

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

DECISIONS OF 105th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 23-10-2025 (MANUAL APPLICATION)

105th 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 16th October, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr. Salik Zahid, CDI, Nominee of DGHS Balochistan	Member (attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
4.	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)
5.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
6.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
9.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)
10.	Prof Dr M Nadeen Ahmed, Department of Radiology, Agha Khan University Hospital, Karachi.	Member (attended meeting through videolink)

11.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
12.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary
13.		

Sr.No.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-I
2.	Mr. Waqar Ahmad	Deputy Director-II
3.	Mst. Sadaf Ahmad	Deputy Director-III
4.	Mr. Dr. Ghayoor Ahmad	Deputy Director-IV
5.	Mr. Muhammad Ashfaq	Deputy Director-VI
6.	Mr. Hafiz Muhammad Asif Iqbal	Deputy Director-VII
7.	Mr. Rana Ahsan-ul-Haq Athar	Deputy Director-VIII
8.	Mr. Muhammad Amin	Deputy Director-IX
9.	Mr. Ammar Ashraf Awan	Deputy Director-X
10.	Mr. Dr. Hanif Ullah	Deputy Director-XI

(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

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

(FRESH CASES-ESTABLISHMENT LICENSE IMPORT)

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Science&technologies, office/Godown: office No. FLT 257C 2nd floor Opposite Zain Marriage Hall Khayaban-e-Sir Syed Rawalpindi Rawalpindi	Kifayat Ullah Medical Laboratory Technology	Approved
2.	M/s Ahmed Traders, Shop No # 3 Office/ Godown: Al Ashraf Plaza, Opposite to the Educator School , Range Road, Rawalpindi, Cantt.	Ahmad Raza Pharm-D	Approved
3.	M/s Endo Urology Solution, Office/Godown: W-0, 24-C, Commercial Area, Hasmi Garden, Bahawalpur.	Muhammad Shoaib Akmal Bachelor of Science in Biochemistry	Approved
4.	M/s oriental and Co, Office House # 986 Block 4, 1st Floor Shah Faisal Colony Karachi.	Muhammad Amir BS Biomedical Engineering	Rejected. The board considered the report and observed that the firm is not interested in

	Godowon: Shop No. 1 & 2 House NO. A-3, Rizwia Housing Project, Al-Falah Society, Karachi		obtaining establishment license to import medical devices therefore it was decided to reject application of the firm to obtain establishment license to import medical devices
5.	M/s Zonya Ipex, 43, Sector-2, street 12, HBCHS, Hub river road, Karachi.	Shariq shoukat BS Biomedical Engineering	Rejected. The board considered the report and observed that the firm is not interested in obtaining establishment license to import medical devices therefore it was decided to reject application of the firm to obtain establishment license to import medical devices.

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

(FRESH RENEWAL CASES- ESTABLISHMENT LICENSE IMPORT)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s 3J Diagnosticcs, Office: Office No. 5, 2 nd Floor, Liberty Plaza, Opposite Rawalpindi General Hospital (RGH) , Murree road, Rawalpindi Godown: Office No. 9, 2 nd Floor, Liberty Plaza, Opposite Rawalpindi General Hospital (RGH) , Murree road, Rawalpindi ELI-00325	Mukhtiar Ahmad Medical Lab technologist	Johnson John	Approved
2.	M/s Meher Enterprises, Office: First Floor Az-Zainab Court Campbell Street Karachi Godown: A-IV 1st Floor, Azzainab Court, Campell Street, Karachi. Additional godown: A-VI 1st Floor, Azzainab Court, Campell Street, Karachi. ELI-00241	Shah Noor Bashir Pharm-D	Muhammad Anwar Idrees	Approved

3.	M/s Qualitron Corporation Office/Godown: E-172, Block 2, Tariq Road, P.E.C.H.S., Karachi ELI-00550	Muhammad Umair Pharm-D	Shahzad Tazam Shaikh	Approved
4.	M/s UNIQUE VISUAL SYSTEM Office/Godown: L-18, Block 17, 2 nd Floor, Gulshan-e-Iqbal, Karachi. ELI-00449	Samia Faisal Hada Pharm-D	MUHAMMAD JAVED Mr. Abdul Samad Mr. Muhammad Raees	Approved
5.	M/s UDL DISTRIBUTION (PVT) LTD Office: 1-D-13, SECTOR 30, KORANGI INDUSTRIAL AREA, KARACHI. Godown: S-8/A Translyari Quarters, S.I.T.E Near Gul Bai In Line of Meezan Bank Head Office, KARACHI ELI-00073	Amna Pharm-D	Tahir Khaliq Arshad Abdullah Nasir Abdullah Ahsan Khaliq	Approved
6.	M/s. Al Qazi Marketing Group Office/Godown: 10-11-E, Karachi Market, Khyber Bazar, Peshawar, Pakistan ELI-00540	Saif Ullah Pharm-D	Ihsan-ul-Haq Inam-ul-Haq	Approved
7.	M/s. Heartec Office/ Godown: First Floor, 734 Shadman 1 inside Alam Audiology Clinic, Faisalabad ELI-00375	Touqeer Hanif BS Hons in Medical Laboratory Technology	Saima Afzaa	Approved
8.	M/s. Global Marketing Services Office: 111,Hali Road Westridge 1 Cantt Rawalpindi,Pakistan Godown: plot. no. 36A, PSIC, SIE, Taxila Rawalpindi ELI-00109	Wajiha Saleem Pharmacist	Zafar Mahmood Muhammad Ayub Naheed Dilshad	Approved
9.	M/s. Digionics Pvt Ltd Office/Godown: 15 Shadman, Jail Road, Lahore ELI-00371	Shanzaib Bint-e- Naeem Pharm D	Riaz Masood Abbasi Qasim Masood	Approved

10.	M/s. Bristol Mayer Biotech Pakistan (Pvt) Ltd Office / Godown: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt ELI-00093	Ume Kalsoom Pharm-D	Abdul Razaq Khan Zaheer Ahmed khan Munawer Ali Tariq	Approved
11.	M/s Friends Traders, Office: Peshawar Medical Centre Hussain Plaza, Shoba Chowk Near Khyber Bazar Peshawar Godown: Lodhi Katrage, Old Bara Road, University Town, Peshawar ELI- 00457	Syed Ahmed Shah Bio-Medical Engineer	Asad Ullah Khan Lodhi	Approved
12.	M/s. Zaidi Traders, Office/ Godown F-263, Satellite Town, Rawalpindi. ELI-000328	Muhammad Raza Zaidi, Doctor of Medical Laboratory Sciences	Syed Masood Akhtar Zaidi Syed Yousaf Raza Zaidi	Approved
13.	M/s K.M Enterprises, Office/Godown: KM Mansion 605-D block M.A Johar Town Lahore. ELI-00054	Noor Safia Pharm-D	Khalid Mehmood	Approved. The firm shall submit undertaking that the premises shall not be used for residential purposes and inspectors can enter premises without hindrance.
14.	M/s AA Enterprises, Office: 57, 15-16 First Floor Mobi Plaza, Haider Road, Saddar, Rawalpindi Godown: Plot No. 4, House No. 286/4 , Main Peshawar Road, Rawalpindi Westridge, Adjacent to Am-Anglo School, Near Polo Ground, Rawalpindi. ELI-00525	Abu Bakar Siddique Bs Bio medical Engineering	Muhammad Waqas	Deferred for approval of technical staff and undertaking that the premises shall not be used for residential purposes and inspectors can enter premises without hindrance
15.	M/s. Meritorious Business Solutions (Pvt.) Ltd. Office/Godown: Office # 202, 2nd Floor, 153-D, Block-D, Civic Center, Phase-4, Bahria Town, Rawalpindi. ELI-00208	Muhammad Haris Mustaib Bio Medical Engineer	Mohammad raza jaffary	Approved

16.	M/s. ANWAR & SONS Office: Apt #10, Safari Villas 2 Commercial Complex, Phase 7 Bahria Town, Rawalpindi Godown: LG 1 & 2, Asian Business Centre, GT Road (Main Gate Bahria Town Phase 7) ELI-00017	Gohar Abid Pharmacist	Tahir Mahmood Khan	Approved
17.	M/s. Blazon Diagnostic Office no. 102, Muhammadia Plaza, Gordon College, Road Godown: Blazon House No.45, 46, 47, Rawalpindi cricket stadium, Double road, Rawalpindi ELI-00307	Muhammad Asif Pharm-D	Ahmar Zaman Khan	Approved
18.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi Godown: B-41, Street No. 27, Sector F, DHA Phase 1, Islamabad ELI-00327	Muhammad Aqib Shahzad Pharmacist	Shagufta Naz	The board considered the findings of the insepector and found gross viloations of the Medical Devices Rules 2017 and Drap Act 2012. Therefore the board decided to issue show cause notice to the firm.
19.	M/s. Promed International Office/Godown: Cb-6349, Amar Pak Plaza, Jhelum Road, Rawalpindi, Pakistan ELI-00000	Arooj Khalid alvi Pharmacist	Ahmed Jamal	The board considered the findings of the insepector and found gross viloations of the Medical Devices Rules 2017 and Drap Act 2012. Therefore the board decided to issue show cause notice to the firm.

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

Deferred Renewal Cases:

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Bay G Pharma, House No. 103A, A-Block, Satellite Town, Rawalpindi (ELI- 00016)	Ms. Bushra Ansari Pharm-D	Abdul Farooq Abdul Shakoor Awan	Approved
2.	M/s Promax Technology Pakistan, Suite No. 13, 2 nd Floor Majeed Plaza Bank Road, Saddar Rawalpindi (ELI – 00014)	Fariha Khan Pharm-D	Akhter Ehsan	Approved

REGISTRATION OF MEDICAL DEVICES FOR IMPORT

Fresh Application Submitted in Hard (Evaluator Ammar Ashraf Deputy Director MDMC)

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 78960163728	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) IDW01, IDW02, IDW03 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

		declaration from M/s Farshine Medical Technology Co. Ltd., “ that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
2.	M/s Link Traders, Office No.1& 2, Mezzanine Floor, Ahmad Trade Center, 2- B Commercial Area Nazimabad No, 2 Karachi. (ELI- 00727) R&I detail 25-08-2022 Fee: 20,000/- Slip: 23050005309 Fee: 11,000/- Slip: 783236993 Fee: 21,200/- Slip: 2033558701	Name of Manufacturer: Ortus Medi-Tech Co., Ltd. 203, Building C4, Tong Fu Yu Industrial Park, FuPing Road, Pin Di, Longgang 518117 Shenzhen, P.R. China. • LOA Type: Copy Attested By: CCPIT Validity: 01-06-2027 • FSC (China) Type: Copy Issued By: Market Supervision Administration Legalization: Not Legalized Validity: 28-02-2025 • FSC (Germany) Type: Copy of legalized Issued By: M/o Justice and Consumer Protection Legalization: Legalized Issue Date: 05-04-2017 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Validity: 06-08-2025 • CE Certificate Type: Copy Notarization: Not notarized Validity: 31-12-2028	Brand name: ORTUS Generic Name: Disposable Peripheral Guide Wire Applied as: Family Class: B Model/Codes/Sizes as Per FSC (Germany) and application: • OM-GW-P14150S • OM-GW-P14180S • OM-GW-P18150S • OM-GW-P18180S • OM-GW-P25150S • OM-GW-P25180S • OM-GW-P28150S • OM-GW-P28180S • OM-GW-P32150J • OM-GW-P32150S • OM-GW-P32260S • OM-GW-P35150J • OM-GW-P35260J • OM-GW-P35150S • OM-GW-P35260S • OM-GW-P38150J • OM-GW-P38150S • OM-GW-P38260S • OM-GW-P38180S • OM-GW-P38260J Shelf life: 3 Years	Approved
3.	M/s Link Traders, Office No.1& 2, Mezzanine Floor, Ahmad Trade Center, 2- B Commercial Area Nazimabad No, 2 Karachi. (ELI- 00727)	Name of Manufacturer: Ortus Medi-Tech Co., Ltd. 203, Building C4, Tong Fu Yu Industrial Park, FuPing Road, Pin Di, Longgang 518117 Shenzhen, P.R. China.	Brand name: ORTUS Generic Name: Disposable Hemostasis Valve Kit	Approved

	R&I detail 25-08-2022 Fee: 5,000/- Slip: 857157773	• LOA Type: Copy Attested By: CCPIT Validity: 01-06-2027 • FSC (China) Type: Copy Issued By: Market Supervision Administration Legalization: Not Legalized Validity: 28-02-2025 • FSC (Germany) Type: Copy of legalized Issued By: M/o Justice and Consumer Protection Legalization: Legalized Issue Date: 05-04-2017 Validity: Not mentioned • ISO Certificate Type: Copy Notarization: Not Validity: 06-08-2025	Applied as: Kit Class: A Model/Codes/Sizes as Per FSC: HV01, HV02 & HV03 Shelf life: 5 Years	
4.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 381024934787	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) JDW07, JDW06, JDW05, JDW04, JDW03, JDW02 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		on medical devices. They are in process for the renewal of our CE certificate.		
5.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 381024934787	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Artificial Vertebral Replacment Applied as: Family Class: C Models/Code/sizes (as per FSC & application) JCV-01, JCV-02, JCV-03, JCV-04 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
6.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 7252837416	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) JMQ08, JMQ07, JMQ06, JMQ05, JMQ04, JMQ03, JMQ02, JMQ01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
7.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 27829315931	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) INQ01, INQ02 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system
8.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address:	Brand Name: Farshine Generic Name:	Approved. Firm shall submit undertaking that the applied product will be compatible

	ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 7912139354	No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “ that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Craniomaxillofacial Internal Fixation System Applied as: Single Class: C Models/Code/sizes (as per FSC & application) LHAQ01 Shelf Life: 5year	and will only be used with the Farshine system
9.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 7254983183	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024	Brand Name: Farshine Generic Name: Spinal Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) RCA01,RCA02, RCA03, RCA04, RCA05 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “ that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
10.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 965331199	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Original Notarization: Notarized Validity: 18-03-2030 • FSC Type: Original Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Original Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “ that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Single Class: C Models/Code/sizes (as per FSC & application) CV-I Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
11.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 965331199	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Single Class: C Models/Code/sizes (as per FSC & application) IMQ01	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		• FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Shelf Life: 5year	
12.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 655397348	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) ZCV-01, ZCV-02, ZCV-03, ZCV-04 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

		process for the renewal of our CE certificate.		
13.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 51415510053	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) JNQ01. JNQ02, JNQ03 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system
14.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 620,000 vide deposit slip no. 94188296496	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale:	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) THAQ01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

		ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
15.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 88588450	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Single Class: C Models/Code/sizes (as per FSC & application) JZ01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system
16.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be

	ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 665668978476	Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Applied as: Single Class: C Models/Code/sizes (as per FSC & application) YZ01 Shelf Life: 5year	used with the Farshine system
17.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 5299626801	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) MSS-01, MSS-02, MSS-03, MSS-04, MSS-05, MSS-06 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

		declaration from M/s Farshine Medical Technology Co. Ltd., “ that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
18.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 050984835496	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “ that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Artificial Vertebral Replacement Applied as: Family Class: C Models/Code/sizes (as per FSC & application) YCV-01, YCV-02, YCV-03, YCV-04, YCV-05 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system
19.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 121049907825	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Single Class: C Models/Code/sizes (as per FSC & application) LN-01 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

		Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
20.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 26853109172	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Interbody Fusion Cage System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) LV-I, LV-II, LV-III Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

21.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 63815712761	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: 3D-Printed Porous Hip System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) HJ-I, HJ-II, HJ-III, HJ-IV Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system
22.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 972932766	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy	Brand Name: Farshine Generic Name: 3D-Printed Titanium Porous Artificial Vertebral Replacement Applied as: Single Class: C Models/Code/sizes (as per FSC & application) CV Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will are compatible and will only be used with the Farshine system

		Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.		
23.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434 R&I Date: 01-07-2025 Fee: Rs. 100,000 vide deposit slip no. 448267529195	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Brand Name: Farshine Generic Name: Spinal Internal Fixation System Applied as: Family Class: C Models/Code/sizes (as per FSC & application) RLP01, RLP02, RLP03, RLP04, RLP05, RLP06, RLP08 Shelf Life: 5year	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system
24.	Farshine Medical Technology Co. Pvt., Ltd., Office No. 3, 2nd Floor, Plot No. 20-D, Sharja Plaza, G10 Markaz, Islamabad ELI-01434	Name of Manufacturer: Farshine Medical Technology Co. Ltd., Address: No. 58 Jinshui West Road, Ningxiang High-Tech Industrial Park, Changsha City, Hunan Province, China	Brand Name: Farshine Generic Name: Craniomaxillofacial Internal Fixation System Applied as: Single Class: C	Approved. Firm shall submit undertaking that the applied product will be compatible and will only be used with the Farshine system

	R&I Date: 01-07-2025 Fee: Rs. 62,000 vide deposit slip no. 321766868049	LOA Type: Copy Notarization: Notarized Validity: 18-03-2030 • FSC Type: Copy Issued By: Hunan Medical Product Administration Legalization: Apostille Validity: 07-04-2027 Free sale: ISO – Certificate: Type: Copy Notarization: Yes Validity: 07-04-2028 CE certificate: Notarized copy of CE certificate, valid till 27-05-2024 has been submitted along with declaration from M/s Farshine Medical Technology Co. Ltd., “that we have engaged 3 rd party (Uden Adriatic d.o.o) a notified body on 05-12-2020 for regulation on medical devices. They are in process for the renewal of our CE certificate.	Models/Code/sizes (as per FSC & application) DHAQ01 Shelf Life: 5year	
25.	M/s 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) R&I Date: 10-07-2025 Fee: 31,000/- Slip # 83157121383	Name of Manufacturer: Legal Manufacturer: ShenzhenEver-Blue Biotech Co., Ltd, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong Manufacturing Site: Commissioned Production Enterprise): SHENZHEN YHLO BIOTECH CO., LTD. Address: Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin)	Brand Name: Autoimmune Diabetes Multi Control Generic Name: Immunoassay Controls (Negative: 2 x 2.0ml) (Positive: 2 x 2.0ml) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): CC829 Shelf Life: 48 Months	Approved

		RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 20-12-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 14-11-2025 CE certificate: N/A		
26.	M/s 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) R&I Date: 17-07-2025 Fee: 31,000/- Slip # 7526832805	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A	Brand Name: iFlash-17 α -OH-P Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): C86061 Shelf Life: 18 Months	Approved
27.	M/s 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) R&I Date:	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China	Brand Name: iFlash-Androstenedione Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit)	Approved

	17-07-2025 Fee: 31,000/- Slip # 426434124	LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A	Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): C86062 Shelf Life: 18 Months	
28.	M/s 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) R&I Date: 17-07-2025 Fee: 31,000/- Slip # 148876279103	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A	Brand Name: iFlash – AMH Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): C86316 Shelf Life: 18 Months	Approved
29.	M/s Martin Dow Specialties (Pvt) Limited	Name of Manufacturer:	Brand Name: iFlash – Folate	Approved

	7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi (ELI-00160) R&I Date: 17-07-2025 Fee: 31,000/- Slip # 44570875	SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A	Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): C86318 Shelf Life: 18 Months	
30.	M/s 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) R&I Date: 17-07-2025 Fee: 31,000/- Slip# 99766340445	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy	Brand Name: iFlash-25-OH Vitamin D Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): C86319 Shelf Life: 18 Months	Approved

		Notarization: No Validity: 09-06-2028 CE certificate: N/A		
31.	M/s 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) R&I Date: 17-07-2025 Fee: 31,000/- Slip# 375652935	Name of Manufacturer: SHENZHEN YHLO BIOTECH CO., LTD, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China LOA Type: Copy Notarization: No Validity: 31-12-2025 • FSC Type: Copy Issued By: Provincial supervision body (Country of Origin) RRA FSC issued by Australian Government (TGA) Legalization: No Validity: 12-01-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 CE certificate: N/A	Brand Name: iFlash-Anti-TSHR Generic Name: Chemiluminescent Immunoassay (2 x 50 Tests/Kit) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): C86049-S Shelf Life: 18 Months	Approved
32.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150) R&I Date: 17-06-2021 Fee: 5,000/- Slip# 50441495384	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmö Sweden LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Brand Name: Sara Combilizer and Sara Stedy, Sara Stedy Compact Generic Name: Standing and Raising Aid Applied as: Single Class: A Models/Code/sizes (as per FSC & application): Sara Stedy NTB2000 Sara Stedy Compact NTB 3000 Shelf Life: 10 years	Deferred for clarification for applying different products and models in the same application shall be provided.

33.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150) R&I Date: 17-06-2021 Fee: 5,000/- Slip# 8517158444	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Brand Name: Concerto Generic Name: Shower Trolley Class: A Models/Code/sizes (as per FSC & application): Concentro: BABxxX-XX Shelf Life: 10 years	Approved
34.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150) R&I Date: 17-06-2021 Fee: 5,000/- Slip# 988217621186	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Brand Name: Carevo Generic Name: Shower Trolley Class: A Models/Code/sizes (as per FSC & application): BAC11xX-XX Shelf Life: 10 years	Approved
35.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150) R&I Date: 17-06-2021 Fee: 5,000/- Slip# 988217621186	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy	Brand Name: Sara Combilizer Generic Name: Standing and Raising Aid Class: A Models/Code/sizes (as per FSC & application): APA1000xx Shelf Life: 10 years	Approved

		Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A		
36.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150) R&I Date: 22-03-2021 Fee: 5,000/- Slip# 2078014	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Brand Name: Miranti Hygiene Lifters Generic Name: Standing and Raising Aid Class: A Models/Code/sizes (as per FSC & application): CEB8xxX-XX Shelf Life: 10 years	Approved
37.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore (ELI-0000150) R&I Date: 22-03-2021 Fee: 5,000/- Slip# 2078013	Name of Manufacturer: ArjoHuntleigh AB Address: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Legalized Validity: 31-12-2025 • FSC Type: Copy Issued By: Swedish Medical Products Agency Legalization: Legalized Issued date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 05-01-2027 CE certificate: N/A	Brand Name: Bolero Hygiene Lifters Generic Name: Standing and Raising Aid Class: A Models/Code/sizes (as per FSC & application): CEB6xxx-Xx Shelf Life: 10 years	Approved

DEFERRED CASES IMPORT (Ahsan Ul Haq Athar)

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Akash Traders, Flat No. 302, Office No. 07, Hina Palace, Housing Road, Civil Line Clifton, Karachi (ELI-00585)	Eyeol UK Ltd. 8 Apex Business Centre, Boscombe Road, Dunstable, UK LU5 4SB	EyeRhex (Trypan Blue Ophthalmic Solution)	Approved
2.	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju-cho, Adachi-ku, Tokyo 120-0035, Japan Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650, Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory LOA valid till 31.12.2027 FSC Japan Issue date 01.01.2025	TOP-5530 Syringe Pump 9018.1900 Class C Shelf life 6 years	Deferred for the following: 1. The LOA has been issued by Medicalnet International Singapore. 2. FSC states that the medical devices exported by TOP Corporation is manufactured under our supervision as stipulated in PMOT act of Japan. It does not clarify product marketing status in Japan. The availability status in the market of Japan is not clear. 3. copy of ISO is not notarized. 4. On FSC two manufacturing sites while as per Form 8A only one registrations site.
3.	Noor International Noor House, 29-D, Block-6, PECHS, Karachi -75400 (ELI-00061 Fee 62000/-	Top Corporation, 19-10 Senju- Nakai-Cho, Adachi-Ku Tokyo 120-0035, Japan Inside Country of Origin: Top Corporation Koshigaya Factory, 40-34 Noborito-cho, Koshigaya-shi Saitama, Japan Meditop Corporation (M) SDN. BHD. (Plant 2), No. 3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650,	Infusion Pump MJ-210 Class C Shelf life 6 years	Deferred for the following: 1. The LOA has been issued by Medicalnet International Singapore. 2. FSC states that the medical devices exported by TOP Corporation is manufactured under our supervision as stipulated in PMOT act of Japan. It does not clarify product marketing status in Japan. The availability status in the market of Japan is not clear. 3. copy of ISO is not notarized.

		Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia Factory FSC issue date: 22-01-2025		4. On FSC two manufacturing sites while as per Form 8A only one registrations site.
4.	Applicant: M/s. Moody Global Services Address: Office No. 14, 2nd Floor, Mujahid plaza, Jinnah Avenue, Blue area, Islamabad, 44000, Pakistan. License No. ELI-00926 R&I date: Not clear. Track ID: 7MP-68L-EWQ4 Fee: PKR 5000/- Slip: 33438994 Dated: 08-12-2022	Legal Manufacturer Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A 4th floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong province, 518055, P.R China. FSC Country of origin (China) Validity period: 24-09-2022 FSC Reference country (Germany) Date of issuance: 22-06-2021 LOA validity: 31-12-2027	Brand name: Lifotronic Generic name: HBA1c Reagent Kits (IEC) Size/specification: ☐ 100T/box ☐ 200T/box ☐ 400T/box Class: A Shelf life: 18 months	Approved
5.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 666882948276 25000 dated 24/10/2023	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	Brand name: Lifotronic Generic name: LUTEINIZING HORMONE (Electrochemiluminescence Immunoassay) Size/specification: 50T, 100T, 2x100T Class: B Shelf life: 12 months	Approved.
6.	M/s Moody Global Services Address: Office No	Name: Shenzhen Lifotronic Technology Co., Ltd	Brand name: Lifotronic Generic name: CHOLYGLYC	Approved.

	14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 0028351879 25000 dated 24/10/2023	Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	INE -CG (Electrochemil uminescence Immunoassay) Size/specifica tion: 50T, 2x50T, 100T, 2x100T Class: B Shelf life: 12 months	
7.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 01539320195 25000 dated 24/10/2023	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	Brand name: Lifotronic Generic name: ESTRADIOL (Electrochemil uminescence Immunoassay) Size/specifica tion: 50T, 100T, 2x100T Class: B Shelf life: 6 months	Approved.
8.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 01539320195	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity:	Brand name: Lifotronic Generic name: TOTAL TRIIODOTHY RONINE KIT (Electrochemil uminescence Immunoassay) Size/specifica tion: 100T, 2x100T Class: B	Approved

	25000 dated 24/10/2023	31/12/2027 ISO13485 VALID until 25.4.24	Shelf life: 12 months	
9.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 741065938 25000 dated 24/10/2023	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	Brand name: Lifotronic Generic name: PROCOLLAG EN III N TERMINAL PEPTIDE (PIIINP) (Electrochemil uminescence Immunoassay) Size/specification: 50T, 2X50 T , 100T, 2x100T Class: B Shelf life: 15 months	Approved.
10.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 741065938 25000 dated 24/10/2023	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	Brand name: Lifotronic Generic name: FOLLICLE STIMULATING HORMONE (Electrochemiluminescen ce Immunoassay) Size/specification: 50T, 2X50 T , 100T, 2x100T Class: B Shelf life: 14 days	Approved.
11.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza,	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008	Brand name: Lifotronic Generic name: HYPERSENST IVITYC- REACTIVE	Approved.

	Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 R&I detail: 26/10/2023 Fee Challan no.: 6876681318 25000 dated 24/10/2023	Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	PROTEIN (hs CRP) Assay kits(Lateral Flow Immunoassay) Size/specification: 1X 100T, 2X 100T, Class: B Shelf life: 10 months	
12.	M/s Moody Global Services Address: Office No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan License No. ELI 00926 Receipt No. R&I detail: 26/10/2023 Fee Challan no.: 15003630924 25000 dated 24/10/2023	Name: Shenzhen Lifotronic Technology Co., Ltd Address: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China FSC Origin. China validity: 07/11/2022 LOA validity: 31/12/2027 ISO13485 VALID until 25.4.24	Brand name: Lifotronic Generic name: FOLATE (Electrochemiluminescence Immunoassay) Size/specification: 50T, 100T Class: B Shelf life: 12 months	Approved.
13.	Cardiac Care, 848-C, Shadman-1, Lahore-54610, Pakistan. ELI-00070	Legal Manufacturer: HSINER Co., Ltd 312, Jhongshan Rd., Shengang Dist, Taichung City 426, Taiwan. FSC: Germany Date of Issuance: 14-11-2019.	Oxygen Mask and Accessories Oxygen delivery mask Class-B Shelf Life: 3 Years Codes as per FSC	Rejected in the light of MDB decision taken in its 90 th meeting.
14.	Cardiac Care, 848-C, Shadman-1, Lahore-54610, Pakistan. ELI-00070	Legal Manufacturer: HSINER Co., Ltd 312, Jhongshan Rd., Shengang Dist, Taichung City 426, Taiwan. FSC: Germany	HME and HMEF Humidifiers Heat / Moisture Exchange Class-B Shelf Life: 3 Years	Rejected in the light of MDB decision taken in its 90 th meeting.

		Date of Issuance: 14-11-2019.	Codes as per FSC	
15.	Cardiac Care, 848-C, Shadman-1, Lahore-54610, Pakistan. ELI-00070	Legal Manufacturer: HSINER Co., Ltd 312, Jhongshan Rd., Shengang Dist, Taichung City 426, Taiwan. FSC: Germany Date of Issuance: 14-11-2019.	CPAP/VPAP MASK Positive airway pressure mask. Class-B Shelf Life: 3 Years Codes as per FSC	Rejected in the light of MDB decision taken in its 90 th meeting.
16.	Cardiac Care 848-C Shadman-I Lahore. ELI-00070 5984-P 31,000/-	Legal Manufacturer: EUROSETS S.r.l. Strada Statale 12, n°143 41036 Medolla (MO) Italy. FSC: Italy. Date of Issuance: 12-07-2024. LOA validity 31-12-2026 ISO 13485 validity 24-08-2025 CE certificate validity 26-05-2024 with extension notification.	HORIZON AF PLUS Oxygenator Class-B Shelf Life: 3.5 years Model: AG5300	Deferred for the followings: 1. clarification that firm claimed that original documents were submitted with Kompass A. L. One vide R&I dated 01.07.2024 while FSC issuance date is 12.07.2024. 2. The Form 7A is without undertaking and annexures. 3. The name of device on submitted Form 7A is KOMPASS A.L. ONE oxygenator.
17.	Aston Medical Pakistan 4-A 4th Floor 38c Bukhari Commercial, Lane 8, Phase 6, Dha, Karachi (ELI-00797 Date of R&I 30-04-2025 Fee Details: Paid Fee: 62030/- Fee Challan No: 135864189	Semikal Teknoloji Sanayi VE Ticaret Anonim Sirketi, AOSB 3, Kisim 25, Cad. No: 14/11, Dosemealti, Antalya/Turkiye LOA Validity: 25-03-2033 (notarized) FSC Valid till: 30-01-2028 (notarized) ISO Validity: 17-03-2026 (notarized) EC (FQA) certificate 27- 05-2024 (notarized) Design Examination Certificate valid up to 27- 05-2024 (notarized)	Sectalon Intra-Articular Gel Sodium Hyaluronate 30mg/2ml, Sodium Hyaluronate 40mg/2ml, Sodium Hyaluronate 60mg/2.5ml, Sodium Hyaluronate 75mg/3ml, Sodium Hyaluronate 90mg/3ml, Sodium Hyaluronate Cross Linked % 2.4/2.5ml, Sodium Hyaluronate Cross Linked % 2.5/3ml, Sodium Hyaluronate Cross Linked % 3/3.0ml Class C	Deferred for: 1. submission of FSC or FQA and Design Examination Certificate where strength and pack size of the product is mentioned. 2. Firm will apply separately for each strength. 3. Firm will provide the stability data for each product.

			Shelf Life: 5 years Applied as: Single Models/ Specification; as above	
18.	Applicant Name: MBS Distributor Address: Flat 101, Shah Alam road Arcade, Defence road Rawalpindi (ELI-01287) Date of R&I 15-04-2025 Fee Details: Paid Fee: 6,000/- Fee Challan No: 735163614509 Dated: 26-04-2025	Name of Manufacturer: M/s. Nanyang Major Medical Products Co. Ltd. Address: No.16 County Road, Jinhua Town, Wancheng District, Nanyang City, Henan Province, China LOA Validity: 31-12-2028 FSC: China Validity: 04-03-2027 ISO Validity: 14-08-2026	Brand name: Surgical Pack Class-A Shelf life: 03 Years Models/ Specification: Spinal pack Craniotomy pack, Cardiovascular pack, Biopsy pack, Universal pack, Cesarean pack, or customized	Deferred for the following: 1. FSC issued by chamber of commerce instead of relevant regulatory authority. 2. Clarification that the name of device on FSC is Surgical Pack (Spinal Pack), name of the device on sample label is Spinal Drape Set and name of device on Form 6A is Spinal Pack.
19.	Applicant Name: M/s Biocare Enterprises, Plot No. 64/2 St#17, FECHS (NPF) 0-9 PWD Road, Islamabad (ELI-00220) Date of R&I 11-04-2025 Fee Details: Paid Fee: 50000/- Slip No. 1165944563	M/s Shenzhen Cornley Bio-Medical Co., Ltd., 6/F Building 10, Block 3, Yangbei Industrial Park, Huangtian Community, Hangcheng Street, Bao'an 518128, China LOA Validity: 16-01-2030 FSC: Germany Issue date: 28-02-2022 FSC: China Validity: 04-08-2026 ISO Validity: 08-12-2026	Cornley Vitagas 5 Series Blood Gas and Electrolyte Analyser and their related reagent, consumables, Accessories and Spare parts Class-B Shelf life: not mentioned Models/ Specification: Not specified	Deferred for the following: 1. original documents not provided. 2. FSC of RRA or Ce marking Certificate not provided. 3. manufacturing credential not provided. 4. shelf life/ stability data not provided. 5. clarification required that name of product on DOC is Blood Gas Electrolyte Analyzer.
20.	Hospital Supply corporation 42 Darul Aman Housing Society, Block 7&8, Karachi (ELI-00005)	Medkonsult Medical technology s.r.o., Pasteurova 67/15, Klasterni Hradisko, 77900 Olomouc, Czech Republic	MMT Denflow Chord PC Class B	Deferred for the followings: 1. submitted LOA is not notarized. 2. FSC of RRA or CE marking certificate not attached.

				3. Multiple codes has been applied in single medical device.
21.	M/s 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 Date of R& I 10-01-2022 Fee: PKR 25,000/- Slip #610948064 Dated: 05-01-2022	Legal Manufacturer Fortress Diagnostic Limited, Unit 2C Antrim Technology Park, Belfast Road, Antrim BT41, 1QS, UK Documents Submitted: ISO 13485 certificate validity: 28-02-2022 LOA validity: 17-Jan-2023	Brand name: HbA1c-Modified Enzymatic Reagent Generic Name: HbA1c-Modified Enzymatic Reagent (IVD for HbA1c in human blood) (Reagent 01: 1x30ml) (Reagent 02: 1x10ml) Models/ Specification (as per Free sale certificate): BXC0670A Class-B Shelf life: At Optimum Temperature: 24 Months On board Stability: 06 months Storage Conditions: 2 - 8°C FSC country of origin validity: Date of Issue: 01-03-2017 FSC RRA validity: N/A	Deferred for the following. 1. Firm has not submitted the brand name. 2. The volume 30ml and 10ml not mentioned in FSC. 3. The address of manufacture on LOA and FSC is different from address provided on Form 7A.
22.	M/s 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 Date of R& I 10-01-2022 Fee: PKR 25,000/- Slip #6429326603 Dated: 05-01-2022	Legal Manufacturer Fortress Diagnostic Limited, Unit 2C Antrim Technology Park, Belfast Road, Antrim BT41, 1QS, UK Documents Submitted: ISO 13485 certificate validity: 28-02-2022 LOA validity: 17-Jan-2023 FSC country of origin validity: Date of Issue: 01-03-2017	Brand name: HbA1c-Calibrator Set (2 levels) Generic Name: HbA1c- Calibrator Set (Level 01: 2x0.5ml) (Level 02: 2x0.5ml) Models/ Specification (as per Free sale certificate): BXC0678A Class-B Shelf life: 18 months Storage Conditions: 2 - 8°C	Deferred for the followings: 1. Firm has not submitted the brand name. 2. The (Level 01: 2x0.5ml) (Level 02: 2x0.5ml) not mentioned in FSC. 3. The address of manufacture on LOA and FSC is different from address provided on Form 7A.

23.	M/s 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 Date of R& I 10-01-2022 Fee: PKR 25,000/- Slip #2813460301 Dated: 05-01-2022	Legal Manufacturer Fortress Diagnostic Limited, Unit 2C Antrim Technology Park, Belfast Road, Antrim BT41, 1QS, UK Documents Submitted: ISO 13485 certificate validity: 28-02-2022 LOA validity: 17-Jan-2023 FSC country of origin validity: Date of Issue: 01-03-2017	Brand name: HbA1c-Control Set (2 levels) Generic Name: HbA1c- Control Set (Level 01: 1x0.5ml) (Level 02: 1x0.5ml) Models/ Specification <i>(as per Free sale certificate):</i> BXC0669A Class-B Shelf life: 24 months Storage Conditions: 2 - 8°C	Deferred for the followings: 1. Firm has not submitted the brand name. 2. The (Level 01: 1x0.5ml) (Level 02: 1x0.5ml) not mentioned in FSC. 3. The address of manufacture on LOA and FSC is different from address provided on Form 7A.
24.	Applicant Name: M/s. Martin Dow Specialties Private Limited. Nice Trade Orbit Building 7 th Floor, 44-A, Block 6, PECHS, Shahrah0-e-Karachi. ELI:00160 Date of R&I: 25-02-2025 Fee details: Slip: 1968105377 Paid: PKR 6000/- Dated: 14-02-2025	Legal Manufacturer: M/s Nova Biomedical Corporation, 200 Prospect Street, Waltham, MA 02454-9141, USA FSC (USA): Validity: 21-01-2026 LOA Validity: 27-03-2025 ISO 13485 Validity: 24-10-2027	Brand name: Prime CCS Comp Stat Profile Prime CCS Analyzer System Class A Shelf life: not applicable	Deferred for the following: 1. The name of the device Prime CCS Comp not mentioned in LOA. 2. Firm has not submitted the fee for the system. 3. Firm has not submitted the shelf life of the medical device. 4. Firm need to submit all documents that have the same name of the device.
25.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3591 Submission date: 21/09/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valit till: 2023/01/17	Acon Mission Plus Hemoglobin(Hb) Testing strips (Hemoglobin (Hb) Testing strips) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Deferred for the following: 1. Form 7A along with undertaking required. 2. The name of the device on FSC is Mission® Plus Hb Hemoglobin Test Strips while name on Form 7A is Acon Mission Plus Hemoglobin(Hb) Testing strips. 3. copy of ISO 13485 of manufacturing site valid

				till 14.07.2025 attached. ISO 13485 of legal manufacturer not attached. 4. The name Acon not mentioned in LOA. 5. Class of device not mentioned on DOC. 6. Firm has not submitted original documents.
26.	A.S Enterprises, 03- Mozang Lahore, Pakistan. ELI: 00190 Dossier# 3592 Submission date: 21/09/2022 Evaluator: DD-III	Legal Manufacturer: Acon laboratories Inc., 5850 Oberlin Drive, # 340, San Diego, CA, 92121, United States of America Manufacturing site: Acon Biotech (Hangzhou) co, Ltd. No 210 Zhenzhong road west lake district Hangzhou P.R. China 310030 FSC: China Valid till: 2023/01/17	Acon Mission Plus Hemoglobin (Hb) Testing Meter (Hemoglobin (Hb) Testing System) Codes & Sizes: As per FSC Class-C Shelf Life: 24 Months	Deferred for the following: 1. Form 7A along with undertaking required. 2. The name of the device on FSC is Mission® Plus Hb Hemoglobin Testing system while name on Form 7A is Acon Mission Plus Hemoglobin(Hb) Testing meter. 3. copy of ISO 13485 of manufacturing site valid till 14.07.2025 attached. ISO 13485 of legal manufacturer not attached. 4. The name Acon not mentioned in LOA. 5. Class of device not mentioned on DOC. 6. Firm has not submitted original documents.
27.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi ELI-00073 Date of R& I 29.04.2025 Fee: Rs.`62000/ through slip no. 9182038880	M/s Karex Industries Sdn. Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia. LOA: Valid till: 21-04-2030 (Copy) FSC: Not provided ISO 13485 - Validity Date: 02-07-2025 (Copy)	Pulse-Strawberry Natural Rubber Latex Male Condoms Pulse – Strawberry (Identifier: P53S-N1-180-Red) Applied as: Family Class C Shelf Life : 5 Years	Deferred for clarification that address of manufacturer mentioned on FSC, CE QMS and ISO 13485 certificates is different from address given on Form 7A.

		EC Certificate (FQA) Valid till: 26-05-2024 (Copy)	Code/sizes:	
28.	M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi ELI-00073 Date of R& I 29.04.2025 Fee: Rs. `62000/ through slip no. 6379675693	M/s Karex Industries Sdn. Bhd. Lot 2244, Batu 39 ½ Pontian Besar, 82000 Pontian, Johor, Malaysia. LOA: Valid till: 21-04-2030 (Copy) FSC: Not provided ISO 13485 - Validity Date: 02-07-2025 (Copy) EC Certificate (FQA) Valid till: 26-05-2024 (Copy)	Pulse-Extra Sensitive Natural Rubber Latex Male Condoms Pulse – Extra Sensitive Applied as: Family Class C Shelf Life : 5 Years Code/sizes:	Deferred for clarification that address of manufacturer mentioned on FSC, CE QMS and ISO 13485 certificates is different from address given on Form 7A.
29.	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	Deferred for submission of original and notarized FSC and valid QMS certificate.
30.	Treu-Dynamic International(Pvt) Ltd Office no.C-206,2 nd Floor, City Towers, Main Boulevard, Gulberg, Lahore. (Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)	<u>Legal Manufacture</u> Conmed Corporation 525 French Road, Utica, New York 13502, USA T+1 404.855.4592 • F+1 404.344.0283 • www.matrixsurgicalusa.com <u>LOA:</u> Validity 03-Year (Sept-2023 to Dec-2025). <u>FSC:</u> Country of Origin USA Validity: 31-12-2025	Brand Name Shoulder Arthroscopy System Class C Shelf life: 05 Years Code Description H6100 Anchor Suture, CFK-475DT Anchor Suture CFK-55DT Anchor Suture 9971 anchor suture	Rejected due to following: 1. Firm has not submitted fee for the codes. 2. Firm has not submitted the brand names. 3. The undertaking and annexures of Form 7A not attached. 4. Firm has not justifies the grouping of the applied codes.

		ISO 13485: Validity 03-Years March 2024 –March 2027.	C7465 For anchor suture C7385 For anchor suture CKP-3500 Anchor suture CKP-4502 Anchor suture CF6140HB Anchor suture CF6140H Anchor suture C6140H Anchor suture Y1802A Anchor suture GKP-2801 Anchor suture GKP-3301 Anchor suture BKL-00M For Anchor Suture BGU-00M For Anchor Suture T50S Anchor Suture SMI-02N For Anchor Suture C6005 Anchor Suture H5000 Anchor Suture H5120 Anchor Suture C7480 For Anchor Suture BB23X30 Anchor Suture BB40X60 Anchor Suture PRO7450B Anchor Suture L3000 Advantage for Anchor Suture L3000L Advantage for Anchor Suture 5059532 Anchor Suture	
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			PRO6125 Anchor Suture MC5057 Universal Suture PRO2043 For Anchor Suture PRO203 For Anchor Suture PRO2041 For Anchor Suture PRO6228 For Anchor Suture PRO6240 For Anchor Suture PRO3011 For Anchor Suture PRO8500SB For Anchor Suture PRO6100 For Anchor Suture PRO3115 For Anchor Suture PRO3110 For Anchor Suture PRO3600 For Anchor Suture E8030LSO For Anchor Suture E8050LSO Anchor Suture E8130LSO Anchor Suture E8150LSO Anchor Suture E9011-2 Anchor Suture C8803 Anchor Suture D4240 For Anchor Suture D4000 For Anchor Suture 9299A, 9263A, 9247A For Anchor Suture 9599A, C9254, C9264 For Anchor Suture	
31.	Treu-Dynamic International(Pvt) Ltd	<u>Legal Manufacture</u> Conmed Corporation 525 French Road, Utica, New York 13502,USA	Brand Name Knee Arthroscopy System	Rejected due to following: 1. Firm has not submitted fee for the codes.

	Office no.C-206,2nd Floor, City Towers, Main Boulevard, Gulberg, Lahore. (Licence No.ELI-00175) File submitted on : 19.02.2025 Fee challan No. 121540329(13.02.25)	T+1404.855.4592• F+1404.344.0283• www.matrixsurgicalusa.com LOA: Validity 03-Year (Sept-2023 to Dec-2025). FSC: Country of Origin USA Validity: 31-12-2025 ISO 13485: March 2024 –March 2027.	Class C Shelf life: 05 Years Code Description 10K Arthroscopic for knee 10K150 Arthroscopic for knee AES-1 Arthroscopic for knee KFL100 Arthroscopic for knee 8750 Arthroscopic for knee AES-FC Arthroscopic for knee AES-90SN, PS8834 Arthroscopic for knee MR007C Arthroscopic for knee MR004C, Arthroscopic for knee KTB014,KFB035 Arthroscopic for knee H5100, DMS70 Arthroscopic for knee E9414, E9415A Arthroscopic for knee C8011, C8012, C8013, ACL Screw for Knee C8015, C8017, C8018, C8019 ACL Screw for Knee C8022, C8023, C8024, C8025 ACL Screw for Knee IA-2000-S, C7359 , C7368 ACL Screw for Knee.	2. Firm has not submitted the brand names. 3. The undertaking and annexures of Form 7A not attached. 4. Firm has not justifies the grouping of the applied codes.
32.	M/s Ear Technic Pvt. Ltd., Office No. 03, 2nd Floor, G.8 Square Plaza, G.8 Markaz Islamabad ELI-00956 Date of R& I 25.04.2025 Fee: Rs. `62000/ through slip no. 241458572445	Desu Medikal Urunler Ve Tibbi Cihazlar San. Ve Tic A.s. Universiteler mah. 1596 Cad. Safir Bloklan E Blok Ofis No. 02/03 Zemin Kat Kapi No. 6 Beytepe – Cankaya – Ankara Turkiye. LOA: Valid till: 10-03-2026 (Copy)	Brand Name: Desu Medical Shunt Valves and Catheters with accessories Generic: Total PSA (CLIA) and Total PSA (CLIA) controls Applied as: Kit	Deferred for the followings: 1. for submission of valid design examination certificate. 2. clarification of brand name. 3. Firm has applied Ventriculoperitoneal shunt, Peritoneal/ arterial cerebrospinal fluid catheter and Cerebrosinal

		FSC: Turkiye issue date 25.01.2024. Validity Date: 24-01-2027(Copy) ISO - Validity Date: 21-10-2027 (Copy) EC Certificate Valid till:	Class D Shelf Life : Code/sizes:	External Drainage Kit etc in single application. 4. Firm has not justified the grouping. 5. Firm has attached multiple stability reports of multiple devices. Device wise stability report required. 6. Justification for applying multiple codes. 7. submission of original documents.
33.	LINK TRADERS OFFICE NO 1 & 2 MEZZAINE FLOOR AHMAD TRADE CENTER, 2, B COMMERCIAL AREA NAZIMABAD NO 2, KARACHI (ELI-00727	Dongguan TT Medical, Inc. BID # 1, 1 Taoyuan Road, Songshan lake National Hi-Tec Industrial Park, Dongguan, Guangdong, PR China	ORTUS PTCA Balloon Catheter	Deferred for the followings: 1. The name on FSC is Ortus Disposable PTCA Balloon Catheter. Further firm has mentioned on Form 7A that fee of Rs.50000 deposited. 2. Legalized copy of the FSC China valid till 06.02.2025. The name of device on FSC is Coronary Dilation catheter. 3. Firm has attached two FCS (China) that have different product codes and product name is Coronary Dilation catheter. 4. FSC (Netherland) is neither original, nor notarized. The name of product on FSC is Coronary Dilation Catheter with names Vespentrator®, VesTraveler®, VexPander® and EverFlow®. 5. Tha name of device as per agreement is CTO PTCA Balloon catheter, NC PTCA Balloon Catheter and Paclitexel

				coated PTCA Balloon Catheter. 6. Firm has not submitted FQA and Design Examination Certificate.
34.	Tech Zone, 764 Askari 9, Zarar Shaheed Road Cantt Lahore. ELI-00040 Date of R&I 28-04-2025 Fee Details: Paid Fee: 62030/- Fee Challan No: 968000045229	Legal Manufacturer: Adeor Medical AG Address: Martinshof 5, 83626 Valley Germany LOA Validity(Notarised): 31-12-2027 FSC: Germany Issuance date : 05-02-2025 (Original) expiry not mentioned ISO Validity: 30-12-2025(notarized) EU QMS certificate validity: 26-05-2024 (Original) EU Design Examination certificate validity: 26-05-2024 (Original) Extension letter given	Brand Name: Perneczky Aneurysm Clip 2 Aneurysm Clip Class D Shelf Life: 10 years Applied as: Single Models/ Specification AS per FSC	Approved subject to submission of fee for family and codes/sizes exceeding 20.
35.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan No. 144385778263 Dated: 28-04-2025	Legal Manufacturer: LumiraDx UK Ltd, Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & Cliniqa Corporation. 495 Enterprise Street, San Marcos, CA 92078, USA	LumiraDx NT-proBNP Class: B Product Name: 1. LumiraDx NT-proBNP Roche CAT #: 10418320001 LumiraDx CAT #: L023000101012 Pack size: 12 Tests Shelf life: 40 weeks at 2 - 8°C	Approved

		FSC: Validity: 17-12-2029 LOA Validity: 16-03-2030 EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026 Cliniqa ISO Validity: 04-06—2025 DOC: Issuance date. 25-05-2022.	2. LumiraDx NT-proBNP Quality Controls Roche CAT #: 10418354001 LumiraDx CAT #: L023080101002 Pack size: 2 Sets/pack Shelf life: 24 months at 2 - 8°C The LumiraDx NT-proBNP test is an in vitro diagnostic test for the quantitative determination of N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) in human capillary and venous whole blood and plasma samples (Lithium Heparin).	
36.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan No. 9675535926 Dated: 28-04-25	Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & Aalto Scientific Ltd. 230 Technology Parkway, Eatonton, Georgia, 31024, USA FSC: Validity: 15-12-2029 LOA Validity: 16-03-2030	LumiraDx HbA1c Test Strips Class: B Product Name: 1. LumiraDx HbA1c Roche CAT #: 10418109001 LumiraDx CAT #: L006000101024 Pack size: 24 Test Strips Shelf life: 39 weeks at 2 - 30°C 2. LumiraDx HbA1c Quality Controls Roche CAT #: 10418133001 LumiraDx CAT #: L006080101003 Pack size: 3 sets/pack Shelf life: 18 months at 2 - 30°C	Approved

		EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026 Aalto ISO Validity: 30-05-2026		
37.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 31,000/- Challan No. 0681274647 Dated: 28-04-25	Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom FSC: Validity: 15-12-2029 LOA Validity: 16-03-2030 EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026	LumiraDx CRP Test Strips Class: B Product Name: 1. LumiraDx CRP Roche CAT #: 10418044001 LumiraDx CAT #: L004000101024 Pack size: 24 Test Strips Shelf life: 36 weeks at 2 - 30°C	Approved
38.	Roche Pakistan Limited. 1 st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 50,000/- vide Challan No 068112877488 dated 28.04.2025.	Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & Cliniq Corporation.	LumiraDx Coagulation Markers Class: B Product Name: 1. LumiraDx D-Dimer Test Strips Roche CAT #: 10418087001 LumiraDx CAT #: L005000101012 Pack size: 12 Test Strips Shelf life: 52 weeks at 2 - 30°C	Approved

		495 Enterprise Street, San Marcos, CA 92078, USA & Hart Biologicals Ltd. 2 Rivergreen Business Centre, Queens Meadow, Hartlepool, TS25 2DL, United Kingdom FSC: Validity: 15-12-2029 LOA Validity: 16-03-2030 EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026 Cliniqa ISO Validity: 04-06—2025 Hart ISO Validity: 10-01-2027	2. LumiraDx Multi Quality Controls Roche CAT #: 10418281001 LumiraDx CAT #: L020080101003 Pack size: 3 sets/pack Shelf life: 52 weeks at 2 - 8°C 3. LumiraDx INR Test Strips Roche CAT #: 10418010001 LumiraDx CAT #: L003000101048 Pack size: 48 Test strips Shelf life: 12 months at 5 - 32°C 4. LumiraDx INR Quality Controls Roche CAT #: 10418036001 LumiraDx CAT #: L003080101003 Pack size: 3 sets/pack Shelf life: 24 months at 2 - 8°C	
39.	Roche Pakistan Limited. 1st Floor, 37-B, Block 6, P.E.C.H.S, Karachi. (ELI-00009) R&I Date: 14-05-2025 Fees: 50,000/- Challan No. 05398418718 Dated:28-04-25	Legal Manufacturer: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom Manufacturing Site: LumiraDx UK Ltd. Dumyat Business Park, Bond Street, Tullibody, Alloa, FK10 2PB, United Kingdom & MRN Diagnostics 101 Constitution Blvd, Suite G, Franklin, MA	LumiraDx SARS- CoV-2 Cluster Class: B Product Name: 1. LumiraDx SARS- CoV-2 Ag Test Strips Roche CAT #: 10418141001 LumiraDx CAT #: L016000101048 Pack size: 48 Test Strips Shelf life: 18 months at 2 - 30°C	Approved

		02038, United States of America FSC: Validity: 15-12-2029 LOA Validity: 16-03-2030 EU QMS Certificate: N/A ISO 13485: Lumira ISO Validity: 16-04-2026 MRN ISO Validity: 21-09-2025	2. LumiraDx SARS-CoV-2 Ag Ultra Roche CAT #: 10418184001 LumiraDx CAT #: L016000401048 Pack size: 48 Test Shelf life: 70 weeks at 2 - 30°C 3. LumiraDx SARS-CoV-2 Ag Quality Controls Roche CAT #: 10418206001 LumiraDx CAT #: L016080101002 Pack size: 2 sets/pack Shelf life: 25 months at 2 - 8°C 4. LumiraDx SARS-CoV-2 & Flu A/B Roche CAT #: 10418222001 LumiraDx CAT #: L019000101024 Pack size: 24 Tests Shelf life: 77 weeks at 2 - 30°C 5. LumiraDx SARS-CoV-2 & Flu A/B Quality Controls Roche CAT #: 10418265001 LumiraDx CAT #: L019080101002 Pack size: 2 sets/pack Shelf life: 24 months at 2 - 8°C 6. LumiraDx SARS-CoV-2 & RSV Roche CAT #: 10418303001 LumiraDx CAT #: L021000101024 Pack size: 24 Tests	
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			Shelf life: 52 weeks at 2 - 30°C 7. LumiraDx SARS- CoV-2 & RSV Quality Controls Roche CAT #: 10418311001 LumiraDx CAT #: L021080101002 Pack size: 2 sets/pack Shelf life: 25 months at 2 - 8°C	
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DEFERRED CASES (LOCAL MANUFACTURING)

	Manufacturer details	Medical device details	
40.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad. (ELM-0097) [1029-6L] R & I. 15313 dated 29-05-2025 Approved Sections: i. Personal Protective Equipment (PPE) Section ii. Ultrasound Gel Section iii. Injection Molding Section (For components like nebulizer machine Body oxygen mask cord clamp airways) iv. Injection Molding Section (breast pump steamer tourniquet urine bag parts and vacuum bottle. (Not for auto- disable / disposable syringe) v. EO (Ethylene Oxide) Sterilization Section vi. Blistering / packing Section of IV Cannula / Cord Clamp vii. Surgical Drapes Section viii. Surgical Swab Section (Packing & Sterilization only) ix. Surgical Gloves Section (Packing & Sterilization only) x. Orthopedic Soft Wears Section (soft braces belts slings and binders xi.	Medi Plus BP Bulb Class: A Configuration code: BB-5020 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 5846127042	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
41.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1000-7L]	Medi Plus Nebulizer Machine Class: B Configurations Code:	Approved subject to verification of manufacturing facility.

	D. No. 15350 dated 29-05-2025 Approved Sections: (As stated above)	NM-9026 (Nebulizer machine) NM-9025 (Mini Nebulizer Machine) Shelf Life: 5 Years Fee: 25000 Fee Slip No. 337851399241	The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
42.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [1027-6L] R & I. 15333 dated 29-05-2025 Approved Sections: As above	Medi Plus BP Cuff Class: A Configuration code: CB-5021 (BP Cuff) CB-5020 (BP Cuff with Bladder) Sizes: S, M, L. Shelf Life: 5 Years Fee: 6000 Fee Slip No. 3533197159	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
43.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [983-6L] D. No. 15354 dated 29-05-2025 Approved Sections: As above	Medi Plus Inhaler Spacer (Aerosol Holding Chamber) Class: A Sizes: Small, Medium, Large Shelf Life: 5 Years Fee: 6000 Fee Slip No. 599636956917	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
44.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [943-6L] D. No. 13955 dated 20-05-2025 Approved Sections: As Above	Medi Plus Nurse Cap Class: A Model: NC-1690 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 13005433061	Approved. The firm will submit samples of the device before issuance of Registration letter.
45.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [967-6L]	Medi Plus Air Mattress (Medical Pressure Relief Air Mattress)	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility.

	D. No. 15328 dated 29-05-2025 Approved Sections: As above	Class: A Code: AM-2510 Shelf Life: 5 Years Fee: 6000 Fee Slip No. 33136855935	1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
46.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [980-7L] D. No. 15341 dated 29-05-2025 Approved Sections: As above	Medi Plus Skin Traction Kit Configuration code: ST-1285 Sizes: Adult, Child, Infant Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 175996150588	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
47.	Blue Birds Enterprises, Plot No. 292, Humak Industrial estate, Kahuta Road, Islamabad (ELM-0097) [955-7L] D. No. 13967 dated 20-05-2025 Approved Sections: As Above	Medi Plus Non-Woven Tape Class: B Code: NWT-1800 Sizes: 1, 2, 3 & 4 inches Shelf Life: 5 Years Fee: 25000 Fee Slip No. 21469469	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.
48.	Blue Birds Enterprises, Plot No. 292, Humak Industrial Estate, Kahuta Road, Islamabad (ELM-0097) [984-7L] D. No. 15363 dated 29-05-2025 Approved Sections: As Above	Medi Plus Ear Syringe (Ear Irrigation Syringe) Class: B Configuration Code: ES-1020 Sizes: 60ml, 90ml Shelf Life: 5 Years Fee: 25000 Fee Slip No. 6736115842	Approved subject to verification of manufacturing facility. The MDB constituted following panel for verification of the facility. 1. Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). 2. Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.