EGYCRYL Polyglactine 910 (PGLA) abrorbable suture Shelf Life: 5 years Class D Codes/Sizes: List provided	Approved
197.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	<u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026 LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)	EGYLON mono® Polyamide non-absorbable monofilament suture Shelf Life: 5 years Class D Codes/Sizes: List provided	Approved in class-C
198.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi.	<u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El	EGYTAPE Polyester (non-coated) surgical tape Shelf Life: 5 years	Approved

	<p>ELI-00203</p> <p>Fee Rs. 100,000/- Submitted</p>	<p>Obour City - Zip Code 11828 - Cairo - Egypt.</p> <p>FSC: Egypt. Date of Validity: 25-03-2026</p> <p>LOA validity: 1st of July 2026</p> <p>CE Design Examination Validity: 26 May 2026</p> <p>CE Certificate Validity: 26-05-2024 (Extension Letter Provided)</p>	<p>Class C</p> <p>Codes/Sizes: List provided</p>	
199.	<p>Easha Enterprises,</p> <p>2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi.</p> <p>ELI-00203</p> <p>Fee Rs. 100,000/- Submitted</p>	<p><u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt.</p> <p>FSC: Egypt. Date of Validity: 25-03-2026</p> <p>LOA validity: 1st of July 2026</p> <p>CE Design Examination Validity: 26 May 2026</p> <p>CE Certificate Validity: 26-05-2024 (Extension Letter Provided)</p>	<p>EGYCRYL FAST Braided Polyglactine 910 (Degraded Coating)</p> <p>Shelf Life: 5 years</p> <p>Class D</p> <p>Codes/Sizes: List provided</p>	Approved
200.	<p>Easha Enterprises,</p> <p>2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi.</p> <p>ELI-00203</p> <p>Fee Rs. 100,000/- Submitted</p>	<p><u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt.</p> <p>FSC: Egypt. Date of Validity: 25-03-2026</p> <p>LOA validity: 1st of July 2026</p> <p>CE Design Examination Validity: 26 May 2026</p> <p>CE Certificate Validity: 26-05-2024 (Extension Letter Provided)</p>	<p>EGYBOND Polyester (silicon coated) non-absorbable, braided synthetic suture</p> <p>Shelf Life: 5 years</p> <p>Class D</p> <p>Codes/Sizes: List provided</p>	Approved in class-C

201.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	<u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026 LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)	EGY-PDS Polydioxanone absorbable monofilament suture Shelf Life: 5 years Class D Codes/Sizes: List provided	Approved
202.	Easha Enterprises, 2B-04, Third Floor Adyala Towers, Adyala Road, Rawalpindi. ELI-00203 Fee Rs. 100,000/- Submitted	<u>Legal Manufacturer:</u> TAISIER MED 1st Industrial Zone-Block 13023-St. 100-Building No. 8-P.O Box 29- El Obour City - Zip Code 11828 - Cairo - Egypt. FSC: Egypt. Date of Validity: 25-03-2026 LOA validity: 1 st of July 2026 CE Design Examination Validity: 26 May 2026 CE Certificate Validity: 26-05-2024 (Extension Letter Provided)	EGYBIOLIFT Polydioxanone lifting thread absorbable monofilament suture Shelf Life: 5 years Class D Codes/Sizes: List provided	Approved
203.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) Date of R&I: 12-Mar-23	<u>Legal Manufacturer:</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland <u>FSC:</u> Ireland Date of Issue: 08-Dec-22 <u>LOA</u> Date of Issue: 23-Dec-22	Lactic Acid2 Codes/Sizes: 04T3020 Class B Shelf Life: 15 Months <u>EC Certificate</u> Explanation Letter Provided ISO 13485 Validity: 31-08-23	Approved

204.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p> <p>Date of R&I: 12-Mar-23</p>	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland</p> <p><u>FSC:</u> Ireland Date of Issue: 08-Dec-22</p> <p><u>LOA</u> Date of Issue: 23-Dec-22</p>	<p>Lactic Acid2 Codes/Sizes: 04U2620</p> <p>Class B</p> <p>Shelf Life: 15 Months</p> <p><u>EC Certificate</u> Explanation Letter Provided</p> <p>ISO 13485 Validity: 31-08-23</p>	Approved
205.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p> <p>Date of R&I: 12-Mar-23</p>	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford, Ireland</p> <p><u>FSC:</u> Ireland Date of Issue: 04-Oct-22</p> <p><u>LOA</u> Date of Issue: 19-Dec-22</p>	<p>Rheumatoid Factor</p> <p>Class B Shelf Life: 15 Months</p> <p>Codes/Sizes: 08G66-21</p> <p><u>EC Certificate</u> Explanation Letter Provided</p> <p>ISO 13485 Validity: 31-08-23</p>	Approved
206.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p> <p>Date of R&I: 22-May-23</p>	<p><u>Legal Manufacturer:</u> Abbott Ireland Diagnostic Division, Finisklin Business Park Sligo Ireland</p> <p><u>FSC:</u> Ireland Validity: May 25</p> <p><u>LOA</u> Date of Issue: 27-Feb-23</p> <p><u>EC Certificate</u> Explanation Letter Provided</p> <p>ISO 13485 Validity: 24-03-26</p>	<p>ARCHITECT Anti-Tg Calibrators</p> <p>ARCHITECT Anti-Tg Controls</p> <p>ARCHITECT Anti-Tg Reagent Kit</p> <p>ARCHITECT Anti-TPO Calibrators</p> <p>ARCHITECT Anti-TPO Controls</p> <p>ARCHITECT Anti-TPO Reagent Kit</p> <p>Class B</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes:</p> <p>ARCHITECT Anti-Tg Calibrators 2K46-01 ARCHITECT Anti-Tg Controls 2K46-10</p>	Approved

			ARCHITECT Anti-Tg Reagent Kit 2K46-20, 2K46-25 ARCHITECT Anti-TPO Calibrators 2K47-01 ARCHITECT Anti-TPO Controls 2K47-10 ARCHITECT Anti-TPO Reagent Kit 2K47-20, 2K47-25, 2K47-27	
207.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) Date of R&I: 24-July-23	<u>Legal Manufacturer:</u> Abbott Ireland Diagnostic Division, Finisklin Business Park Sligo Ireland <u>FSC:</u> Ireland Validity: May 25 <u>LOA</u> Date of Issue: 21-March-23 <u>EC Certificate</u> Explanation Letter Provided ISO 13485 Validity: 24-03-26	ARCHITECT Cortisol Reagent Kit ARCHITECT Cortisol Calibrators Class B Shelf Life: 18 Months Codes/Sizes: ARCHITECT Cortisol Reagent Kit 8D15-25, 8D15-25 ARCHITECT Cortisol Calibrators 8D15-02	Approved
208.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) Date of R&I: 23-Jan-2020	<u>Legal Manufacturer:</u> Diatron MI Plc. H-1097, Budapest, Táblás u 39. Hungary <u>FSC:</u> Hungary Issuance: 22-Nov-19 <u>LOA</u> Issuance:10-Dec-19 <u>EC Certificate</u> Explanation Letter Provided ISO 13485 Validity: 27-05-21	H 380 Hemo Control Low H 380 Hemo Control Medium H 380 Hemo Control High H 380 Hemo Control Kit H Hemo Calibrator Class B Shelf Life: H 380 Hemo Controls: 105 days H Hemo Calibrator:45 Days Codes/Sizes: H 380 Hemo Control Low	Approved

			HAL35001 H 380 Hemo Control Medium HAL35002 H 380 Hemo Control High HAL35003 380 Hemo Control Kit HAL35004- KIT H Hemo Calibrator HAL30001	
209.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) Date of R&I 09-Oct-2024	<u>Legal Manufacturer:</u> Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland <u>Manufacturing Site</u> Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland <u>FSC:</u> Ireland Date of Issuance 16-Apr- 2024. Validity: N/A <u>LOA</u> Validity: N/A (Abbott is operating directly)	GFAP Class: C Shelf Life: 12 Months Codes/Sizes: GFAP Reagent Kit 4W16-25 GFAP Calibrators 4W16-01 GFAP Controls 4W16-10 <u>EC Certificate</u> EU QMSC IVDR Date of Validity 26-09 2026 <u>ISO 13485</u> Validity: 24-03-26	Approved
210.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) Date of R&I 09-Oct-2024	<u>Legal Manufacturer:</u> Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland <u>Manufacturing Site</u> Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland <u>FSC:</u> Ireland Date of Issuance 16-Apr- 2024. Validity: N/A <u>LOA</u> Validity: N/A (Abbott is operating directly)	UCH-L1 Class: C Shelf Life: UCH-L1 Reagent Kit 18 Months UCH-L1 Calibrators 08 Months UCH-L1 Controls 8 Months Codes/Sizes: UCH-L1 Reagent Kit 4W18-25 UCH-L1 Calibrators 4W18-01 UCH-L1 Controls 4W18-10	Approved

		<p><u>EC Certificate</u> EU QMSC IVDR Date of Validity 26-09 2026</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>		
211.	<p>M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi</p> <p>(ELI-00019)</p>	<p><u>Legal Manufacturer:</u></p> <p>Abbott Ireland Diagnostic Division Finisklin Business Park Sligo, Ireland</p> <p><u>Manufacturing Site</u> Denka Co., Ltd Kagamida Factory 1359-1, Kagamida, Kigoshi Gosen-shi Niigata, 959-1695, Japan</p> <p><u>Date of R&I</u> 11-Dec-2024</p> <p><u>FSC:</u> Sligo Ireland Date of Issuance: 07-Oct-24 Validity: N/A</p> <p><u>LOA</u> Issuance: 14-Aug-24 Validity: N/A (Abbott is operating directly)</p> <p><u>EC Certificate</u> EU QMSC IVDR Ireland, Date of Validity 26-09 2026</p> <p><u>ISO 13485</u> Validity: 24-03-26</p>	<p>ARCHITECT iPhenytoin</p> <p>Class: C</p> <p>Shelf Life: 18 Months</p> <p>Codes/Sizes: ARCHITECT iPhenytoin Reagent Kit 1P34-25</p> <p>ARCHITECT iPhenytoin Calibrators 1P34-01</p>	Approved
212.	<p>Applicant: M/s QASIM TRADERS SHOP NO.7 MEDICINE CENTRE, KUTCHI GALI NO.1, MARRIOT ROAD, KARACHI.</p> <p>(ELI- 00832)</p> <p>R& I Date: (18/03/2025)</p> <p>Fee details: Amount paid: PKR 31,000/- Paid Slip / challan No.:</p>	<p>(Legal Manufacturer) Name: M/S. JIANGSU KANGYOU MEDICAL INSTRUMENT CO., LTD. Tangzhuang, Yaotang Town, Jintan District, Changzou City, Jiangsu Province, China.</p> <p>Free Sale Certificate Validity: (05/07/2026)</p> <p>ISO 13485 certificate validity: (30/06/2025)</p>	<p>Brand Name: PACCO PLUS Generic: STERILE HYPODERMIC NEEDLES FOR SINGLE USE Models / Sizes: 31G, 30G, 29G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G, 16G, 15G. MD Group: SINGLE</p> <p>Class-B Declaration of</p>	Approved

	005031954 Dated: (10/03/2025)	EC certificate Validity: (31/12/2028) Letter of authorization: Validity: (25/12/2030)	conformity: Issuance date: (26/08/2024) Shelf life: 5 YEARS Storage Conditions: Store in a cool and dry place. Store at room temperature.	
213.	Ms Biocare Pharma Address: B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi ELI:00634 Deposit Slip No: 232836281188 Fee: 5030/- Dated: 13-3-2025	Name of Product Manufacturer & Legalization Holder: Cathay Manufacturing Crop: ADDRESS: No.328, Xishe Rd Maogang Town, Songjiang District, Shanghai, 201607 China	Brand Name; Disposable ECG electrodes Generic Name; IV- Disposable ECG electrodes Class A Shelf Life: 2-Years LOA Validity: 16 th Dec-2027 FSC validity: Jan 31 st 2026	Approved. The firm will submit codes/ sized as per FSC before the issuance of registration letter.
214.	M/s Health Solutions. 28-B, Second floor, Zeenat Medicine Market, North Napier Road, Karachi. (ELI-01153) D.O.I: 07-09-2023 Dy. No.: 16222 DRAP (R&I) Dated: 25-09-2024 Fee Challan No.: 657320693649 PKR: 50000/- Dated: 14-03-2024	Legal Manufacturer: Name: M/s Shanghai Transfusion Technology Co. Ltd. Manufacturer Address: No. 500, Youdong Road, Minhang, 201100 Shanghai, China. ISO 13485 Certificate validity: 26- 10-2024 EC Certificate validity: 26-05-2024 LOA Validity: 20-12-2028 FSC Validity: China (country of origin): 01-02-2025 FSC (MHRA-UK) Dated 22-01-2022	Vcare Disposable Plastic Blood Collecting Bag CPDA-1 (Single) Size: 250ml, 500 ml Class: D Shelf life: 02 years .	Approved
215.	M/s- Health Solutions 28B, Second Floor, Zeenat Medicine Market, North Napier Road, Karachi. ELI-01153 R&I details 10/05/2024 Fee Details: Amount Paid: PKR Rs. 50,030	M/s Shanghai Transfusion Technology Co., Ltd Address: No.500, Youdong Road, Minhang, 201100, Shanghai, P.R. China.	Vcare Disposable Blood Bag CPDA-1 (Double) D250, D500 Class: D Shelf Life: 2 Years Shelf Life	Approved

	Challan NO: 657320693649 Dated: 14/03/2024		Code/sizes: 250ML, 500ML	
216.	M/s- Health Solutions 28B, Second Floor, Zeenat Medicine Market, North Napier Road, Karachi. ELI-01153 R&I detail 10/05/2024 Fee Details: Amount Paid: PKR 50,030 Challan NO: 10188338200 Dated: 14/03/2024	Legal Manufacturer: Name: M/s Shangai Transfusion Technology Co. Ltd. Manufacturer Address: No. 500, Youdong Road, Minhang, 201100 Shanghai, China. ISO 13485 Certificate validity: 26- 10-2024 EC Certificate validity: 26-05-2024	Vcare Disposable Blood Bag CPDA-1 (Triple) T250, T500 Class: D Shelf Life: 2 Years Shelf Life Code/sizes: 250ml, 500ml FSC (China): Validity: 01-02-2025 LOA Validity: 20-12-2028	Approved
217.	M/s Noor International. Noor House, 29-D, Block-6, PECHS, Karachi. ELI-000061 R&I detail 28-02-2025 Fee Details: Amount Paid: PKR 62000 Challan: 825308289 Dated: 26-02-2025	M/s Top Corporation 19-10 Senju Nakai-cho, Adachi-ku, Tokyo, Japan. Manufacturing site: Top Corporation Koshigaya Factory. 40-34 Noborito-cho, Koshigaya-shi, Sitama, Japan. ISO 13485 Certificate validity: 24- 02-2025	TOP-2500 Infusion Pump Class: C Shelf Life: 05 Years Codes: PPL0611X3, PPL1510X3, PPL1515, PPL2020, PPL3030, TCM1106, TCM1106X3, TCM1510, TCM1510X3, TCM1515, TCM1515X3, TCM2020, TCM2020X3, TCM3015, TCM3030, TCM4530 EU QMS Certificate: 03-11-2026	Approved
218.	M/s. United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi ELI:00293 Date of R&I 25-01-2023 Fee Challan: 2750747547	Legal Manufacturer: M/s Sunkiss Healthcare (Zhejiang) Co Ltd No. 6 Panlongshan Road, Changkou New Zone, Fuyang Hangzhou City, Zhejiang Province 311413, PR China FSC: China Validity: 20/11/2024	Brand Name: Senior Underpads (Dignity Sheets) Generic Name: Dignity Sheets Class A Shelf Life: 05 years Codes / Sizes (if any) M, L ISO 13485 Validity:08/03/2027	Approved

219.	M/s United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi ELI:00293 Date of R&I 13-08-2024 Fee Challan: 979483492051	Legal Manufacturer: M/s Top Glove SDN BHD Address: Lot 4969, Jalan Teratai Batu 6 Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan, Malaysia FSC: Malaysia Validity: 02-07-2029	Brand Name: Safety Latex Examination Powdered Gloves Generic Name: Latex Examination Powdered Gloves Class A Shelf Life: 05 Years Codes / Sizes (if any) XS, S, M, L, XL	Approved
220.	M/s United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi ELI:00293 Date of R&I 13-08-2024 Fee Challan: 58425248170	Legal Manufacturer: M/s Top Glove SDN BHD Address: Lot 4969, Jalan Teratai Batu 6 Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan, Malaysia FSC: Malaysia Validity: 02-07-2029 ISO 13485 Validity: 30-04-2026	Brand Name: Safety Latex Examination Powder Free Gloves Generic Name: Latex Examination Powder Free Gloves Class A Shelf Life: 05 Years Codes / Sizes (if any) XS, S, M, L, XL	Approved
221.	M/s United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi ELI:00293 Date of R&I 13-08-2024 Fee Challan: 387059938865	Legal Manufacturer: M/s Top Glove SDN BHD Address: Lot 4969, Jalan Teratai Batu 6 Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan, Malaysia FSC: Malaysia Validity: 02-07-2029 LOA Validity: 18-07-2028	Brand Name: Safety Nitrile Examination Powdered Gloves Generic Name: Nitrile Examination Powdered Gloves Class A Shelf Life: 05 Years Codes / Sizes (if any) XS, S, M, L, XL	Approved
222.	M/s United Healthcare Address: Plot No. 330/A 2nd Floor, Block 3, DMCHS, Alamgir Road, Karachi ELI:00293 Date of R&I 13-08-2024 Fee Challan: 78807487	Legal Manufacturer: M/s Top Glove SDN BHD Address: Lot 4969, Jalan Teratai Batu 6 Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan, Malaysia FSC: Malaysia Validity: 02-07-2029 LOA Validity: 18-07-2028	Brand Name: Safety Nitrile Examination Powder Free Gloves Generic Name: Nitrile Examination Powder Free Gloves Class A Shelf Life: 05 Years Codes / Sizes (if any) XS, S, M, L, XL	Approved

<p>223.</p>	<p>Applicant: M/s DATA DIAGNOSTIC INTERNATIONAL, Office address: - Memmona center, office No 26-30 LG Freed court Road, Lahore.</p> <p>(ELI- 00844)</p> <p>R& I Date: (28/03/2025)</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.:62347266548 Dated: (20/03/2025)</p>	<p>(Legal Manufacturer) Name: M/S. TERSACO AG Calenderiaweg 2 6405 Immensee, Switzerland Phone +417293639 Fax +417293635 www.tersco.ch</p> <p>Free Sale Certificate Validity: (20/06/2025)</p> <p>ISO 13485 certificate validity: (31/10/2025)</p> <p>EC certificate Validity: (26/05/2027)</p> <p>Letter of authorization: Validity: (31/12/2025)</p>	<p>Brand Name: <u>T-7710 ALT(GPT)</u> <u>(ALANINE AMINO TRANSFERASE)</u> Generic: <u>(ALANINE AMINO TRANSFERASE)</u> Models / Sizes: T-7710 (ALT) (11.01.01) GENERAL IVD <i>(write model and sizes here as mentioned on Free sale certificate)</i></p> <p>T-7709 ALT 1 x 60 ml, 1 x 15 ml T-7710 ALT 1 x 240 ml, 1 x 60 ml MD Group: <i>(single/kit)</i></p> <p>Class-B Declaration of conformity: Issuance date: (26/05/2027)</p> <p>Shelf life: 18 months at 2-8°C Working reagents at 8°C 21 days 3 days at room temperature 30 days at 37°C</p>	<p>Deferred for the provision of following:</p> <p>All legal documents are copies.</p> <p>Brand name is not mentioned.</p> <p>Fee is not as per the revised SRO for Cluster.</p> <p>Intended use is missing.</p>
<p>224.</p>	<p>Applicant: M/s DATA DIAGNOSTIC INTERNATIONAL, Office address: - Memmona center, office No 26-30 LG Freed court Road, Lahore.</p> <p>(ELI- 00844)</p> <p>R& I Date: (28/03/2025)</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.: <u>41277881</u> Dated: (20/03/2025)</p>	<p>(Legal Manufacturer) Name: M/S. TERSACO AG Calenderiaweg 2 6405 Immensee, Switzerland Phone +417293639 Fax +417293635 www.tersco.ch</p> <p>Free Sale Certificate Validity: (20/06/2025)</p> <p>ISO 13485 certificate validity: (31/10/2025)</p> <p>EC certificate Validity: (26/05/2027)</p> <p>Letter of authorization: Validity: (31/12/2025)</p>	<p>Brand Name: <u>AMYLASE</u> <u>(CHEMICAL REAGENTS) T-7712-7713(AMYLASE)</u> Generic: <u>(AMYLASE)</u> Models / Sizes: T-7712, T-7713 (AMYLASE) (11.01.01) GENERAL IVD <i>(write model and sizes here as mentioned on Free sale certificate)</i></p> <p>T-7712 AMYLASE CNP3-KINETIC 20 x 2 ml, T-7713 AMYLASE CNP3-KINETIC 2 x 60 ml MD Group: <i>(single/kit)</i></p> <p>Class-B Declaration of</p>	<p>Deferred for the provision of following:</p> <p>All legal documents are copies.</p> <p>Brand name is not mentioned.</p> <p>Fee is not as per the revised SRO for Cluster.</p> <p>Intended use is missing.</p>

			<p>conformity: Issuance date: (26/05/2027)</p> <p>Shelf life: Shelf life: 18 months at - 2-8°C during 26 days</p> <p>- 40°C during 1 day - 2-8°C during 1 day - 40°C during 1 day - 2-8°C during 1 day - 40°C during 5 days - 2-8°C during 2-3 hours</p>	
225.	<p>Applicant: M/s DATA DIAGNOSTIC INTERNATIONAL, Office address: - Memmona center, office No 26-30 LG Freed court Road, Lahore. (ELI- 00844)</p> <p>R& I Date: (28/03/2025)</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.:62347266548 Dated: (20/03/2025)</p>	<p>(Legal Manufacturer) Name: M/S. TERSACO AG Calenderiaweg 2 6405 Immensee, Switzerland</p> <p>Free Sale Certificate Validity: (20/06/2025)</p> <p>ISO 13485 certificate validity: (31/10/2025)</p> <p>EC certificate Validity: (26/05/2027)</p> <p>Letter of authorization: Validity: (31/12/2025)</p>	<p>Brand Name: <u>CHOLESTEROL</u> <u>(CHEMICAL REAGENTS)</u> Generic: <u>(CHOLESTEROL)</u> Models / Sizes: T-7723 (CHOLESTEROL) (11.02.01) GENERAL IVD T-7724 (CHOLESTEROL) (11.02.01) GENERAL IVD T-7725 (CHOLESTEROL) (11.02.01) GENERAL IVD T-7726 (CHOLESTEROL) (11.02.01) GENERAL IVD <i>(write model and sizes here as mentioned on Free sale certificate)</i></p> <p>T-7723 CHOLESTEROL CHOD-POD 2 x 50 ml, T-7724 CHOLESTEROL CHOD-POD 2 x 100 ml, T-7725 CHOLESTEROL CHOD-POD 2 x 150 ml, T-7726 CHOLESTEROL CHOD-POD 2 x 1000 ml,</p>	<p>Deferred for the provision of following:</p> <p>All legal documents are copies.</p> <p>Brand name is not mentioned.</p> <p>Fee is not as per the revised SRO for Cluster.</p> <p>Intended use is missing.</p>

			<p>MD Group: <i>(single/kit)</i></p> <p>Class-B Declaration of conformity: Issuance date: (26/05/2027)</p> <p>Shelf life: Shelf life: 18 months at - 2-8°C during 26 days - 40°C during 1 day - 2-8°C during 1 day - 40°C during 1 day - 2-8°C during 1 day - 40°C during 5 days - 2-8°C during 2-3 hours</p>	
226.	<p>Applicant: M/s DATA DIAGNOSTIC INTERNATIONAL, Office address: - Memmona center, office No 26-30 LG Freed court Road, Lahore.</p> <p>(ELI- 00844)</p> <p>R& I Date: (28/03/2025)</p> <p>Fee details: Amount paid: PKR 31000/- Paid Slip / challan No.:62347266548 Dated: (20/03/2025)</p>	<p>(Legal Manufacturer) Name: M/S. TERSACO AG Calenderiaweg 2 6405 Immensee, Switzerland Phone +417293639 Fax +417293635 www.tersco.ch</p> <p>Free Sale Certificate Validity: (20/06/2025)</p> <p>ISO 13485 certificate validity: (31/10/2025)</p> <p>EC certificate Validity: (26/05/2027)</p> <p>Letter of authorization: Validity: (31/12/2025)</p>	<p>Brand Name: <u>CRP (C-REACTIVE PROTEIN)</u> <u>(CHEMICAL REAGENTS)</u></p> <p>Generic: <u>(C-REACTIVE PROTEIN)</u> <u>(CHEMICAL REAGENTS)</u></p> <p>Models / Sizes: T-7710 (ALT) (11.01.01) GENERAL IVD T-7788 CRP (C-REACTIVE PROTEIN) TURBILATEX 1x40ml,1x10ml,1x2ml (CAL) T-7789 CRP (C-REACTIVE PROTEIN) T-7789 R1: Diluent 1 x 200 mL R2: Latex 1 x 50 mL CAL:1 x 1 mL MD Group: <i>(single/kit)</i></p> <p>Class-B Declaration of conformity: (26/05/2027)</p> <p>Shelf life: Shelf life: 2-8°C during at least 26 days 40°C during 1 day 2-8°C during at least</p>	<p>Deferred for the provision of following:</p> <p>All legal documents are copies.</p> <p>Brand name is not mentioned.</p> <p>The subject product falls in Class-C</p> <p>Intended use is missing.</p>

			1 day 40°C during 1 day 2-8°C during at least 1 day 40°C during 5 days 2-8°C during 2-3 hours	
227.	Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi (ELI-1152) R&I date 21.02.2025 Fee 6000/-	Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China Apostille FSC of China Valid till: 24-11-2026 LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028	Golden Vac TM Plain Tube Class A Shelf life 15 months	Approved
228.	Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi (ELI-1152) R&I date 21.02.2025 Fee 6000/-	Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China Apostille FSC of China Valid till: 24-11-2026 LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028	Golden Vac TM K2EDTA Tube Class A Shelf life 15 months	Approved
229.	Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi (ELI-1152) R&I date 21.02.2025 Fee 6000/-	Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China Apostille FSC of China Valid till: 24-11-2026 LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028	Golden Vac TM Sodium Heparin Tube Class A Shelf life 15 months	Approved

230.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p> <p>Fee 6000/-</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p> <p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>	<p>Golden VacTM K2EDTA Tube (Separator Gel)</p> <p>Class A Shelf life 15 months</p>	Approved
231.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p> <p>Fee 6000/-</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p> <p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>	<p>Golden VacTM Glucose Tube</p> <p>Class A Shelf life 15 months</p>	Approved
232.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p> <p>Fee 6000/-</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p> <p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>	<p>Golden VacTM K2EDTA Tube</p> <p>Class A Shelf life 15 months</p>	Approved
233.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar,Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p>	<p>Golden VacTM Clot Activator Tube</p> <p>Class A Shelf life 15 months</p>	Approved

	<p>Fee 6000/-</p>	<p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>		
234.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar, Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p> <p>Fee 6000/-</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p> <p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>	<p>Golden VacTM K3EDTA Tube (Separator Gel)</p> <p>Class A Shelf life 15 months</p>	Approved
235.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar, Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p> <p>Fee 6000/-</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p> <p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>	<p>Golden VacTM ESR Tube</p> <p>Class A Shelf life 15 months</p>	Deferred for the clarification since the product is not mention in FSC.
236.	<p>Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar, Karachi</p> <p>(ELI-1152) R&I date 21.02.2025</p> <p>Fee 6000/-</p>	<p>Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China</p> <p>Apostille FSC of China Valid till: 24-11-2026</p> <p>LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028</p>	<p>Golden VacTM Coagulation Tube</p> <p>Class A Shelf life 15 months</p>	Deferred for the clarification since the product is not mention in FSC.

237.	Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar, Karachi (ELI-1152) R&I date 21.02.2025 Fee 6000/-	Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China Apostille FSC of China Valid till: 24-11-2026 LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028	Golden VacTM Serum Separation Tube Class A Shelf life 15 months	Deferred for the clarification since the product is not mention in FSC.
238.	Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar, Karachi (ELI-1152) R&I date 21.02.2025 Fee 6000/-	Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China Apostille FSC of China Valid till: 24-11-2026 LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028	Golden VacTM Heparin Tube (Separator Gel) Class A Shelf life 15 months	Deferred for the clarification since the product is not mention in FSC.
239.	Mckesson Medical Solutions, FF-35, Jable Rehmat, Block 16-A, Gulistan-e- Jauhar, Karachi (ELI-1152) R&I date 21.02.2025 Fee 6000/-	Zhejiang Gongdong Medical Technology Co., Ltd., NO. 10 Beiyuan Ave. Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China Apostille FSC of China Valid till: 24-11-2026 LOA valid till 20.10.2029 ISO 13485 valid till 28.02.25 CE certificate valid till 10.04.2028	Golden VacTM Lithium Heparin Tube Class A Shelf life 15 months	Approved
240.	Applicant Name: M/s. Audi-Med Pakistan. Address: 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz	Name of Manufacturer: Interacoustics A/S Audiometer Allé 1, Middelfart, Denmark Manufacturing Site: DGS Diagnostics Sp. zo.o.	Brand Name: Interacoustics AD226 Diagnostic Audiometer Class: B	Approved

	Hospital, Lahore. (ELI-000596) R&I: 24-03-2025 Fee Details: Paid fee: 31000 Chalan No. 344714626 Dated: 18-03-2025	Rosówek 43, 72-001 Kołbaskowo, Poland LOA: Validity: 31-12-2025 FSC of Reference Country: Validity: 09-09-2026 ISO 13485: Validity: 28-11-2025	HS Code: 901890	
241.	Applicant Name: M/s. Audi-Med Pakistan. Address: 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore. (ELI-000596) R&I: 24-03-2025 Fee Details: Paid fee: 31000 Chalan No. 0277765705 Dated: 18-03-2025	Name of Manufacturer: Interacoustics A/S Audiometer Allé 1, Middelfart, Denmark Manufacturing Site: DGS Diagnostics Sp. zo.o. Rosówek 43, 72-001 Kołbaskowo, Poland LOA: Validity: 31-12-2025 FSC of Reference Country: Validity: 09-09-2026 ISO 13485: Validity: 28-11-2025	Brand Name: Interacoustics Affinity Compact Universal Audio Analyzer Platform Class: B HS Code: 901890	Approved
242.	Applicant Name: M/s. Audi-Med Pakistan. Address: 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore. (ELI-000596) R&I: 24-03-2025 Fee Details: Paid fee: 31000 Chalan No. 0482075165 Dated: 18-03-2025.	Name of Manufacturer: Interacoustics A/S Audiometer Allé 1, Middelfart, Denmark Manufacturing Site: DGS Diagnostics Sp. zo.o. Rosówek 43, 72-001 Kołbaskowo, Poland LOA: Validity: 31-12-2025 FSC of Reference Country: Validity: 09-09-2026 ISO 13485: Validity: 28-11-2025	Brand Name: Interacoustics Eclipse Medical PC Platform Class: B HS Code: 901890	Approved

243.	Applicant Name: M/s. Audi-Med Pakistan. Address: 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore. (ELI-000596) R&I: 24-03-2025 Fee Details: Paid fee: 31000 Chalan No. 163543947039 Dated: 18-03-2025	Name of Manufacturer: Interacoustics A/S Audiometer Allé 1, Middelfart, Denmark Manufacturing Site: DGS Diagnostics Sp. zo.o. Rosówek 43, 72-001 Kołbaskowo, Poland LOA: Validity: 31-12-2025 FSC of Reference Country: Validity: 09-09-2026 ISO 13485: Validity: 28-11-2025	Brand Name: Interacoustics PA5 Screening Audiometer Class: B HS Code: 901890	Approved
244.	Applicant Name: M/s. Audi-Med Pakistan. Address: 63/3A, Block D-1, Gulberg-III, Sir Syed Road, Opposite Hijaz Hospital, Lahore. (ELI-000596) R&I: 24-03-2025 Fee Details: Paid fee: 31000 Chalan No. 4443733547 Dated: 18-03-2025	Name of Manufacturer: Interacoustics A/S Audiometer Allé 1, Middelfart, Denmark Manufacturing Site: DGS Diagnostics Sp. zo.o. Rosówek 43, 72-001 Kołbaskowo, Poland LOA: Validity: 31-12-2025 FSC of Reference Country: Validity: 09-09-2026 ISO 13485: Validity: 28-11-2025	Brand Name: Interacoustics Titan Auditory Analysis Platform Class: B HS Code: 901890	Approved
245.	Applicant Name: M/s Biologic Medical Systems Karachi. Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi (ELI-00346) DRAP (R&I) Dated:18-02-2025	Name of Manufacturer: M/s Laborie Medical Technologies,corp. Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA LOA Validity: 31-12-2026 FSC Validity (country of origin):	Brand Name: FLOWMASTER UROFLOWMETER U1-1 Class: B MD group: Kit	Approved. The firm will submit the shelf life and shelf life studies.

	<p>Fee Chillan No.: 626906341299 PKR: 31030/- Dated:17-02-2025</p>	<p>19-03-2026</p> <p>MDR/EC Certificate validity: 18-06-2026</p> <p>ISO 13485 18-06-2026</p> <p>Shelf life: Seven Years Storage condition: 10 – 40°C</p>		
246.	<p>Applicant Name:</p> <p>M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025</p> <p>Fee Chillan No.: 10817931860 PKR: 31030/- Dated:17-02-2025</p>	<p>Name of Manufacturer:</p> <p>M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p> <p>MDR/EC Certificate validity: 18-06-2026</p> <p>ISO 13485 18-06-2026</p> <p>Shelf life: Seven Years Storage condition: 10 – 40°C</p>	<p>Brand Name:</p> <p>OHMEGA MEASURING INSTRUMENT IMPEDANCE G2-1.</p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>
247.	<p>Applicant Name:</p> <p>M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025</p>	<p>Name of Manufacturer:</p> <p>M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p>	<p>Brand Name:</p> <p>NEXAM URODYNAMIC MEASUREMENT SYSTEM U-8-3.</p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>

	<p>Fee Chillan No.: 7082537122 PKR: 31030/- Dated:17-02-2025</p>	<p>MDR/EC Certificate validity: 18-06-2026</p> <p>ISO 13485 18-06-2026</p> <p>Shelf life: Seven Years Storage condition: 10 – 40°C</p>		
248.	<p>Applicant Name:</p> <p>M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025</p> <p>Fee Chillan No.: 6158981605 PKR: 31030/- Dated:17-02-2025</p>	<p>Name of Manufacturer:</p> <p>M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p> <p>MDR/EC Certificate validity: 18-06-2026</p> <p>ISO 13485 18-06-2026</p> <p>Shelf life: Seven Years Storage condition: 10 – 40°C</p>	<p>Brand Name:</p> <p><u>Solar Blue.</u> <u>Urodyunamic</u> <u>Measurement System</u> <u>U3-1</u></p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>
249.	<p>Applicant Name:</p> <p>M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025</p> <p>Fee Chillan No.:</p>	<p>Name of Manufacturer:</p> <p>M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p>	<p>Brand Name:</p> <p><u>SOLAR GI</u> <u>GASTROINTESTINAL</u> <u>MOTILITY</u> <u>SYSTEMS</u> <u>G3-10</u></p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>

	042883927670 PKR: 31030/- Dated:17-02-2025	MDR/EC Certificate validity: 18-06-2026 ISO 13485 18-06-2026 Shelf life: Seven Years Storage condition: 10 – 40°C		
250.	<p>Applicant Name:</p> <p>M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025</p> <p>Fee Chillan No.: 221655557 PKR: 31030/- Dated:17-02-2025</p>	<p>Name of Manufacturer:</p> <p>M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p> <p>MDR/EC Certificate validity: 18-06-2026</p> <p>ISO 13485 18-06-2026</p> <p>Shelf life: Seven Years Storage condition: 10 – 40°C</p>	<p>Brand Name:</p> <p><u>SOLAR GI</u> <u>GASTROINTESTINAL</u> <u>MOTILITY</u> <u>SYSTEMS</u> <u>G3-12</u></p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>
251.	<p>Applicant Name:</p> <p>M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025</p> <p>Fee Chillan No.: 258900902 PKR: 31030/-</p>	<p>Name of Manufacturer:</p> <p>M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p> <p>MDR/EC Certificate validity:</p>	<p>Brand Name:</p> <p>UniTop High Resolution Catheter K83659-E-10107-D</p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>

	Dated:17-02-2025	18-06-2026 ISO 13485 18-06-2026 Shelf life: Three Years Storage condition: 10 – 40°C		
252.	<p>Applicant Name: M/s Biologic Medical Systems Karachi.</p> <p>Address: 166-E Annexe 'B' Block-3 PECHS Off Khalid Bin Waleed Road, Karachi</p> <p>(ELI-00346)</p> <p>DRAP (R&I) Dated:18-02-2025 Fee Chillan No.: 261576424252 PKR: 31030/- Dated:21-02-2025</p>	<p>Name of Manufacturer: M/s Laborie Medical Technologies,corp.</p> <p>Manufacturer Address: 180,International Drive Portsmouth New Hampshire 03801 USA</p> <p>LOA Validity: 31-12-2026</p> <p>FSC Validity (country of origin): 19-03-2026</p> <p>MDR/EC Certificate validity: 18-06-2026</p> <p>ISO 13485 18-06-2026</p> <p>Shelf life: Three Years Storage condition: 10 – 40°C</p>	<p>Brand Name: UniTop High Resolution Catheter (K121259-L5-1444-D).</p> <p>Class: B MD group: Kit</p>	<p>Approved.</p> <p>The firm will submit the shelf life and shelf life studies.</p>
253.	<p>M/s Reliable Medical Supply</p> <p>Address: Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar</p> <p>ELI-00618</p> <p>R&I: 17/04/2025</p> <p>Fee Chalan No. 47363288</p> <p>Fee Chalan Date: 11/04/2025</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Zhejiang Xinke Medical Technology Co., Ltd</p> <p>Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China</p> <p>LOA Validity: 1/03/2030</p> <p>FSC Validity:</p>	<p>Hematology Analysis Diluent</p> <p>Model: MEK Diluent</p> <p>Class: A</p> <p>Shelf Life: 2 Years</p> <p>Sizes: 1L, 5L, and 20L</p>	Addressed at Sr. No. 186
254.	<p>M/s Reliable Medical Supply</p> <p>Office No.204, 2nd Floor, Makkah Tower, Namak Mandi, Peshawar</p> <p>ELI-00618</p>	<p><u>Legal Manufacturer:</u></p> <p>M/s Zhejiang Xinke Medical Technology Co., Ltd</p>	<p>Hematology Analysis Lytic Agent</p> <p>Model: BCII Lyse</p> <p>Class: A</p>	Addressed at Sr. No. 187

	R&I: 17/04/2025 Fee Chalan No. 09159423 Fee Chalan Date: 11/04/2025	Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 1/03/2030 FSC Validity:	Shelf Life: 2 Years Sizes: 500ml, 1L, 5L, and 20L	
255.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 R&I: 17/04/2025 Fee Chalan No. 2345846369 Fee Chalan Date: 11/04/2025	<u>Legal Manufacturer:</u> M/s Zhejiang Xinke Medical Technology Co., Ltd Address: No.133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Validity: 1/03/2030 FSC Validity:	Cleaning Solution Model: Rinse Cleaning Solution Class: A Shelf Life: 2 Years Sizes: 500ml, 1L, 1L x 4, 5L, 5L x 2, 5.5L and 20L	Addressed at Sr. No. 188
256.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 R&I: 17/04/2025 Fee Chalan No. 92530528 Fee Chalan Date: 11/04/2025	<u>Legal Manufacturer:</u> M/s Zhejiang Bangli Medical Products Co., Ltd Address: No.118, Yuegui South Road, City West New District, 321300 Yongkang City, Zhejiang Province, China LOA Validity: 16/03/2035 FSC Validity:	Medical Tapes Class: A Shelf Life: 5 Years Sizes: As per FSC	Addressed at Sr. No. 189
257.	M/s Reliable Medical Supply Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 R&I: 17/04/2025 Fee Chalan No. 38080996 Fee Chalan Date: 11/04/2025	<u>Legal Manufacturer:</u> M/s Hebei Free Trade Zone Shenghong Medical Devices Co., Ltd. Address: 1305-1, Konggang North Street Office Building, Shijiazhuang Comprehensive Bonded Zone, Zhengding District, China (Hebei) Pilot Free Trade Zone LOA Validity: 02/04/2030	Single-use Container for Human Venous Blood Collection Specimen Collection Class: A Shelf Life: 3 Years Sized: As per FSC	Addressed at Sr. No. 190

		FSC Validity:										
258.	M/s Reliable Medical Supply Address: Office No.204, 2 nd Floor, Makkah Tower, Namak Mandi, Peshawar ELI-00618 R&I: 17/04/2025 Fee Chalan No. 738123418 Fee Chalan Date: 16/04/2025	<u>Legal Manufacturer:</u> M/s Shenzhen Yurucheng Dental Materials Co., Ltd Address: 101, 201, 301, Building A, No.35, Zhuqing Rd., Shijing Community, Shijing Street, Pingshan District, Shenzhen, China LOA Validity: 11/04/2026 FSC Validity:	Yucera (Zirconia Dental Ceramics) Class: B Shelf Life: 5 Years Sizes: As per FSC	Deferred for the submission of valid and original LOA, FSC, ISO 13485 and CE certificates.								
259.	<u>Reliable Medical Supply</u> Office No,204.2 nd Floor Makkah Tower, Namak Mandi, Peshawar. Mob# +92 3459202628 ELI No.: ELI-00618 DATE: 22/04/2025 DEPOSITED SLIP: 04715202624 FEE.RS.6000/= R&I.22/2/2025	M/S NANYANG JIUDING MATERIAL TECHNOLOGY CO., LTD. XIAWANGZHUANG VILLIAGE XINDIAN TOWN, DEMONSTRATION AREA OF URBAN-RURAL INTEGRATED NANYANG CITY.CHINA FSC Valid till: 23/4/2025 ISO Valid till: 25/05/2027 LOA Valid till: 01/12/2025	Generic Name: INKJET MEDICAL X-RAY FILM. Brand Name; Reliable Medical <u>Model:</u> A3, A4, B5,16K, . Class: A Shelf life: 5 YEARS	Approved								
260.	M/S Global Marketing Services (ELI- 00109)	Legal Manufacturer: Radiometer Medical ApS Åkandevvej 21 DK-2700 Brønshøj Denmark Manufacturing Site: SenDx Medical, Inc. 1945 Palomar Oaks Way Carlsbad, CA 920011 USA ISO 13485:2016 Attached CE Certificate validity date:	Brand Name ABL9 Analyzer System Generic Name: Blood Gas, Electrolyte, and Metabolite Analyzer Class: A Shelf life: <table><tr><th>Code</th><th>Shelf Life</th></tr><tr><td>393-899</td><td>N/A</td></tr><tr><td>996-546</td><td>N/A</td></tr><tr><td>933-625</td><td>N/A</td></tr></table>	Code	Shelf Life	393-899	N/A	996-546	N/A	933-625	N/A	Approved. The firm shall submit fee as per revised SRO for System
Code	Shelf Life											
393-899	N/A											
996-546	N/A											
933-625	N/A											

		N/A Design Examination Certificate: N/A	<table><tr><td>615-303</td><td>N/A</td></tr><tr><td>903-594</td><td>N/A</td></tr><tr><td>984-077</td><td>N/A</td></tr><tr><td>945-852</td><td>120 days</td></tr><tr><td>945-862</td><td>120 days</td></tr><tr><td>945-854</td><td>120 days</td></tr><tr><td>945-861</td><td>120 days</td></tr><tr><td>945-853</td><td>120 days</td></tr><tr><td>945-860</td><td>120 days</td></tr><tr><td>945-863</td><td>120 days</td></tr><tr><td>945-855</td><td>120 days</td></tr><tr><td>944-506</td><td>150 days</td></tr></table> Codes: 393-899, 933-625, 615-303, 903-594, 996-546, 945-852, 945-853, 945-854, 945-855, 945-860, 945-861, 945-862, 945-863, 944-506, 984-077	615-303	N/A	903-594	N/A	984-077	N/A	945-852	120 days	945-862	120 days	945-854	120 days	945-861	120 days	945-853	120 days	945-860	120 days	945-863	120 days	945-855	120 days	944-506	150 days	
615-303	N/A																											
903-594	N/A																											
984-077	N/A																											
945-852	120 days																											
945-862	120 days																											
945-854	120 days																											
945-861	120 days																											
945-853	120 days																											
945-860	120 days																											
945-863	120 days																											
945-855	120 days																											
944-506	150 days																											
261.	M/S Global Marketing Services (ELI- 00109)	Legal Manufacturer: Radiometer Medical ApS Åkandevvej 21 DK-2700 Brønshøj Denmark Manufacturing Sites: Radiometer Solutions Sp. Z o.o Atalowa 6 73-110 Stargard Poland Radiometer Sp. Z o.o Podmiejska 3 73-110 Stargard Poland Shandon Weigao Group Medical Polymer Co. Ltd No. 1 Weigao Road Torch Hi-tech science Park	Brand Name safePICO A Generic Name: Blood Gas Syringe Class: A Shelf life: 2 Years configurations:	Approved. The firm shall submit codes/ sizes as per FSC before the issuance of registration letter.																								

		264210 Weihai, Shandong Province People's Republic of China ISO 13485:2016 Attached CE Certificate validity date: N/A Design Examination Certificate: N/A		
262.	M/S Global Marketing Services (ELI- 00109)	Legal Manufacturer: Radiometer Medical ApS Åkandevvej 21 DK-2700 Brønshøj Denmark Manufacturing Sites: Radiometer Solutions Sp. Z o.o Atalowa 6 73-110 Stargard Poland Radiometer Sp. Z o.o Podmiejska 3 73-110 Stargard Poland Shandon Weigao Group Medical Polymer Co. Ltd No. 1 Weigao Road Torch Hi-tech science Park 264210 Weihai, Shandong Province People's Republic of China ISO 13485:2016 Attached CE Certificate validity date:N/A Design Examination Certificate: N/A	Brand Name: PICO A Generic Name: Blood Gas Syringe Class: A Shelf life: 2 Years configurations:	Approved. The firm shall submit codes/ sizes as per FSC before the issuance of registration letter.

DEFERRED CASE OF IMPORT

S.#	Name & Address of the importer	Name & Address of Legal Manufacturer, Manufacturer, Manufacturing Site, Contract Manufacturer	Name of Medical Devices/ Shelf life / codes / sizes (if any)	Decision
1.	M/s. Ali Gohar & Company (Pvt) Ltd. ELI-00004 R&I details: 13-Dec-2022	<u>Legal Manufacturer:</u> Smiths Medical ASD Inc., 6000 Nathan Lane North Minneapolis Minnesota 55442 USA FSC: United Kingdom Validity: 18/03/2024 LOA Validity: 14/12/2027 FSC: FSC of Reference Country Validity: 00-00-20— OR EC Certificate: Validity: 18/03/2023	Brand Name: Portex® BLUperc® Percutaneous Dilation Tracheostomy Kit Class C Shelf Life: 05 years Codes / Sizes (if any) 101/561/070, 101/561/080 101/561/090	Approved subject to the submission of fee

REGISTRATION OF MEDICAL DEVICES LOCAL.

S#	Name of Manufacturer	Name of Medical Device	Decision
1.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim General Surgery Drape Pack Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 958784014	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
2.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Non-Woven Adhesive Wound Dressing Strip with Pad Pack Size: 5x7.5,6x7,10x10,10x15, 10x20, 10x25,10x30 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 939583152	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as

			family for all their applied sizes of the product.
3.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Silicone Scar Sheet Pack Size: 5x7.5, 6x12, 5x15, 10x20 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 2454912706	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
4.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Surgical Tape Pack Size: 1.25cm x 9.14m, 2.5cm x 9.14m, 5cm x 9.14m, 7.5cm x 9.14 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 082277854	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
5.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Foam Dressing Non-adhesive Pack Size: 5x5, 9x9, 10x 10, 15x15 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 84758647455	Deferred for the following: Revise & justify the Class of the applied medical Device as per MDR 2017 along with submission of revised fee & revised application Form (Form-7) signed & stamp with properly filled data/information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.

6.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Foam Dressing Silicone Adhesive Border Pack Size: (cm) 15x12, 18x18, 15x15, 5x12.5, 7.5x7.5, 15x20, 20x20, 14x23, 7x11 Class: A Shelf Life: 4 Years Fee: 6000 Fee Slip No. 2396054555	Deferred for the following: Revise & justify the Class of the applied medical Device as per MDR 2017 along with submission of revised fee & revised application Form (Form-7) signed & stamp with properly filled data/information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
7.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim H 560 Dil 5 P for H 560 Analyzers Product detail of Glim H 560 Dil 5 P for H 560 Analyzers Composition: Sodium Chloride <1.0 % Buffer <1.1 % Preservative <0.4 % Stabilizers <0.4% In lon free Water Pack Sizes: 1L, 5L, 10L, 15L, 20L, 25L, 30L Shelf Life: 05 Years Class: A Fee: 6,000 Fee Slip No: 173452225018	Approved subject to submission of the following: Properly filled Form-6 signed & stamp with information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
8.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Silver Alginate Dressing Pack Size (cm) 2x30, 10x20, 10x10 10x20, 20x20 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 1122958162	Deferred for the following: Revise & justify the Class of the applied medical Device as per MDR 2017 along with submission of revised fee & revised application Form (Form-7) signed & stamp with properly filled data/information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.

9.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Transparent Surgical Tape Pack Size: 1.25cm x 9.14m, 2.5cm x 9.14m, 5cm x 9.14m, 7.5cm x 9.14 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 37041898726	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
10.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Film Island Dressing Pack Size:(cm) 6x7, 9x10, 9x15, 9x20, 9x25, 9x30 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 61176522	Deferred for confirmation of manufacturing & testing facility for the applied product. The firm shall justify the class of the applied product as per MDR 2017 & revised the class of the applied accordingly along with the submission of revised fee (if applicable) & revised & properly signed Form-6/Form-7 with filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
11.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Non-Woven Adhesive Wound Dressing Strip Pack Size: (cm x m) 2.5x5, 5x5, 7.5x5, 10x5, 2.5x10, 5x10, 7.5x10, 10x10 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 430771345992	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.

12.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Surgical Gown Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 2617969061	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
13.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Sterile Surgical Angiography Drape Pack Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 66757794777	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
14.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Cohesive Elastic Bandage Pack Size: (cm x m) 2.5x 4.5, 5x4.5, 7.5x4.5, 10x4.5 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 8954256107	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
15.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim X-Ray Film Developer Liquid Pack Size: (Fixer A 5 liter, Fixer B 650ml) (Dev. A 5 liter, Dev. B 650ml) Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 77164125225	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.

16.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim X-Ray Film Fixer Liquid Pack Size: 20 liter X 2 (Fixer A 5 liter, Fixer B 650ml) Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 8261052933	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
17.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Hydrocolloid Dressing Pack Size: (cm) With Border size: 10x10, 20x20, 15x15, 7.5x7.5, 5x5, 15x18, 18x15 With Super thin Size: 10x10, 5x5, 7.5x7.5, 20x20 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 313910521394	Deferred for the following: Revise & justify the Class of the applied medical Device as per MDR 2017 along with submission of revised fee & revised application Form (Form-7) signed & stamp with properly filled data/information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
18.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim H 380 Cleaner for H 380 Analyzers Composition: Detergent: <1.0 % Buffer: <1.0 % Preservative: <0.5 % Stabilizers: <0.5% In Ion free Water Pack Sizes: 1L, 5L, 10L, 15L, 20L, 25L, 30L Shelf Life: 05 Years Class: A Fee: 6,000 Fee Slip No: 94628634	Approved subject to submission of the following: Properly filled Form-6 signed & stamp with information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.

19.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim H 380 Lyse Diff 3 P for H 380 Analyzers Composition: Surfactant <3.5 % Buffer <1.0 % Preservative <0.5 % Stabilizers <0.5% In ION free Water Pack Sizes: 1L, 5L, 10L, 15L, 20L, 25L, 30L Shelf Life: 05 Years Class: A Fee: 6,000 Fee Slip No: 4243848066	Deferred for submission of the following: Confirmation of manufacturing & testing facility for the applied product. Properly filled Form-6 signed & stamp with information in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
20.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Pop Bandage Pack Sizes: (cm x m) 5x2.7, 7.5x2.7, 10x2.7, 15x2.7, 2.x2.7 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 38566302	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
21.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Termapore Surgical Tape Pack Sizes: 5cm*7m, 6cm*10m, 10cm*10m, 15cm*4.5m, 09cm*10m, 25mm* 4.5m, 50mm*4.5m, 75mm*4.5m Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 6092565212	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.

22.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Non-woven Paper Adhesive Micropore Tape Pack Sizes: 3cm, 5cm*5m, 7.5cm*6m, 10cm*9m Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 1305166474	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
23.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Adhesive Zinc Oxide Plaster Surgical Tape Pack Sizes: 3cm, 5cm*5m, 7.5cm*6m, 10cm*9m Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 2598016070	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
24.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	UreaLact Cream 10/5 Composition: Each tube contains: Urea 10% w/w Lactic acid 5% w/w Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 714073397783	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
25.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Ureasil Cream Composition: Each tube contains: Salicylic acid: 2 % w/w Shelf Life: 04 Years Class: A	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including

		<p>Fee: 6,000 Fee Slip No: 1723643537</p>	<p>information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>
26.	<p>Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)</p>	<p>Glim Adhesive Zinc Oxide Plaster Medical Tape Pack Sizes: 5cm*5m, 7.5cm*6m, 10cm*9m</p> <p>Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 7009755303</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.</p> <p>The same product has already applied in the Adhesive Zinc Oxide Plaster Surgical Tape name as in no.23 clarification required.</p>
27.	<p>Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)</p>	<p>Ureaflo-S 60%/2% Cream Composition: Each tube contains: Urea 60% w/w Salicylic acid: 2 % w/w</p> <p>Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 578571416</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>
28.	<p>Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)</p>	<p>Ureaflo-E Cream Composition: Urea 10% w/w & Vitamin E per tube</p> <p>Pack Sizes: 20gm, 30gm, 50gm, 150gm, 500gm</p> <p>Shelf Life: 04 Years Class: A Fee: 6,000</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability</p>

		Fee Slip No: 6229764750	Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
29.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Salipro 12% Cream Composition: Each tube contains: Salicylic acid: 12 % w/w Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 7610519177	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
30.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Ureaflo 20% Cream Composition: Urea 20% w/w per tube Pack Sizes: 30gm, 50gm, 120gm, 150gm, 500gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 40554414346	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
31.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Ureaflo 40% Cream Composition: Urea 40% w/w per tube Pack Sizes: 30gm, 50gm, 120gm, 150gm, 500gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 218135932	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee

			as per the new SRO.
32.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Ureaflo 30% Cream Composition: Urea 30% w/w per tube Pack Sizes: 30gm, 50gm, 120gm, 150gm, 500gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 939266156	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
33.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Ureaflo-S 40/2 Cream Composition: Each tube contains: Urea 40% w/w Salicylic acid: 2 % w/w Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 56251411	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
34.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Soda Lime SuperSorb Pack Sizes: 1 liter, 5 liter Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 478171212339	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO if intend to apply as family for all their applied sizes of the product.
35.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan	Glim Rexi gel Composition: Chlorhexidine gluconate solution I.P. equivalent to	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for

	(ELM-0096)	Chlorhexidine gluconate 1.0 % w/w Pack Sizes: 15gm, 30gm, 50gm, 80gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 86685561156	the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
36.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Salipro Serum Composition: Each 30ml contains: Salicylic acid: 2 % Pack Sizes: 15ml, 25ml, 30ml, 50ml Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 0958762393	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
37.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Paraffin Gauze Dressing Pack Sizes: (cm) 10x10, 10x20, 10x40 Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 9211569609	Deferred for the following: Confirmation of manufacturing & testing facility for the applied product. Revise & justify the Class of the applied medical Device as per MDR 2017 along with submission of revised fee & revised application Form (Form-7) signed & stamp with properly filled data/information in each & every section/ point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
38.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Salipro Gel Composition: Each tube contains: Salicylic acid: 6 % w/w Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 64553490	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including

			information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
39.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Elolex Composition: Lidocaine 5% Pack Sizes: 15gm, 30gm, 45gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No:13665003055	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
40.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Eltigel Composition: Each tube contains: Chlorhexidine gluconate: 1 % w/w Benzocaine.....10% w/w Pack Sizes: 15gm, 30gm, 45gm, 120gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 622434458	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
41.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Adopain Composition: Each tube contains: Benzocaine I.P.....20% w/w in a water miscible base. Pack Sizes: 15gm, 30gm, 45gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 7502186256	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the

			Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
42.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Kenacare Cream Composition: Each gm contains: Nystatin...100,000 units Neomycin base (as Neomycin Sulphate) ...2.5 mg Gramicidin ...0.25 mg Triamcinolone Acetonide ...1.0 mg Pack Sizes: 15gm, 30gm, 45gm, 60gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 984942752977	The Board rejected the application as the applied product is a pharmaceutical drug & not regulated under MDR 2017.
43.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Adoulcer Composition: Choline Salicylate: 87mg/gm Pack Sizes: 15gm, 30gm, 45gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 73358729501	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
44.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Adocain Plus Composition: Benzocaine I.P.....20% Menthol....0.5% Zinc Chloride ..0.15% Pack Sizes: 15gm, 30gm, 50gm, 150gm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 837333270728	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee

			as per the new SRO.
45.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Salipro 5% Cream Composition: Each tube contains: Salicylic acid: 5 % w/w Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 197791375319	Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit fee as per the new SRO.
46.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Enzo Eze Repair Cement Composition: Inorganic powder of Tricalcium and Dicalcium silicate Pack Size: 2 gm Bottle-Powder Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 501936639566	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.
47.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Dexamet Dexamethasone Acetate, Formaldehyde, Phenol, Iodoform Composition: Ratio 1 powder / 1 liquid Dexamethasone Acetate:... 1.1 % , Formaldehyde, Phenol, Gaiacol, Lodoform, excipient Pack Size 20gm Powder with 15ml liquid Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 7853351923	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.
48.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan	Glim Endoimet Hydrocortisone Acetate, Thymol Iodide, Barium	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly

	(ELM-0096)	<p>Sulphate, Zinc Oxide</p> <p>Composition: Hydrocortisone acetate...1.0 g Excipients: Thymol iodide, Barium Sulfate, Zinc Oxide... 100.0 g Magnesium Stearate q.s.ad. PACK SIZE i 10ml, 20ml, 30ml, 50ml, 100ml Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 246048858</p>	filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
49.	<p>Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)</p>	<p>Glim Ethysel</p> <p>Ethyl Acetate, Amyl Acetate</p> <p>Composition: Ethyl acetate Amyl acetate Thymol</p> <p>Pack Size 30ml, 50ml, 100ml</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 7021219752</p>	Deferred for confirmation of manufacturing & testing facility for the applied product along with the submission of properly signed Form-6 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.
50.	<p>Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)</p>	<p>Glim Derobutal</p> <p>Chlorobutanol, Eugenol, Oil of Cinnamon, Methyl Salicylate</p> <p>Composition: Chlorobutanol hemihydrate 30%, Eugenol 57.5%, Oil of Cinnamon 10%, Methyl Salicylate 2.5%</p> <p>Pack Size: 30ml, 50ml, 100ml</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 7021219752</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>

51.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	<p>Glim Dentanol</p> <p>Chlorobutanol, Oil of Cloves, Oil of Cassia, Methyl Salicylate</p> <p>Composition: 24% Chlorobutanol...7.2gm</p> <p>Oil of Cassia 1.5gm</p> <p>Oil of Cloves 1.5gm</p> <p>Methyl Salicylate.. 0.6gm</p> <p>Vehicle qs</p> <p>Pack Size 30ml, 50ml, 100ml</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 282570728</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>
52.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	<p>Glim Cresophene</p> <p>Capsicum oleo resin USP, Menthol, Polypropylene Glycol, Glycerine, Camphor, Thymol, Parachlorophenol</p> <p>Pack Size: 15ml, 30ml, 50ml</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 8755063383</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>

53.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	<p>Glim Delasept 2ml with 10 Needles</p> <p>Calcium Hydroxide, Barium Sulphate, isotonic Saline</p> <p>Calcium Hydroxide >41% ..0.82gm Barium Sulphate :9%, Sterile Isotonic Saline Solution..qs</p> <p>Pack Size: 2ml</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 72701689309</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>
54.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	<p>Glim Pulpotec powder & Liquid</p> <p>Powder: Iodoform, Polyoxymethylene Liquid: Phenol, Guaiacol, Formaldehyde, Dexamethasone Acetate</p> <p>PACK SIZE Powder 15gm and 15ml Liquid</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 29651170060</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>
55.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	<p>Glim Lidocaine Spray</p> <p>Composition: 10 mg of Lidocaine per 100 mL of solution</p> <p>Pack Size: 50ml, 100ml, 300ml</p> <p>Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 50853964391</p>	<p>Deferred for clarification regarding the nature of the product whether the applied product is Medical Device as per MDR or otherwise along with its correct class & for the confirmation of manufacturing & testing facility for the applied product with the submission of properly signed Form-6/Form-7 with properly filled data in each & every section /point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit fee as per the new SRO.</p>

56.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Open Wove Bandage Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 470227436147 Sizes (in cm): not mentioned	Approved with 2 years of Shelf Life subject to submission of the following: Form-6 signed & stamp with properly filled data/information in each & every section /point including information related to manufacturing & Quality Control processes, & Stability Study commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
57.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Kytostate Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 1116058878 Sizes (in cm): not mentioned	Deferred for confirmation of manufacturing & testing facility for the applied product. The firm shall justify the class of the applied product as per MDR 2017 & revised the class of the applied accordingly submit revised & properly signed Form-7 with filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
58.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Poly Gras Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 5599960033 Sizes (in cm): not mentioned	Deferred for confirmation of manufacturing & testing facility for the applied product & submission of the following: Revised Form-7 with filled data/information in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
59.	Intra Health Sciences Pvt. Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Shell Dressing Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 588715310 Sizes (in cm): not mentioned	Approved with 2 years of Shelf Life subject to submission of the following: The firm shall justify the class of the applied product as per MDR 2017 & revised the class of the applied accordingly submit revised & properly signed Form-7 with filled data/information in each & every section/point including information

			<p>related to manufacturing & Quality Control processes, Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.</p>
60.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	<p>Ultimed First Aid Bandage</p> <p>Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 6612583422 Sizes (in cm): not mentioned</p>	<p>Approved with 2 years of Shelf Life subject to submission of the following: Revised & properly signed Form-7 with filled data/information in each & every section/point including information related to manufacturing & Quality Control processes, Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.</p>
61.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	<p>Ultimed Paragaz</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 32334640 Sizes (in cm): not mentioned</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product.</p> <p>The firm shall submit clarification regarding the exact composition/content of the product that which of the antiseptics or antimicrobial agents is included in the applied product & accordingly revised the class of the product as per MDR 2017 & submit revised & properly signed Form-7 with filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing.</p> <p>The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.</p>
62.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	<p>Ultimed Povidone Tulle</p> <p>Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 91534288 Sizes (in cm): not mentioned</p>	<p>Deferred for confirmation of manufacturing & testing facility for the applied product.</p> <p>The firm shall justify the class of the applied product as per MDR 2017 & revised the class of the applied accordingly submit revised & properly signed Form-7 with filled data in each & every section/point including information related to manufacturing & Quality Control processes along with annexures where required, & Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the</p>

			product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
63.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed Optical Eye Pad Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 3552047840 Sizes (in cm): not mentioned	Approved with 2 years of Shelf Life subject to submission of the following: Revised & properly signed Form-7 with filled data/information in each & every section/point including information related to manufacturing & Quality Control processes, Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
64.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed IV Catheter with wings and Heparin Cap Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 979554463790 Sizes: Not mentioned.	Deferred for confirmation of manufacturing & testing facility for the applied product. Revised & properly signed Form-7 with filled data/information in each & every section/point including information related to manufacturing & Quality Control processes, Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
65.	Intra Health Sciences Pvt Ltd FD21 A7, Korangi creek Industrial Park, Korangi Karachi (ELM-0078)	Ultimed IV Catheter Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 2486023507 Sizes: Not mentioned.	Deferred for confirmation of manufacturing & testing facility for the applied product. Revised & properly signed Form-7 with filled data/information in each & every section/point including information related to manufacturing & Quality Control processes, Stability Study protocol along with commitment/ undertaking that they will perform the Stability study of the product before marketing. The firm shall also be advised to submit the demanded sizes for the applied product & fee as per the new SRO if intend to apply as family for different sizes of the product.
66.	Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi (ELM-0055)	B.T Plain Catgut Suture Class: D Shelf Life: 60 Months Fee: 25000 Fee Slip No. 793975159758 Sizes: 0,1,2,2/0,3/0,4/0,	The Board deferred the case for the following: i. List of all materials of animal, human, microbial or recombinant origin used in the applied medical device and in the manufacturing process of the medical device. ii. Detailed information concerning the selection of sources or donors

			<p>iii. Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances</p> <p>iv. Process full description of the system for record keeping allowing traceability from sources to the finished medical device</p>
67.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [878-7L]	<p>Care Gauze Sterile X-Ray Detectable woven Gauze/cloth</p> <p>Class: B Shelf Life: 5 years Fee: 25000 Fee Slip No. 9430238935</p> <p>Sizes: (cm) 5x5, 7.5x7.5, 10x10, 15x15,</p>	<p>Deferred the case for confirmation of manufacturing facility.</p> <p>The firm is advised to apply on Form-1 with the required fee for the approval the required section.</p>
68.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [879-7L]	<p>X-Ray Lap Sponges</p> <p>X-Ray Detectable Open Wove Bandage Abdominal Cloth</p> <p>Class: B Shelf Life: 3 years Fee: 25000 Fee Slip No. 2270953395</p> <p>Sizes: (cm) 5x5, 7.5x7.5, 10x10, 15x15,</p>	<p>Deferred the case for confirmation of manufacturing facility.</p> <p>The firm is advised to apply on Form-1 with the required fee for the approval the required section.</p>
69.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [880-7L]	<p>ARSO-MAX Combine Dressing X-Ray Detectable Non-Woven Gauze Cloth</p> <p>Class: B Shelf Life: 5 years Fee: 25000 Fee Slip No. 2751421858</p> <p>Sizes: (cm) 10x10, 15x20,</p>	<p>Deferred the case for confirmation of manufacturing facility.</p> <p>The firm is advised to apply on Form-1 with the required fee for the approval the required section.</p>
70.	Arsons Pharmaceuticals Industries (Pvt) Ltd, 2.5 KM, Defense Road, Off Multan Road, Lahore (ELM-0051) [881-6L]	<p>MEDIPLAST First Aid Bandage Acriflavine Pad (Cold Seal)</p> <p>Class: A Shelf Life: 5 years Fee: 6000 Fee Slip No. 2646997454</p> <p>Sizes: 19mm x 72mm 100 bandages (20x5)</p>	<p>Approved subject to submit valid GMP Certificate.</p>
71.	Al-Badar Manufacturing (Pvt) Ltd., Plot No. 193/3, Road No.7, Industrial Estate, Gadoon Amazai, Distt. Swabi (ELM-0029) [882-7L]	<p>Zindagi U-100/1ml Insulin Syringe</p> <p>Class: B Shelf Life: 5 years Fee: 25000</p>	<p>Approved with 2 years' shelf life subject to submission of the following:</p> <p>Stability Study data or commitment/undertaking that they will perform the Stability study of the product before marketing.</p>

		Fee Slip No. 38908420773	Valid GMP Certificate
72.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [751-6L]	Medi Crepe Bandage BP Cotton Crepe Bandage BP Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 40482586879 Sizes: (cm x m): 5x3, 7.5x3, 10x3, 15x3, 5x4.5, 7.5x4.5, 10x4.5, 15x4.5	Approved subject to submission of fee as per New SRO.
73.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [752-6L]	Medi Cot BP Absorbent Cotton Wool BP Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 30314710970	Approved the non-Sterile subject to submission of fee as per New SRO.
74.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [753-7L]	Soft Gauze Swab BP X-rays Thread/without x-rays threads (Sterilized/non-Sterilized) Class: C Shelf Life: 5 Years Fee: 25000 Fee Slip No. 324076326455 Sizes: (cm x cm): 5x5, 7.5x7.5, 10x10, 15x15, 10x30	Approved the non-Sterile without x-rays thread with 2 year of Shelf life in Class-A subject to submission of fee as per New SRO. The firm is advised to apply the rest of the products separately with application on Form-7A prescribed fee.
75.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [754-6L]	Soft Gauze BP Absorbent Gauze Roll BP Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 161877190 Sizes: (cm x m): 100x2.5, 100x10, 100x20, 100x.30, 100x40, 100x50	Approved the non-Sterile with 2 year of Shelf life subject to submission of fee as per New SRO.
76.	Karim Industries, 135-C, Nawab Town, Thokar Niaz Baig, Lahore (ELM-0014) [755-6L]	Medi Band BP Open Wove Bandage BP Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 891288982688 Sizes: (cm x m): 5x3, 5x4, 5x5, 5x6, 6.5x3, 6.5x4, 6.5x5, 6.5x6, 7.5x3, 7.5x4, 7.5x5, 7.5x6,	Approved the non-Sterile with 2 year of Shelf life subject to submission of fee as per New SRO.

		10x3,10x4,10x5,10x6, 15x3,15x5,15x4,15x6	
77.	Lahore Medical Instruments (Pvt) Ltd., 48KM Lahore-Kasur Road, Kasur (ELM-0052) [777-7L]	INJEKT 1CC, 10CC Disposable Sterile Disposable Syringes Class: B Shelf Life: 2 Years Fee: 20,000 + 20,000 Fee Slip No. 73903952968 & 7835750651	Approved the 1cc syringe subject to submission of differential fee as per New SRO. The firm is advised to apply the 10cc Syringe separately with application on Form-7A prescribed fee. Valid GMP Certificate

DEFERRED PRODUCTS OF M/S UNISA PVT. LTD, ADAMZAI AKORA KHATTAK, NOWSHERA KPK PAKISTAN:

Sr. No.	Name of Medical Devices With Size	Decision
1.	UniUBAG Sterile Single urine Collection Bag with Outlet 1000ml and 2000ml Class: A Shelf Life: 5 years Fee: 6000 Fee Slip No. 5250741856	Approved for assembling, packing & final release of the Product.
2.	UniCLINE Central Venous Pressure Line (Peripherally Inserted Central Vein Access Catheter) Single Lumen Double Lumen and Triple Lumen Class: D Shelf Life: 5 Years Fee: 25000 Fee Slip No. 23332422034	Approved the product UNCLINE CVP Triple Lumen for assembling, packing & final release of the Product subject to submission of applied sizes of the product. The other products UNCLINE CVP Single Lumen & UNCLINE CVP Double Lumen are approved for assembling, packing & final release of the Product subject to submission of fee as per New SRO & form along with submission of applied sizes for the products.
3.	UniBREATH Endotracheal Tube with Cuff Standard Sizes I.D. (internal Diameter) 2.0mm to 11.0mm Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 51337979515 Sizes:2,2.5,3,3.5,4,4.5,5, 5.5,6,6.5, 7, 7.5,8,8.5,9, 9.5,10,10.5,11	Approved for assembling, packing & final release of the Product subject to submission of fee as per New SRO.
4.	UniCATH Latex Foley Balloon Catheter- 100% Silicone Coated 1. Type: 2-Way Sizes: 6FR-30FR Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 9596739293	Rejected on the ground that the firm does not have the facility for manufacturing & testing for the applied product as per inspection report.

	Sizes (FR):6,8,10,12, 14,16,18,20,22,24,26, 28,30	
5.	UniTAP Paper Tape Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 84086004840	Approved for repacking of pre-sterilized product & final release of the Product
6.	UniZPLASTER Zinc Oxide Adhesive Plaster Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 44075454689	Approved for repacking of pre-sterilized product & final release.
7.	UniBLADE Surgical Blades Carbon Coated Black and Blue 20G and 22G Class: C Shelf Life: 5 Years Fee: 25000 Fee Slip No. 4978493346	Rejected on the ground that the firm does not have the facility for manufacturing & testing for the applied product as per inspection report.
8.	UNiTULLE Paraffin Gauze Dressing Tulle Grass B.P. 5cm x 5cm Paraffin Gauze Dressing Tulle Grass B.P. 7.5cm x 7.5cm Paraffin Gauze Dressing Tulle Grass B.P. 10cm x 10cm Paraffin Gauze Dressing Tulle Grass B.P. 10cm x 15cm Paraffin Gauze Dressing Tulle Grass B.P. 15cm x 20cm Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 276262396188	Approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.
9.	UNiROLL Absorbent Gauze Cloth Roll BPC Sizes: 100cm x 20m 100cm x 30m 100cm x 40m Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 45475115049	Approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.
10.	UNiWOOL Absorbent Cotton Wool B.P. Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 187662009239 Sizes:25gm,50gm,75gm,100gm,	Approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.

	150gm,175gm,200gm,250gm,300gm, 350gm,400gm,450gm,500gm	
11.	<p>UNiCRED Crepe Bandage B.P.C.</p> <p>Sizes:2.5cm x 4m, 5cm x 4.5m, 7.5cm x 4.5m, 10cm x 4.5m, 15cm x 4.5m</p> <p>Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 45379616438</p>	Approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.
12.	<p>UNiCOT Cotton Bandage BP Type II</p> <p>Sizes:5cm x 4m, 6.5cm x 4m, 7.5cm x 4m, 10cm x 4m, 15cm x 4m</p> <p>Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 1153520810</p>	Approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.
13.	<p>UNiSWAB</p> <p>Gauze Swabs / Sponges USP-IV</p> <p>Sizes:7.5cm x 7.5cm 4-ply, 7.5cm x 7.5cm 8-ply, 10cm x 10cm 4-ply, 10cm x 10cm 8-ply, 15cm x 15cm 4-ply, 15cm x 15cm 8-ply</p> <p>Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 882326225</p>	<p>Approved the product Gauze Swabs for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.</p> <p>The other product / Sponges USP-IV is also approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO & form along with submission of applied sizes for the products.</p>
14.	<p>UNiPLASTER</p> <p>Plaster of Paris</p> <p>Sizes:5cm x 2.7m to 3.5m Plaster of Paris 7.5cm x 2.7m to 3.5m Plaster of Paris 10cm x 2.7m to 3.5m Plaster of Paris 12.5cm x 2.7m to 3.5m Plaster of Paris 15cm x 2.7m to 3.5m Plaster of Paris 20cm x 2.7m to 3.5m</p> <p>Class A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 45281574</p>	Approved for repacking of pre-sterilized product & final release subject to submission of fee as per New SRO.
15.	<p>UNiWAY</p> <p>One-Way Stop Cock, Two-Way Stop Cock, Three-Way Stop Cock, Four-Way Stop Cock.</p> <p>Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 2730995387</p>	<p>Approved the product Two-Way Stop Cock for assembling, packing & final release of the Product.</p> <p>The other products One-Way Stop Cock, Three-Way Stop Cock, Four-Way Stop Cock are also approved for assembling, packing & final release of the Product subject to submission of fee as per New SRO & Form-7 along with submission of applied sizes for the products.</p>

16.	<p>UNiHD One-Way, Two-Way, Three-Way, Four-Way Stop Cock with Extension Tube Sizes: Ranging 10cm to 100cm</p> <p>Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 449556021</p>	<p>Approved the product three-Way Stop Cock with extension for assembling, packing & final release of the Product.</p> <p>The other products One-Way, Two-Way, Four-Way Stop Cock with Extension Tube are also approved for assembling, packing & final release of the Product subject to submission of fee as per New SRO & Form-7 along with submission of applied sizes for the products.</p>
17.	<p>UNiLiNE One-Way, Two-Way, Three-Way, Four-Way, Extension Tube Sizes: ranging from 10cm to 100cm Class B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 993729747994</p>	<p>Approved the product One Way extension tube for assembling, packing & final release of the Product.</p> <p>The other products Two-Way, Three-Way, Four-Way, Extension Tube are also approved for assembling, packing & final release of the Product subject to submission of fee as per New SRO & Form-7 along with submission of applied sizes for the products.</p>

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