

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

DECISIONS OF 139TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
13-08-2026 (MANUAL APPLICATIONS PART-II)

139th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 13.08.2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S#	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	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.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
4.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad	Member
5.	Dr. Farid Khan, Senior Consultant Neurosurgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
6.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
7.	Mr. Wajahat Ali, Biomedical Manager, Biomedical Engineering Department, Darul Sehat Hospital, Street-19, Block-15, KDA Scheme 36, Gulistan-e-Johar, Karachi.	Member (attended meeting through videolink)
8.	Mrs. Tazeen S Bukhari, 192 Cavalry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co -Opted Expert (attended meeting through videolink)
9.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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

Evaluator: Mr. Muhammad Amin (Deputy Director)

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

I. (FRESH RENEWAL CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Shahid Surgical, Office/godown: Flt No. 1 st , Frist floor, Muhalla Gulab Khanna, namak mandi, Peshawar. ELI-00492	Zeeshan Khan Pharm D	Mr. Muhammad Shahid	Approved For room temp products
2.	M/s Zaidi Chemist, Office/godown: 15 Soekarno Square, Khyber Bazar, Peshawar. ELI-00338	Mr. Azhar Hafeez Pharm D	Mr. Zahid Ahmed	Approved For room temp products
3.	M/s Trans Continental Pharma (Pvt) Ltd, Office: House No. 01, Street No. 04, near Iqra School, Abshar colony, Canal road, Warsak road, Peshawar. Godown: House No. 02, Street No. 04, near Iqra School, Abshar colony, Canal road, Warsak road, Peshawar. ELI-00524	Muhammad Zakria	Mr. Asmat Asar Muhammad Sudais Mr. Ahmar Asmat	Deferred. The board deferred the case for fee and documents of technical staff and change of management.
4.	M/s Medilink International, Office/godown: office No. 609, Pak Medical Centre, Khyber bazar, Peshawar. ELI-000456	Muhammad Kashif Ihsan Pharm D	Mr. Abdullah Shah	Deferred. The board deferred the case for fee and documents of tech staff, godown and change of management.

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

DEFERRED CASES AGENDA:

Evaluator: HAJIRA ABID (Intern-2)

IMPORT DEFERRED CASES:

Sr. No.	Importer name	Manufacture details	Name of MD/Class/Code/Shelf life/etc.	Decision
1	M/s. Moon Enterprises, 324, Rewaz Garden Lahore (ELI-00356) R&I Date: 03-06-2025 Fee: 50000/- Slip # 12160535907	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd., Address: Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong, P.R. China LOA Type: Copy Notarization: Apostille Issue Date: 01-01-2025 Validity: 01-01-2030 • FSC Type: Copy Issued By: Shandong Association for Medical Device Industry Legalization: Apostille Validity: 07-01-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025 CE Certificate: Type: Copy Legalization: Notarized Validity: 26-05-2026 Issued by: TUV Rheinald LGA Products GmbH, Germany.	Brand Name: WZ ® Generic Name: Disposable sterile Intravenous Needle (Blood Collecting Butterfly Needle) Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model; 27G-26G-25G-24G-23G 22G-21G-20G-19G-18G Shelf Life: 5 years	Approved as family with Codes/sizes; 27G-26G-25G-24G-23G 22G-21G-20G-19G-18G
2	M/s Ferozsans Laboratories Limited, P.O. Ferozsans, Amangarh, Nowshera-KPK, Pakistan.	Legal Manufacturer: Boston Scientific Corporation,	Intellagen Cardiac Ablation System & Accessories Generic Name:	Approved

	(ELI-00120) Date of R& I 16-06-2025 Fee: PKR 120,000/- Slip # 37227033937	300, Boston Scientific Way, Marlborough, MA 01752 USA. Manufacturing Sites: 1. Stockert GmbH, Boetzinger Strasse 31 Freiburg, Baden- Wurttemberg, Germany 79111. 2. Creation Technologies Ltd., 8977-8999 Fraserton Court Burnaby, British Columbia, Canada V5J 5H8 ☐ LOA Type: Copy of Notarized Notarization: Notarized Validity: 30-06-2025 ☐ FSC (Verified Online) Type: Copy Issued By: US FDA Legalization: Not Legalized Validity: 06-01-2027 ISO – Certificate: Type: Original Notarization: Notarized Validity: 17-07-2027	Cardiac Ablation System & Accessories. Applied as: System Class: C Models/Code/size i. M004GEN100204010- INTELLAGEN RF Generator Kit ii. M004GEN10020401D0- INTELLAGEN RF Generator Kit iii. M004GEN10020401H0- INTELLAGEN RF Generator Kit iv. M004GEN10020401R0- INTELLAGEN RF Generator Kit v. M004GEN100204030- INTELLAGEN Remote Control Kit vi. M004GEN10020403R0- INTELLAGEN Remote Control Kit vii. M004GEN10020403H0- INTELLAGEN Remote Control Kit viii. M004GEN10020403D0- INTELLAGEN Remote Control Kit ix. M004GEN100204020- INTELLAGEN Irrigation Pump Kit x. M004GEN10020402D0- INTELLAGEN Irrigation Pump Kit xi. M004GEN10020402H0- INTELLAGEN Irrigation Pump Kit xii. M004GEN10020402R0- INTELLAGEN Irrigation Pump Kit xiii. M004GEN100200100- INTELLAGEN Foot Pedal M004GEN100206260- INTELLAGEN Tubing Set 1 PK	
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			xv. M004GEN100206251- INTELLAGEN Tubing Set 10 PK xvi. M004GEN100206241- INTELLAGEN Tubing Set 40 PK xvii. M004GEN100199510- INTELLAGEN Catheter Adapter Cable, 0.3 Meter xviii. M004GEN100199430- INTELLAGEN Grounding Cable, 3 Meter xix. M004GEN100199470- INTELLAGEN Grounding Cable, 3 Meter xx. M004GEN100200900- INTELLA GEN Foot Pedal Extension Cable, 7 Meter xxi. M004GEN100200810- INTELLAGEN Irrigation Pump Connection Cable, 1 Meter xxii. M004GEN100200840- INTELLAGEN Irrigation Pump Connection Cable, 3 Meter xxiii. M004GEN100199460- INTELLAGEN Irrigation Pump Connection Cable, 5 Meter xxiv. M004GEN100200870- INTELLAGEN Irrigation Pump Connection Cable, 10 Meter xxv. M004GEN100200720- INTELLAGEN Remote Control Connection Cable, 10 Meter xxvi. M004GEN100200750- INTELLAGEN Remote Control Connection Cable, 15 Meter xxvii. M004GEN100199440-	
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			INTELLAGEN Remote Control Connection Cable, 25 Meter xxviii. M004GEN100200780- INTELLAGEN Remote Control Connection Cable, 30 Meter xxix. M004GEN100200940- INTELLAGEN Serial Communication Cable, 3 Meter xxx. M004GEN100199480- INTELLAGEN Serial Communication Cable, 15 Meter xxxi. M004GEN100199490- INTELLAGEN Serial Communication Cable, 5 Meter xxxii. M004GEN100199450- INTELLAGEN Irrigation Pump IV Pole Clamp xxxiii. M004RA65010- Rhythmia HDx Ablation Connection Box (for INTELLAGEN) xxxiv. M004RA63020- Rhythmia HDx Ablation Connection Box-IntellaNav StablePoint (for INTELLAGEN) Service Life: Not mentioned	
3	M/s Ferozsons laboratories Limited, P. O Ferozsons, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA	Coyote ES Overthe Wire PTA Balloon Dilatation Catheter Peripheral angioplasty Balloon Catheter Codes & Sizes: As per FSC Class-B Shelf Life: 37Months	Approved as single codes: H74939134152010 Coyote ES OTW 1.5mm x 20mm x 142cm

		FSC: USA Valid till: 22/02/2023		
4	M/s Ferozsans Laboratore Limited, P.O Ferozsans, Amangarh, Nowshera (KPK) ELI: 00120	Legal Manufacturer: Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Site: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA FSC: USA Valid till: 22/02/2023	Coyote ES Monorail & OTW PTA Balloon Dilatation Catheters (Peripheral angioplasty balloon catheter) Codes & Sizes: As per FSC Class-B Shelf Life: 37 months	Approved as single codes: H7493918515049 0 Coyote MR 1.5mm x 40mm x 90cm
5	M/s Hoorah Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 28-04-2021 CMS tracking ID: NV7-72A-4V3D Fee: 5,000/-	Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: 62 Flanders- Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 16-01-2026 • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 22-05-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A	Brand Name: Atellica CH 930 Analyzer Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application: 11067000 Shelf Life: N/A	Approved

6	M/S Mediland Pakistan Pvt Ltd Office no B09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 26-06-2022	SCHMITZ und Sohne GmbH & Co.KG Rudolf- DieselStrabe 5, 59199 Bonon Germany Telephone: +49 (0)2383 91001 0 Fax No: +49 (0)2383 91001 98 Web Site: www.schmitzsoehne.com FSC: LOA: 01-10-2026	Brand Name: Patient Trolley (Generic Name): Transport Trolley Class: A Shelf Life: N/A Codes/sizes: STL 285, STS 282, STX 280	Approved as family Codes/sizes: STL 285, STS 282, STX 280
7	Mediland Pakistan Pvt Ltd Office no B-09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 29-06- 2022	SCHMITZ und Sohne GmbH & Co.KG Rudolf-Diesel-Strabe 5, 59199 Bonon Germany Telephone: +49 (0)2383 91001 0 Fax No: +49 (0)2383 91001 98 Web Site: www.schmitz-soehne.com FSC: LOA: 01-10-2026 EC Certificate: ISO 13485:	Brand Name: Gynecological Examination Chairs Generic Name): Gynecological Examination Chairs Class: B Shelf Life: N/A Codes/sizes: Arco 100 Arco 100 M Arco 200 M Arco-matic 200 M Arco Matic 300 M	Approved as single model Arco 100 M In class A
8	M/S Mediland Pakistan Pvt Ltd Office no B-09 2nd Floor, Masood Arcade IJP road near Saidpur Road Rawalpindi ELI:00202 R& I Details: 18-08- 2022	Medivators Inc. 14605 28th Avenue North Minneapolis, MN 55447 USA Toll Free: +1.800.444.4729 Web Site: www.medivators.com FSC:30-08-2025 LOA: 16-10-2025 EC 30-07-2028 ISO: 05-07-2027	Brand Name: Washer Disinfector System Division (Generic Name): Washer Disinfector System Class: B Shelf Life: N/A Codes/sizes: SSD-102LT DSD 201 DSD EDGE Rapid AER CER OPTIMA ADVANTAGE PLUS ADVANTAGE PLUS Pass-thru	Approved single model ADVANTAGE PLUS
9	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address:	Biorad Liquid PA 5L (High Level Medical instruments-devices and endoscopes disinfectant) Class-C	Approved Codes: 5557 in class C

	5816-P 62,000/-	Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)	Shelf Life: 2 Years Codes/sizes: 5557	
10	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5817-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)	Biorad Clean Ak Spray (Surface disinfectant for medical devices) Class-C Shelf Life: 2 Years Codes/sizes: 5001 (1L) 5003 (5L)	Approved code: 5003 (5L) in Class B
11	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5818-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytap, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029	Biorad Thermo Clean 50% (Hemodialysis machines disinfectant) Class-C Shelf Life: 2 Years Codes/sizes: 5314 (5L)	Approved code: 5314 (5L) in Class C

		GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)		
12	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5819-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)	Biorad Thermo Clean 21% (Hemodialysis machines disinfectant) Class-C Shelf Life: 2 Years Codes/sizes: 5442 (5L)	Approved code: 5442 (5L) in Class C
13	The Cure, 1st Floor, Office No. 6, Capri Center, Firdous Market, Gulberg III, Lahore. ELI-00567 5820-P 62,000/-	<u>Legal Manufacturer:</u> Necm Kimya Akaryakit Urunleri Medikal Malzemeler Sanayi ve Ticaret Ltd.Sti. Address: Battalgazi Mah. Sark Cad. Aytop, I Blok No. 14 Sultanbeyli - Istanbul - Turkey. FSC: Turkey. Date of Issuance: 06-03- 2024. LOA validity 01-01-2029 GMP certificate validity 01-03-2024 CE certificate validity 26- 05-2024 issued by SZUTEST (2195-MED- 2004501)	Biorad GDA 2% (High Level Medical instruments-devices and endoscopes disinfectant) Class-C Shelf Life: 2 Years Codes/sizes: 5401 (5L)	Approved code: 5401 (5L) in Class C
14	Applicant: M/s MIRAJ CORPORATION	Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY	Brand Name: Generic Name: 3.2% Sodium Citrate Tube.	APPROVED

	Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326) Track ID: MN5-HZQ-VA41 Fee: PKR 5000/- Slip: 95180375493 Dated: 11-10-2022 Date of R&I 12 10 2022	CO. LTD □ Address: 80 Fuzhong Road, Langli Street, Changsha, Hunan, China.. Jiangxi Exquisite Technology Co,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024 ISO 13485 Validity: 25-12-2027	Product Names: 3.2% Sodium Citrate Tube. Class-A Shelf life: 24 Months. Storage Conditions: Room temperature	
15	Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 000326) Track ID: R9X-NTT-SVLE Fee: PKR 5000/- Slip: 5597059583 Dated: 12-10-2022 Date of R&I 12 10 2022	Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD □ Address: 80 Fuzhong Road, Langli Street, Changsha, Hunan, China.. Jiangxi Exquisite Technology Co,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024 ISO 13485 Validity: 25-12-2027	Brand Name: Generic Name: Glucose, Fluoride Tube. Class-A Shelf life: 24 Months. Storage Conditions: Room temperature	APPROVED
16	Applicant: M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi	Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD □ Address: 80 Fuzhong Road, Langli Street, Changsha, Hunan, China.. Jiangxi Exquisite Technology Co,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024 ISO 13485 Validity: 25-12-2027	Brand Name: Generic Name: K3 EDTA Tube. Class-A Shelf life: 24 Months. Storage Conditions:	APPROVED

	(ELI- 000326) Track ID: NNP-A2G-4PZ8 Fee: PKR 5000/- Slip: 239350145 Dated: 12-10-2022 Date of R&I 12 10 2022	Jiangxi Exquisite Technology Co,Ltd. Address: 1st road of Yuhu West,Xiaolan Economic Development Zone,Nanchang City, Jiangxi Province,P.R. China FSC china: : 26-10-2023 LOA Notarized LOA Valid till 31-12-2024 ISO 13485 Validity: 25-12-2027	Room temperature	
17	M/s MIRAJ CORPORATION Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi (ELI- 00090) Track ID: JQ9-ZAP-NHSW Fee: PKR 5000/- Slip: 3236434012 Dated: 12-10-2022 Date of R&I 12-10-2022	Legal Manufacturer: HUNAN YBK MEDICAL TECHNOLOGY CO. LTD 80 Fuzhong Road, Lijiang Street, Changsha, Hunan, China. FSC Spain: DOI : 15-10-2021 LOA LOA Valid till 31-12-2024 EC Certificate Validity: 26-05-2024 With CE Extension letter ISO 13485 Validity: 13-05-2021 Expired at submission	Brand Name: Gel and Clot Activator Tube. Class-B Letter of authorization: Validity date: 31-12-2024 Shelf life: 24 Months. Storage Conditions: Room temperature	APPROVED
18	M/s United Healthcare, C-271, Ground Floor, Gulshan-Jauhar, Block-24, Karachi (ELI-00907)	Legal Manufacturer & Site: Wellong Instruments Co., Ltd Address (as per form-7A): 2F, 63 Linsen North Road Taipei, Taiwan. R.O.C. Address as per FSC: 5th Floor No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City, Taiwan, Republic of China. FSC Validity: 09-09-2025 (Taiwan) 09-03-2021 (France) ISO 13485 Certificate validity: 08-07-2027 EC (FQA) not provided Design Examination Certificate not provided.	BMI Shunting System Class: D MD group: Family Shelf life: Not mentioned Storage condition: Room Temperature Codes & Sizes: 06124, 06126, 06128, 06120, 06122, 06129,06140,06142, US-62 Fee Challan No.: 948088324 PKR: 62,000/-	Rejected on following grounds: Name of device on FSC is different as applied i.e. <u>BMI</u> <u>CSF Shunting</u> <u>System.</u>

		LOA Validity: 26-07-2026		
19	M/s. Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI-01234) R&I Date: 26-05-2025 Fee: 6,000/- Slip # 751688293	Name of Manufacturer: Hangzhou Tuopusi Medical Products Co., Ltd., Room 606, Mutouqiao 8-36, Donglian Village, Liangzhu Street, Yuhang District, Hangzhou City, Zhejiang Province, China LOA Type: Original Notarization: Apostille Issue Date: 05-02-2025 Validity: 04-2026 • FSC Type: Original Issued by: Zheijiang Medical Product Administration Legalization: Apostille Issue Date: 21-02-2025 Validity: 20-02-2027 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 26-03-2027	Brand Name: CURE+ Hydrocolloid Dressing Generic Name: Hydrocolloid Dressing Applied as: Family Class: A Models/Code/sizes (as per FSC & application) Model: 1.25cmx5y ; 2.5cmx5y ; 5cmx5y ; 7.5cmx5y ; 10cmx5y; 1.25cmx10y; 2.5cmx5y ; 5cmx10y ; 7.5cmx10y; 10cmx10y; 12" x10y; 1.25cmx5m; 2.5cmx5m ; 5cmx5m ; 7.5cmx5m ; 10cmx5m ; 5cmx5cm; 10cmx10cm; 1.25cmx10m; 2.5cmx10m; 5cmx10m; 7.5cmx10m; 10cmx10m;1.25cmx1m; 2.5cmx1m; 15cmx10m ; 20cmx20cm; 15cmx15cm 100cmx4.5m; 100cmx5m; 100cmx10m etc Shelf Life: 5 years	REJECTED on following grounds: Class is not justified as per MDR 2017
20	M/s. Cure Connect Pakistan Plot No. B-204, First Floor, Sector 6-F, Mehran Town, Korangi, Karachi Pakistan. (ELI-01234) R&I Date: 26-05-2025 Fee: 6,000/- Slip # 46346456765	Name of Manufacturer: Hangzhou Tuopusi Medical Products Co., Ltd., Room 606, Mutouqiao 8-36, Donglian Village, Liangzhu Street, Yuhang District, Hangzhou City, Zhejiang Province, China LOA Type: Original Notarization: Apostille Issue Date: 05-02-2025 Validity: 04-2026 • FSC Type: Original Issued by: Zheijiang Medical Product Administration Legalization: Apostille Issue Date: 21-02-2025	Brand Name: CURE+ Hydrogel Dressing Generic Name: Hydrogel Dressing Applied as: Family Class: A Models/Code/sizes (as per FSC & application) Model:	REJECTED on following grounds: Class is not justified as per MDR 2017

		Validity: 20-02-2027 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 26-03-2027	1.25cmx5y ; 2.5cmx5y ; 5cmx5y ; 7.5cmx5y ; 10cmx5y; 1.25cmx10y; 2.5cmx5y ; 5cmx10y ; 7.5cmx10y ; 10cmx10y ; 12" x10y; 1.25cmx5m; 2.5cmx5m ; 5cmx5m ; 7.5cmx5m ; 10cmx5m ; 5cmx5cm; 10cmx10cm; 1.25cmx10m; 2.5cmx10m; 5cmx10m ; 7.5cmx10m ; 10cmx10m;1.25cmx1m; 2.5cmx1m; 15cmx10m ; 20cmx20cm; 15cmx15cm 100cmx4.5m; 100cmx5m; 100cmx10m etc Shelf Life: 5 years	
21	M/s ENDOVISION ENTERPRISES A-173, Block - 3, Gulistan-e-Jauhar, Karachi Establishment License No: ELI 00730	M/s CHANGZHOU NEW DISTRICT GARSON MEDICAL STENT APPARATUS Co., Ltd Address: No. 06, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu, China Embassy attested FSC: China, Valid until: 15-05-2025 LOA Valid until 30th April 2025 ISO 13485 Valid until 25-05-2024 Copy of EC Certificate FQA Valid until 31-08-2024 An undertaking form Manufacturer	Garson Flextent Biliary Stent System Partially Covered Sizes and Codes: As per FSC Class C Shelf life: 1 years Application submission date: 03-11-2021 Fee submitted: Rs 50,000/-	APPROVED

22	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: 123-HEV-9VY7 Fee: 5,000/-	Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretek (China) Medical PLC. Address: Xiguakeng, Guanqiao Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, P.R. China. LOA Type: Copy Notarization: Yes Issue date: 06-02-2026 • FSC Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 03-03-2026 CE Certificate: N/A	Brand Name: Prioma Medical Bed Generic Name: Prioma Medical Bed Applied as: Set Class: A Models/Code/sizes (as per FSC & application: P400, P500, P600 Shelf Life: 10 years	REJECTED on following grounds: As FSC is not issued by the relevant regulatory authority
23	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: 8L9-NJD-NNZB Fee: 5,000/-	Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretek (China) Medical PLC. Address: Xiguakeng, Guanqiao Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, P.R. China. LOA Type: Copy Notarization: Yes Issue date: 06-02-2026	Brand Name: Prioma Medical Couches Generic Name: Prioma Medical Couches Applied as: Family Class: A Models/Code/sizes (as per FSC & application: Prioma Semi Electric Couches: HC1, HC2, HC3 Prioma Electric Couches EC1, EC2, EC Shelf Life: 10 years	REJECTED on following grounds: As FSC is not issued by the relevant regulatory authority

		• FSC Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 03-03-2026 CE Certificate: N/A		
24	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: Z9Z-4LS-VBZ7 Fee: 5,000/-	Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretex (China) Medical PLC. Address: Xiguakeng, Guanqiao Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, P.R. China. LOA Type: Copy Notarization: Yes Issue date: 06-02-2026 • FSC Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 03-03-2026 CE Certificate: N/A	Brand Name: Prioma Birthing Beds (PBB2) Generic Name: Prioma Birthing Beds (PBB2) Applied as: Single Class: A Models/Code/sizes (as per FSC & application): PBB2 Shelf Life: 10 years	REJECTED on following grounds: As FSC is not issued by the relevant regulatory authority

25	M/s Save On Health Care, 101-B, Panjpeer Road, Lalpur Mughalpur, Lahore ELI-00027 Date of R&I 08-05-2025 Fee Details: Paid Fee: 31,000/- Challan No. 11094891288	Hitec Medical CO., LTD. 501, Building 2 Lane 1505, Lane Hang Road, Minhang District 201112 Shanghai, People Republic of China. LOA Type: Scan copy of non-notarized copy. Validity: 30-12-2028 FSC Type: Scan copy of non-notarized copy Issued By: China Chamber of Commerce Validity: 23-09-2026 ISO 13485: Type: Scan copy of non-notarized copy Validity: 02-11-2026 EC Certificate not attached.	Hitecare Nasal Oxygen Cannula Applied as Single. Class-B Service Life: 5 Yrs Model/Codes/Size: Infant, Pediatric, Adult	REJECTED on following grounds: As FSC is not issued by legal manufacturers
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Deferred cases local manufacturers

1	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Lidocaine Spray Composition: 10 mg of Lidocaine per 100 mL of solution Pack Size: 50ml, 100ml, 300ml Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 50853964391	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.
2	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Delasept 2ml with 10 Needles Calcium Hydroxide, Barium Sulphate, isotonic Saline Calcium Hydroxide >41% ...0.82gm Barium Sulphate :9%, Sterile Isotonic Saline Solution...qs Pack Size: 2ml	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.

		Class: A Shelf Life: 2 years Fee: 6000 Fee Slip No. 72701689309	
3	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	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.
4	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	APPROVED
5	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	APPROVED
6	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [1052-6L] Dy. No. 15039 dated 27- 05-2025 Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers)	Glim Semi-Automatic Biochemistry Analyzer BA-SA-100D Kinetic, End point, Two point, Absorbance Class: A Shelf Life: Not Mentioned Fee: Rs 6000/- Fee Slip No. 8036012385	REJECTED on following grounds; The requisite manufacturing facility is not mention As the firm product fall in IVD reagents that is not a approved section by DRAP

	iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only)		
7	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096 valid till 08/04/2030) [887-6L] Dy. No. 11861 dated 06-05-2025 Approved Sections: viii. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ix. Hydrocolloid and Soft Silicone Foam Dressings x. Liquid Section (Diluents and cleaning solutions for analyzers) xi. General IVDs cleaning solutions. xii. Disinfectant solutions for laboratory equipment. xiii. Hematology diluent solutions. xiv. Semi-solid Section (For Ostomy gel only) D. No. 11861 dated 06-05-2025	Glim Ostomy Paste Composition: MonoButyl ester of Poly (Methyl vinyl ether / Maleic Acid), Gelatin, Pectin (USP Grade), Sodium Carboxy methyl cellulose (Na CMC) FCC Grade, Glyceryl 12-Hydroxylstearate, Glyceryl Triacetate FCC, Alcohol L90 proof-USP. Class: A Shelf Life: 3 Years Pack Size: 60gm × 1 tube, 14gm × 20 tubes. Fee: 6000 Fee Slip No. 3181244968	Approved
8	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections:	Glim Ostomy Powder Composition: Pectin, Gelatin, Sodium Carboxy methyl cellulose Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 2185735027	Approved

	i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 11862 dated 06-05-2025		
9	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections: viii. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ix. Hydrocolloid and Soft Silicone Foam Dressings x. Liquid Section (Diluents and cleaning solutions for analyzers) xi. General IVDs cleaning solutions. xii. Disinfectant solutions for laboratory equipment. xiii. Hematology diluent solutions. xiv. Semi-solid Section (For Ostomy gel only)	Surgilit Composition per 100gm; Propan-2-ol....45gm, Propan-1-ol.....30gm, Mecetronium Ethyl Sulphate.....0.2gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 46740700341	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.

	D. No. 11862 dated 06-05-2025		
10	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections: xv. Sachet/Dry Powder Section (For Hemodialysis Concentrates) xvi. Hydrocolloid and Soft Silicone Foam Dressings xvii. Liquid Section (Diluents and cleaning solutions for analyzers) xviii. General IVDs cleaning solutions. xix. Disinfectant solutions for laboratory equipment. xx. Hematology diluent solutions. xxi. Semi-solid Section (For Ostomy gel only) D. No. 11862 dated 06-05-2025	Surgilit Med Ethanol....85gm/100gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 282317116	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.
11	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections: xxii. Sachet/Dry Powder Section (For Hemodialysis Concentrates) xxiii. Hydrocolloid and Soft Silicone Foam Dressings	Surgilit Classic Pure Composition per 100gm. Propan-2-ol....45gm, Propan-1-ol.....30gm Mecetronium Ethyl Sulphate.....0.2gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 4501717555	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.

	xxiv. Liquid Section (Diluents and cleaning solutions for analyzers) xxv. General IVDs cleaning solutions. xxvi. Disinfectant solutions for laboratory equipment. xxvii. Hematology diluent solutions. xxviii. Semi-solid Section (For Ostomy gel only) D. No. 11862 dated 06-05-2025		
12	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections: xxix. Sachet/Dry Powder Section (For Hemodialysis Concentrates) xxx. Hydrocolloid and Soft Silicone Foam Dressings xxxi. Liquid Section (Diluents and cleaning solutions for analyzers) xxxii. General IVDs cleaning solutions. xxxiii. Disinfectant solutions for laboratory equipment. xxxiv. Hematology diluent solutions. xxxv. Semi-solid Section (For Ostomy gel only) D. No. 11862 dated 06-05-2025	Surgilit Gel Pure Composition:  Ethanol.....85gm Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 617288259	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.
13	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096)	Surgilit Gel Composition: Ethanol....85gm	REJECTED on following grounds: The product does not fall within the definition of a medical

	[888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections: xxxvi. Sachet/Dry Powder Section (For Hemodialysis Concentrates) xxxvii. Hydrocolloid and Soft Silicone Foam Dressings xxxviii. Liquid Section (Diluents and cleaning solutions for analyzers) xxxix. General IVDs cleaning solutions. xl. Disinfectant solutions for laboratory equipment. xli. Hematology diluent solutions. xlii. Semi-solid Section (For Ostomy gel only) D. No. 11862 dated 06-05-2025	Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7288137884	device under the Medical Device Rules, 2017.
14	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [888-6L] Dy. No. 11862 dated 06-05-2025 Approved Sections: xliii. Sachet/Dry Powder Section (For Hemodialysis Concentrates) xliv. Hydrocolloid and Soft Silicone Foam Dressings xlvi. Liquid Section (Diluents and cleaning solutions for analyzers) xlvi. General IVDs cleaning solutions.	Levenida Foam Aqua, Butane, Cocamidopropyl Betaine, Isobutane, Propane, Peg-7, Glycerol Cocoate, Peg-75 Lanolin, Phenoxyethanol, Glycerin, Cocamide Dea, Panthenol, parfum, Peg-40 hydrogenated Castor Oil, Trideceth-9, Ethylhexylglycerin, allantoin, Tetrasodium Edta, Benzyl Salicylate, Hexyl Cinnamal Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 14739024326	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.

	xlvii. Disinfectant solutions for laboratory equipment. xlviii. Hematology diluent solutions. xlix. Semi-solid Section (For Ostomy gel only) D. No. 11862 dated 06-05-2025		
15	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [900-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13130 dated 15-05-2025	Levenida Plus Gel Composition: Poloxamer, Polyhexamethylene biguanide (Polyhexanide, 0.1%) water and auxiliary substances Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 26256080016	REJECTED on following grounds: The class is not justified as per MDR 2017
16	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [900-6L] Approved Sections: viii. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ix. Hydrocolloid and Soft Silicone Foam Dressings	Glim Scar Treatment Silicone Gel Composition: Polymerized Siloxanes (Silicone Gel) and Tocopherol (Vitamin E) Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 3511160162	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.

	x. Liquid Section (Diluents and cleaning solutions for analyzers) xi. General IVDs cleaning solutions. xii. Disinfectant solutions for laboratory equipment. xiii. Hematology diluent solutions. xiv. Semi-solid Section (For Ostomy gel only) D. No. 13130 dated 15-05-2025		
17	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [902-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13132 dated 15-05-2025	Glim Bromellin Gel Composition: Methyl sulfonyl methane (MSM), Glucosamine Sulfate, Devil's Claw, Butcher's Broom Extract, Pineapple Extract, Arnica Montana, Centella, Vitamin C, Boswellia, Ivy Extract, Calendula, Menthol Class: A Shelf Life: 2 Years Fee: 6000 Fee Slip No. 960956624319	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.
18	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [903-6L] Approved Sections:	Glim Vaginal Moisturizing Gel Composition: Aqua, Glycerine, Betaine, Panthenol, Hyaluronic acid, Allantoin, Aloe Vera Extract, Citric Acid, Preservative Class: A	REJECTED on following grounds: The product does not fall within the definition of a medical device under the Medical Device Rules, 2017.

	i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13133 dated 15-05-2025	Shelf Life: 2 Years Fee: 6000 Fee Slip No. 30742445	
19	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [904-6L] Approved Sections: i. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ii. Hydrocolloid and Soft Silicone Foam Dressings iii. Liquid Section (Diluents and cleaning solutions for analyzers) iv. General IVDs cleaning solutions. v. Disinfectant solutions for laboratory equipment. vi. Hematology diluent solutions. vii. Semi-solid Section (For Ostomy gel only) D. No. 13134 dated 15-05-2025	Bilirubin (Total and Direct) Kit Composition: RT: Sulfanilic acid 29 mmol/L, HCl 0.24 mol/L, Duposol 3% (w/v) RD: Sulfanilic acid 29 mmol/L, HCl 0.24 mol/L. RN: Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 39983455	REJECTED on following grounds; The requisite manufacturing facility is not mention The approved manufacturing sections do not cover the applied product, i.e., Bilirubin (Total and Direct) Kit, which is an IVD reagent for clinical chemistry testing.

20	Glitz Pharmaceutical, Plot No. 34-C to 41-C, Small Industrial Estate Bhimber Azad Kashmir (ELM-0096) [904-6L] Approved Sections: viii. Sachet/Dry Powder Section (For Hemodialysis Concentrates) ix. Hydrocolloid and Soft Silicone Foam Dressings x. Liquid Section (Diluents and cleaning solutions for analyzers) xi. General IVDs cleaning solutions. xii. Disinfectant solutions for laboratory equipment. xiii. Hematology diluent solutions. xiv. Semi-solid Section (For Ostomy gel only) D. No. 13134 dated 15-05- 2025	Amylase MR (Modified Rate) Kit Composition: R1: MES (2-(N-morpholino) ethanesulfonic acid) buffer 50 mmol/L pH 6.0, Calcium acetate 5 mmol/L, Sodium Chloride 300 mmol/L, Sodium thiocyanate 450 mmol/L, CNP-G3 2.25 mmol/L Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 4306521741	REJECTED on following grounds; The requisite manufacturing facility is not mention The approved manufacturing sections do not cover the applied product, i.e Amylase MR (Modified Rate) Kit which is an IVD reagent for clinical chemistry testing.
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DEFERRED CASES AGENDA:

EVALUATOR: MINAHIL JAVED (intern I)

Sr. No.	Importer name	Manufacture details	Name of MD/Class/Code/Shelf life/etc	Decision
1	M/s Varitron,, First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan. ELI-00510	Smith & Nephew INC, Endoscopy Division 150 Minuteman Rd, Andover, MA, USA as per fsc	Brand name: Biosure HA Screw Generic Name: Interference screws Class-D	Rejected on following grounds: Multiple codes are applied and anatomical region of applied model is not justified

	R& I dated 26-05-2025 Fee details: Amount paid: PKR 100,000 /- Paid Slip/ challan No. 705171599440	Legal Manufacturer: Smith & Nephew INC, Endoscopy Division 150 Minuteman Rd, Andover, MA, USA Manufacturer: Smith & Nephew INC Endoscopy 120 Forbes BLVD / 130 Forbes BLVD Mansfield, MA USA Arthrocare Corporation, B32.1, St2, Zona Franca Coyol, Coyol ALajuela Costa Rica Contract Manufacturer: Henke- Sass Wolf, GmbH Keltenstrasse 1 Tuttlingen, Baden- Wurttemberg Germany Manufacturer: Smith & Nephew INC, Endoscopy 76-S Meridian Ave Oklahoma City, Ok USA LOA Issue date: 02-06-2022 (Copy) Notarized Expiry NA FSC: USA Validity: 14-05-2026 (Copy) apostille attached ISO Validity: 06-03-2028 (Copy) apostille attached EU QA/ EC Certificate Validity: 02-03-2027 (Copy) Notarized	Shelf life: 03 Years Models/ Specification 72201771 72201772 72201773 72201774 72201775 72201776 72201777 72201778 72201779 72201780 72201781 72201782 72201783 72201784 72201785 72201786 72201787 72201788 72201789 72201790	Stability studies does not claim shelf life of the product
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2	M/s Varitron,, First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan. ELI-00510 R& I dated 26-05-2025 Fee details: Amount paid: PKR 100,000 /- Paid Slip/ challan No. 01172465	Legal Manufacturer: Smith & Nephew INC, Endoscopy 150 Minuteman Rd, Andover, MA, USA Manufacturer: Smith & Nephew INC Endoscopy 120 Forbes BLVD / 130 Forbes BLVD Mansfield, MA USA As per fsc Arthrocare Corporation, B32.1, St2, Zona Franca Coyol, Coyol ALajuela Costa Rica Contract Manufacturer: Henke-Sass Wolf, GmbH Keltenstrasse 1 Tuttlingen, Baden-Wurttemberg Germany Manufacturer: Smith & Nephew INC, Endoscopy 76-S Meridian Ave Oklahoma City, Ok USA LOA Issue date: 02-06-2022 (Copy) (Notarized) FSC: USA Validity: 14-05-2026 (Original) Apostille Attached ISO Validity: 06-03-2028 (Original) Notarized EU QA/ EC Certificate Validity: 02-03-2027 (Original) Notrized	Brand name: Biosure Regenesorb Interference Screw Generic Name: Interference screws 72204391 72204392 72204394 72204395 72204397 72204398 72204399 72204401 72204402 72204403 72204404 72204405 72204406 72204407 72204408 72204409 72204410 72204411 72204412 72204413 Class-D Shelf life: 03 Years Models/ Specification	Rejected on following grounds: Multiple codes are applied and anatomical region of applied model is not justified
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3.	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 93546341262	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	Brand Name: Dental Plaque Indicator Generic Name: Dental Plaque Indicator Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LLR-II 2ml, 5ml, 10ml, 15ml Shelf Life: -- 24 months	Approved as LLR-II 2ml, 5ml, 10ml, 15ml
4	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 023028028	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC:	Brand Name: Temporary Filling Material Generic Name: Temporary Filling Material Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LLR-VIII-B 2g, 5g, 10g, 15g, 30g, 50g Shelf Life: --24 months	Approved as LLR-VIII-B 2g, 5g, 10g, 15g, 30g, 50g

		Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026		
5	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 832026559	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	Brand Name: Temporary LC Resin Generic Name: Light Cured, Temporary Crown and Bridge Material Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LLF-I-A2, LLF-I-A3, LLF-I-A3.5, LLF-I-A4 Specification: 5g/tube, 10g/tube, 15g/tube , 30g/tube Shelf Life: --36 months	Approved
6	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical	Brand Name: Caries indicator Generic Name: Caries indicator Applied as: Single Class: A Models/Code/sizes (as per FSC & application)	Approved

	ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 7249810847	Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	LLR-III 2ml, 5ml, 10ml,15ml Specification: 5g/tube, 10g/tube, 15g/tube, 30g/tube Shelf Life: -- 24 months	
7	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore. ELI-01126	<u>Legal Manufacturer:</u> Pacotech Properties Inc. 515 S Mlk JR Ave Clearwater FL 33756 USA. FSC: USA. Validity: 08-02-2026.	Vitalmax 4000 Patient Cardiac Monitor Class-C Shelf Life: N/A Model: Not provided	Rejected on following grounds: Product name is not same as per FSC and USFDA certificate Models are also not mentioned on FSC AND USFDA certificate.
8.	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore. ELI-01126	<u>Legal Manufacturer:</u> Pacotech Properties Inc. 515 S Mlk JR Ave Clearwater FL 33756 USA. FSC: USA. Validity: 08-02-2026.	Vitalmax 800 Plus Patient Cardiac Monitor Class-C Shelf Life: N/A Model: Not provided	Rejected on following grounds: Product name is not same as per FSC and USFDA certificate Models are also not mentioned on FSC AND USFDA certificate.
9	PK Medi Engineering, House No. 38, 2nd Floor, Abbas Block, Mustafa Town, Wahdat Road, Lahore.	<u>Legal Manufacturer:</u> Pacotech Properties Inc. 515 S Mlk JR Ave Clearwater FL 33756 USA. FSC: USA.	Mini Pack 300 Patient Cardiac Monitor Class-C Shelf Life: N/A Model:	Rejected on following grounds: Product name is not same as per FSC and USFDA certificate

	ELI-01126	Validity: 08-02-2026.	Not provided	Models are also not mentioned on FSC AND USFDA certificate.
10	UDL Distribution (pvt) Ltd.1-D-13, Sector 30, Korangi Industrial Area, Karachi. (ELI-00073) Dossier# 1046-c Date:26-01-23 Submitted Fee: 50,000/-PKR Challan No.: 9691575380	Legal Manufacturer: Karex Industries Sdn. Bhd. PTD, 7906 & 7907 Taman Pontian Jaya BT.34 Jalan Johor,82000 Pontian,Johor, Darul Takzim, Malaysia <i>Manufacturing site:</i> Lot 2244,Batu 39 ½ Pontian Besar, 82000 Pontian,Johor, Darul Takzim, Malaysia FSC: Malaysia Valid till: 16-01-2027	Happy Life- Chahat (Natural Rubber Latex Male Condoms) Code: P53S Red Class-C Shelf Life: 05years	Approved
11	Applicant Name: M/s. Universal Enterprises Address of Importer: 29 Block 3, Overseas Cooperative Housing Society, Stadium Road, Karachi. (ELI-00079) R&I Date: 08 November 2022 Fee Challan No.: 3493585041 PKR: 25,000 Dated: 19-10-2022 Tracking ID ZS4-HDW-DAD2	Name of Manufacturer: M/s. Terumo Cardiovascular System Corporation located at 125 blue ball Rd Elkton, Maryland 21921, USA, Contract Manufacturing by: M/s Olympus Winter & Ibe GmbH, Kuchnstrasse 61, 2045 Hamberg Germany, LOA Validity: October 12, 2023 FSC Validity: 19-07-2023	Brand Name: ENDOSCOPE Class: B Shelf life: 03 Years Model: MCENDO550 MCENDO550R	Approved as ENDOSCOPE MCENDO550
12	Z&Z Traders, 15-Km Feroz Pur Road, Lahore. ELI-01310 5937-P 62,000/-	Legal Manufacturer: YASEE BioMedical Inc. No. 9 Xiuyuan Road, High-tech Industrial Development Zone, Qingdao City, 266000 Shandong Province China.	Blood Glucose Meter (GLM-71, GLM-72, GLM-73, GLM-74, GLM-75, GLM-76, GLM-77, GLM-78, GLM-79, GLM-73P, GLM-76L, GLM-77L, GLM-78L, GLM-79L).	Rejected on following grounds: LOA is not submitted, ISO Certificate is not notarized Essential performance checklist not provided

		FSC: China. Validity: 21-04-2025.	Class-C Shelf Life: 1000 Tests	
13	M/S Global Marketing Services (ELI- 00109) Date of R&I 23-09-2022 Fee Details: Paid Fee: 50,000/- Fee Challan No: 26511406800.	<u>Legal</u> <u>Manufacturer:</u> BioMérieux Inc. 100 Rodolphe Street Durham, North Carolina 27712 – USA <u>Manufacturing Site:</u> BioMerieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042 USA LOA Type: Scan copy of notarized copy. Validity date: 31-03-2026 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: CCIP France Issued date: 02-07-2024 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 17-12-2027	VITEK DENSICHEK Bacterial Suspension Turbidity Meter Apply as: System Shelf life: N/A Class: A Codes: VITEK DENSICHEK pod 423000 VITEK DENSICHEK Display Base 422220 VITEK DENSICHEK Connectivity Base 422221	Approved
14	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC &	Approved

	Fee: PKR 25,000/- Slip No. 6186940167	Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Application: • GM700 • GM700/7000 • GM700/500 • GM700D Applied as: Family Service life: 5 Years	
15	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 80159448	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-JR9000 Applied as: Single Service life: 10 Years	Approved

		Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027		
16	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 26704699806	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application): • GM500 • GM500D Applied as: Family Service life: 5 Years	Approved

		Type: Original Notarization: By CCPIT Validity: 25-03-2027		
17	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 4969679121	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application): • STARRY500/700 Applied as: Single Service life: 5 Years	Rejected On Following Grounds: Applied model is not mentioned in FSC
18	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China.	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A	Rejected On Following Grounds: Applied model is not mentioned in FSC

	Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 880337223587	• LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Models/Codes/Sizes (as per FSC & Application): HyGrand E Applied as: Single Service life: 5 Years	
19	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 4128868263	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By:	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application): - GM300 - GM300D Applied as: Family Service life: 5 Years	Approved

		CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027		
20	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 751115544	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application): • GM200 • GM200D Applied as: Family Service life: 5 Years	Approved

		• ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027		
21	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 4582242953	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • HyGrand700T Applied as: Single Service life: 10 Years	Rejected On Following Grounds: Applied model is not mentioned in FSC
22	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi.	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District,	Brand name: Grand Generic Name: Electric Operating Table	Approved

	ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 2495401336	Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Class: A Models/Codes/Sizes (as per FSC & Application): • GM-III Applied as: Single Service life: 10 Years	
23	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 7890249774	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce)	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • HyGrand-III Applied as: Single Service life: 10 Years	Rejected On Following Grounds: Applied model is not mentioned in FSC

		Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027		
24	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 1360367031	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-IV Applied as: Single Service life: 10 Years	Approved

		2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027		
25	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 67757463199	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-1A Applied as: Single Service life: 10 Years	Approved
26	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei	Brand name: Grand Generic Name: Electric Operating	Approved

	EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 086337614	Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-200A Applied as: Single Service life: 10 Years	
27	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 63158488	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-700 • GM-700A • GM-700G • GM-700Q • GM-700I	Approved

		• FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	• GM-700T Applied as: Family Service life: 10 Years	
28	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 8653230085	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-V Applied as: Single Service life: 10 Years	Approved

		Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027		
29	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 6260049746	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-500A Applied as: Single Service life: 10 Years	Approved

30	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 9858269079	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-800A Applied as: Single Service life: 10 Years	Approved
31	M/s Varitron, First Floor 60-D Zahoor Elahi road, Gulberg IV, Lahore, Pakistan. (ELI-00510) R&I Date: 04-07-2024 CMS tracking ID: XJP-7RN-N6M5	Legal Manufacturer: Varian Medical Systems, Inc Address: 3100, Hansen Way Palo Alto CA 94304 USA. CH REP: Siemens Healthineers Intl. AG. Hinterbergstrasse 14,6312 Steinhausen,	Brand Name: Halcyon Generic Name: Linear Accelerator Applied as: Single Class: C Models/Code/sizes (as per FSC & application): BR10, BR60, BR90 Shelf life N/A	Approved as single Linear Accelerator

	Fee: 50,000/-	Switzerland (CHRN-AR-2000721) Manufacturing Sites: Varian Medical Systems 2101 4th Avenue, Suite 100 SEATTLE, WA USA 98121 Varian Medical Systems China Co., Ltd. No.8 Yuncheng Street BDA Beijing, CHINA 100176 Varian Medical Systems Imaging Laboratory GmbH Taefernstrasse 7 Daettwil, Argovia, Aargau SWITZERLAND CH-5405 Varian Medical Systems, Inc 3290 Northside Parkway NW Suite 400 Atlanta, GA USA 30327 Varian Medical Systems, Inc 6212 Hellyer Ave San Jose, CA USA 95138 Varian Medical System Haan GmbH Rheinische Strasse 2 Haan, North RhineWestphalia GERMANY 42781 Varian Medical Systems, Inc Corredor TijuanaRosarito, No 21702 col. El Realito Tijuana, Baja California MEXICO 22250 Varian Medical Systems Haan GmbH Manufacturing site Kemnath Building C10 Roentgenstrasse		
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		19-21, Kemnath, Bavaria Germany 95478 LOA Notarization: Yes Valid: 30-06-2027 • FSC Legalized: Yes Issued by: USFDA Valid: 06-01-2027 ISO – Certificate: Notarization: Yes Valid till: 10-02-2027 EC Certificate: Valid till 15-07-2026		
32	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahr- e-Faisal, Karachi, 75350 (ELI- 00274) R&I Date: 08-07- 2025 Fee: 50000/- Slip # 68474964	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Original Issued By: NZ Medsfae Legalization: Apostille Validity: NA	Brand Name: F&P Breathing circuit Generic Name: Breathing circuit Applied as: Family Class: B Models/Code/sizes (as per FSC & application 950A40, 950A60, 950A61, 950A80, 950A81, 950A82, 950P40, 950P81, 950N40, 950N60, 950N61, 950N62, 950N80, 950N81, 950N82 Shelf Life: 3 years	Approved as kit with code 950A80: Adult Ventilator Dual Heated Circuit Kit

		• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026		
33	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 07-07-2025 Fee: 31000/- Slip # 373335688029	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Copy Issued By: NZ FSC Legalization: Apostille Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	Brand Name: F&P ergonomic T Piece circuit Generic Name: ventilator breathing circuit Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RD1300-10, RD1340-10, RD1350-10, RD1360-10 Shelf Life: 3 years	Rejected on following grounds: The applied product is not mentioned in Australia/RRA FSC

34	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 07-07-2025 Fee: 31000/- Slip # 5260038999	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Copy Issued By: Medsafe of Newzeland Legalization: Apostille Issued date: 20-12-2021 Validity: Not mentioned • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	Brand Name: F&P Humidification chamber Generic Name: Inspiratory line humidification chamber single use Applied as: Single Class: B Models/Code/sizes (as per FSC & application) MR250, MR225, MR225X Shelf Life: N/A	Approved as single with code 950ANZ Fph950 Respiratory Humidifier 230v
35	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 04-07-	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA	Brand Name: F&P Nasal vented mask Generic Name: CPAP/BPAP Nasal Mask Applied as: Single Class: B Models/Code/sizes (as per FSC &	Rejected on following grounds: The applied product is not mentioned in Australia/RRA FSC

	2025 Fee: 31000/- Slip # 977900311	Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Original Issued By: NZ MEdsafe Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	application RT042, RT042L Shelf Life: 5 years	
36	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahr- ah-e-Faisal, Karachi, 75350 (ELI- 00274) R&I Date: 04-07- 2025 Fee: 31000/- Slip # 67984583156	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA	Brand Name: F&P OPTIFLOW+ Nasal Cannula Generic Name: nasal oxygen cannula Applied as: Single Class: B Models/Code/sizes (as per FSC & application OPT942, OPT944, OPT946 Shelf Life: 5 years	Rejected on following grounds: The applied product is not mentioned in Australia/RRA FSC

		Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026		
37	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 07-07-2025 Fee: 31000/- Slip # 337321222979	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued by: 17-04-2025 Validity: NA Type: Copy Issued By: NZ	Brand Name: F&P Resuscitation mask Generic Name: Resuscitation mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RD800-EN, RD803-10, RD804-10, RD805-10, RD806-10, RD807-10 Shelf Life: 3 years	Rejected on following grounds: The applied product is not mentioned in Australia/RRA FSC

		Medsafe Legalization: Apostille Issued by: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026		
38	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrache-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 04-07-2025 Fee: 50000/- Slip # 58112133136	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Original Issued By: NZ Medsafe Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy	Brand Name: F&P Optiflow junior 2 cannula Generic Name: cannula Applied as: family Class: B Models/Code/sizes (as per FSC & application) OJR410, OJR410VT, OJR412, OJR412VT, OJR414, OJR414VT, OJR416, OJR416VT, OJR418, OJR418VT Shelf Life: 5 years	Rejected on following grounds: The applied product is not mentioned in Australia/RRA FSC

		Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026		
39	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 04-07-2025 Fee: 31000/- Slip # 676897783009	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	Brand Name: F&P Visairo RT076 Mask Generic Name: Visairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT076A, RT076B, RT076C Shelf Life: 3 years	Rejected on following grounds: The applied product is not mentioned in Australia/RRA FSC

Case No.3

S.#	Name of Importer	Manufacturer Details	Product Name	Decision of M-115
1.	Martin Dow Specialties (Pvt)	Legal Manufacturer: Ortho Clinical	VITROS Immunodiagnostic	The Board decided to call both M/s Martin Dow Speciality and

	Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Product Anti-HBC IgM Reagent, Calibrator & Control Cal: 1100387 Rgt: 8577413 Cont: 6800834 Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/- Date of submission December 2022 then 27-Sept-23	M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
2.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product, Anti-HBe Reagent, Calibrator & HBe Control Cal: 1523984 Rgt: 8864860 Cont: 6800837 Shelf life: Reagent: 52 weeks Calibrator: 52 weeks Control: 52 weeks Storage Conditions: Reagent: 2-8°C Calibrator: 2-8°C Control: +25°C Class: D Fees: 50,000/-	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.

3.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product HIV Combo Reagent & Calibrator Cal: 6842780 Rgt: 6842779 Shelf life: Reagent: 52 weeks Calibrator:52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/-	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
4.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023	VITROS Immunodiagnostic Product AFP Reagent & Calibrator: Cal: 1515154 Rgt: 1925551 Shelf Life: Reagent: 52 weeks Calibrator:52 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/- Date of submission 27-Sept-23	The Board decided to call both M/s Martin Dow Speciality and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.

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

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

		Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Fees: 50,000/-	weeks only.
9.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product HBeAg Reagent & Calibrator: Cal: 1914498 Rgt: 8211880 Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any. Martin Dow Specialty will provide undertaking of the stamp paper as required in Form 7A.
10.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission:	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested	VITROS Immunodiagnostic Product HBsAg ES Reagent, Calibrator & HBsAg Control : Vitros Immunodiagnostic Product HBsAg ES Reagent and Calibrator. Cal: 6802132 Rgt: 6802131 Cont: 6800598	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any. Martin Dow Specialty will provide undertaking of the stamp paper as required in Form 7A.

	27-Sept-2023	Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Shelf Life: Reagent: 56 weeks 52 weeks Calibrator:56 weeks 52 weeks Control: 56 weeks 52 weeks Storage Conditions: 2-8°C Class: D Fees: 50,000/-	
11.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product hs Troponin-I Reagent & Calibrator: Cal: 6844437 Rgt: 6844436 Shelf Life: Reagent: 52 weeks Calibrator:60 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
12.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics	VITROS Immunodiagnostic Product FSH Reagent & Calibrator: Cal: 1901263 Rgt: 1931922 Shelf Life: Reagent: 52 weeks 36 weeks Calibrator:52 weeks	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter

	Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	36 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	issued by the legal manufacturer, if any.
13.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	VITROS Immunodiagnostic Product LH Reagent & Calibrator: Cal: 1090133 Rgt: 1350198 Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
14.	Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road,	Legal Manufacturer: Ortho Clinical Diagnostics ,100 Indigo Creek Drive Rochester, NY, 14626 USA	VITROS Immunodiagnostic Product Progesterone Reagent & Calibrator: Cal: 8254898 Rgt: 1938570 Shelf Life:	The Board decided to call both M/s Martin Dow Specialty and M/s Sieco Scientific Traders, for personal hearing with the direction to present following documents before the Board; i. Valid, notarized Letter of

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

Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 Initial Submission: 02-Dec-2022 Final Submission: 27-Sept-2023	Rochester, NY, 14626 USA Manufacturing site: Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Embassy attested Free Sale Certificate Ortho Clinical Diagnostics Felindre Meadows Pencoed Bridgend CF35 5PZ United Kingdom Date of Issue: 04-July-2023 Validity: 26-May-2025	Cal: 1113596 Rgt: 1849793 Shelf Life: Reagent: 52 weeks Calibrator: 52 weeks Storage Conditions: 2-8°C Class: C Fees: 50,000/-	direction to present following documents before the Board; i. Valid, notarized Letter of Authorization issued by the legal manufacturer abroad. ii. Notarized Termination letter issued by the legal manufacturer, if any.
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Proceedings and decision of 139th MDB:

- The counsel namely, Mr. Shoukat Ali Joiya Advocate High Court and Mr. Ameer Hamza appeared before board on behalf of M/S Seico Scientific traders and informed that its LOA has been expired and is not valid since 2023. He informed that they have filed the case in the court of Law for financial adjustment with manufacturer. The Board observed that the MDB DRAP has nothing to do with the financial matters of firms. The Counsel further complained that M/S Martin Dow is importing above mentioned products illegally for which Board directed him to file complain with documentary evidence before the forums concerned i.e. QA< Division & Provincial health authorities.

Decision of M-139:

The MDB decided to cancel the enlistment/registration of above-mentioned products in name of M/S Seico Scientific traders by Ortho Clinical Diagnostics due to termination of LOA and approved the same in favor of Martin Dow.