

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

DECISIONS OF 102nd MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 03-10-2025 (PART-II MANUAL APPLICATIONS AGENDA)

102nd 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 03rd 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 Mehtab Afsar, Chief Drugs Inspector, Peshawar on behalf of DG Health, Government of KPK.	Member
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.	Prof. Brig. (Rtd). Nuzhat Mushahid (TI) Pathalogist, Riphah Health Care Services, Riphah University,	Member
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
10.	Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi.	Member (attended meeting through videolink)

11.	Prof Dr M Nadeen Ahmed, Department of Radiology, Agha Khan University Hospital, Karachi.	Member (attended meeting through videolink)
12.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

SR.NO.	NAME OF EVALUATOR	DESIGNATION
1.	Mr. Saadat Ali Khan	Deputy Director-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

Item No. I(A): SITE VERIFICATION APPLICATIONS

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

S.#	Name of Establishment	Name of Panel Inspector (s)	Decision
1.	M/s Tecno Instruments (Pvt) Ltd., 316-C, Small Industrial Estate, 51340, Sialkot	Faisal Shahzad, Additional Director DRAP Lahore	Approved. The Board noticed that the firm is situated in small industrial estate Sialkot and the Municipal Corporation Sialkot has also confirmed address/location in their jurisdiction therefore Board decided to approve the site for establishment of medical device manufacturing facility.

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

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

FRESH CASES

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Med EL Hearing Implants (SMC-Private) Limited, Office No. 24, Block K, Valancia Town, Housing Society Defence Road, Lahore	Mudassar Raza, Pharm-D	Approved
2.	M/s Medi Health Services, 1 st Floor, 16/E, Mehta Street, Temple Road, Lahore	Ms. Afshan Aziz B-Pharm	Approved
3.	M/s Atzan Pharmaceuticals, Commercial Area, Aziz Bhatti Town, Sargodha	Ms. Rida Ilyas Pharm D	Approved
4.	M/s Ka'ab International, Plot No. 87/11, Sector no. 5, Deh Tappo, Ibrahim Hyderi, Korangi Industrial Area, Karachi	Mohammad Abrar Ahmed Pharm D	Approved
5.	M/s FIIVE Stars Pharma International (Pvt) Ltd., Office No. 4, 5 & 6, Situated Umar Plaza First Floor, 1.5 Km Gulyana Road, Gujar Khan, Rawalpindi	Razia Begum B. Pharm	Approved
6.	M/s Smart Medics, Office No. 105, Balad Trade Centre-2, Near Sailkot Milk Shop, Bahadurabad, Karachi	Tahreem Moosani Pharm D	Approved
7.	M/s Hayaat Life Sciences, B-73/1, Block-5, Gulshan-e-Iqbal, Karachi Godown: Warehouse No. 5, KDA Apartment, Block-A, North Nazimabad, Karachi	Amjad Jawaaid Lodhi Pharm D	Approved

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

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

RENEWAL CASES

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s U.M Enterprises, Plot No. 12, Sector No. 15, Korangi Industrial Area, Karachi (ELI-00486)	Junaid Ahmed Khan BS Biomedical Engineering	Muhammad Umer Muhammad Iqbal Badruddin	Approved

			Liquat Ali Malik Muhammad Ali Malik	
2.	M/s A One Traders, House No. 45, Street No. 4, Haroon Abad, Near Malik Tariq Awan Qilla Ring Road, Peshawar` (ELI-00480)	Akhtar Gul BS Medical Lab technology	Jan Alam	Approved
3.	M/s A.Feroz & Co. , Medicine Street No. 1, Marriot Road, Karachi Godown: Plot No. 330/A, 1 st Floor, Block 3, DMCHS, Alamgir Road, Karachi (ELI-00066)	Muhammad Bux Pharm-D	Feroz Ahmed	Approved
4.	M/s Nishat Surgical, Office No. A-114-296, Jail Road, Hyderabad (ELI- 00476)	Dr. Erum Farhan Pharm-D	Noor Ahmed CEO	Approved
5.	M/s Hoora Pharma (Pvt) Ltd., 3 rd Floor Plot No. FD-49, 50 & 54, Korangi Creek Industrial Park, Karachi Godown: Ground Floor, WH-01-20-A7-A8, Korangi Creek Industrial Park, Near Pakistan Refinery Limited, Karachi (ELI-00037)	Miss Ujala Khushbakht Pharm-D	Abdul Rasheed Chohan CEO	Approved
6.	M/s Zam Zam Corporation, Suit No. 205-206, Beaumont Plaza, 6-CL-10, Beaumont Road, Karachi (ELI-00412)	Syed Shahzas Alam B-Pharmacy	Muhammad Iqbal	Approved
7.	M/s Battla Brothers, C-16, 3 rd Floor, H.J Centre, Kutchi Gali No. 2, Marriot Road, Karachi (ELI- 00441)	Old Technical person: Saad Ullah Salari New technical person: Tahir Hussain Pharm-D	Naseem Akhter Battla CEO	Approved
8.	M/s Waseem Brothers, B-45, Block 5, Gulshan-e-Iqbal, Karachi (ELI-00342)	Old Technical Person: Miss Saima Siddiqua New Technical Person: Miss Sania Saeed Pharm D	Abdul Waseem Owner	Approved

9.	M/s Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi (ELI-00471) Godown Plot No. 01, Sector 25, Korangi Industrial Area, Karachi	Old Technical Person: Syed Zubair Hussain New Technical Person: Abu Rehan Bari Pharm-D		Approved
10.	M/s Iqbal and Company, Alfalah Manzil, Opposite National Police Foundation, Street 26, Sector E-11/4, Islamabad (ELI-00117)	Old Technical person: Muhammad Ejaz Riaz New Technical Person Ms Sidra Razzaq Pharmacist	Arshad Iqbal Malik Ms. Saira Arshad	Approved
11.	M/s AMS, Medraf, Office No. 3, 3 rd Floor, 37-C, Bukhari Commerical Lane-8, Phase VI, DHA, Karachi (ELI-00469)	Muhammad Rafiq B-Pharm	Muhammad Rafiq Mishal Waleed Shah	Approved
12.	M/s Briogene (Pvt) Ltd., 196-A, SMCHS, Karachi (ELI-00015)	Sadeem Shahzad MPhil (Molecular biology and Biotechnology)	Muhammad Umer (CEO)	Approved
13.	M/s Hakimsons (Pvt) Ltd., A- 58/B, SITE Mangopir Road, Karachi (ELI-00396)	Faiza Rafiqi Pharm D	Nawazish Ali Hakim Ms. Nayyer Jahan Hakim Naveed Nawazish Ali Hakim	Approved
14.	M/s HAM International, B-49, First Floor Portion, Block-16, KDA Scheme 36, Gulistan-e- Johar, East Gulshan Town, Karachi (ELI-	Old Technical Person: Muhammad Shoaib New Technical person: Kanwal Aijaz Pharm D	Ms. Mina Jahan	Approved
15.	M/s Verizon, 60-D, F.C.C Zahoor Elahi Road Gulberg IV Lahore (ELI-00087)	Old Technical Person: New Technical Person: Ms. Ayesha Fiaz Pharm D	M/s Humaria Farooq	Approved

16.	M/s Womas International, Saddat House, Aqsa Street, Nia Maina Pura, Model Town Sialkot	Mahed Haider Pharm D	Shees Haider Zaidi	Approved
17.	M/s Pharma Consultant Pakistan Pvt. Ltd., Suit No. 207, 207A, Khan Tower, DHA Square, Walton Road, Lahore Cantt. (ELI-00176)	Old Technical Person: Isma Razzaque New Technical Person: Ms. Rimsha Farooq Pharm-D	Muhammad Kashif Saleem Tayyaba Kashif	Approved
18.	M/s Johnson & Johnson Pakistan (Pvt) Ltd., Office No. 506, 5 th Floor, Horizon Tower, Block-3, Scheme Number-5, Clifton, Karachi Godown: 208/1, Sector 23, Korangi Industrial Area, Karachi Additional Godown: Second Floor, WH-01, 20-A7-A8, Korangi Creek Industrial Park, Karachi	Old Technical Person Miss. Aisha Zaman New Technical Person: Sabahat Arif Pharm D Aisha Muhamamd Ilyas Pharm D	Old Management: Khalid Shaaban Mansour Patric Joseph Casey Ahmed Muzammil Ramez Ezzat Aziz Louca New Management: Ayman M.H Atiyeh Ahmed Muzammil Ozgur Baslilar Bashir Khanani ZUbari Farhat	Approved
19.	M/s Health Care International, 1 st Floor 210/J-2 Johar Town, Lahore (ELI-00141)	Old technical person: Hafiz Hammad-ur- Rehman New Technical person: Ms. Momena Rehman Pharm D	Omer Jan Shaukat	Approved
20.	M/s Pak Punjab Cardex Medical System, Ground Floor, 210-J/2, Block M.A. Johar Town Lahore (ELI-00175)	Old Technical Person: Muhammad Rizwan Rafiq	Old Management: Waqas Liaqat New Management	Deferred for provision of notarized copy of sale purchase aggreement and

	Godown: Plot No. 257, Ground Floor, K-Block, DHA, Lahore	New Technical Person: Hafiz Hammad-ur-Rehman Pharm D	Ali Jan Shaukat	original undertaking on stamp paper by seller.
21.	M/s Universal Dental (Pvt) Ltd., 17-Mcleod Road, Lahore (ELI-00071)	Old Technical Person: Muhammad Farooq Saleem New Technical Person: Ms. Ayesha Hameed Pharm D M. Phil (Pharmaceuticals)	Old Management Saleem Hayee Waqar Hayee Saima Hayee New Management: Saleem Hayee Waqar Hayee Asim Hayee Farhan Saleem	Approved
22.	M/s Raffay Associates, Office No. 04, 2 nd Floor, Ahmed Plaza, Range Road, Rawalpindi (ELI-00021)	Old Technical Person: Saira Faris New Technical Person: Naveed Anjum B. Pharmacy	Naveed Aslam (CEO)	Approved
23.	M/s Curelink Pharmaceuticals, Office NO. 6, 3 rd Floor, B.B Shopping Mall, Opposite NED University Block-1, Gulistan-e-Johar, Karachi (ELI-00151)	Sayed Qamar Unnisa Pharm-D	Syed Najam Abbas	Approved
24.	M/s Novo Nordisk Pharma (Pvt) Ltd., 113 Shahrah-e-Iran, Clifton Karachi (ELI-00264) Godown: 208/1, Sector 23, Korangi Industrial Area, Karachi	Old Technical Person: Syed Abdul Azeem New Technical person: Abeer Khan Pharm D	Rashid Rafique Maziar Doustdar Peter Bo Soelberg Ole Falving Ramsby	Approved
25.	M/s Bionta Pharma, Suit No. A-10, Plot B-10, Gulshan-e-Iqbal Block 13-A, Karachi (ELI-00367)	Hafiz Zubair Ikram Pharm D	Bu Amjad Raza Ur Rehman M. Hashim Ali Khan	Approved
26.	M/s Zenith International, Room No. 104, Tahir Plaza, Block 7 &	Old Technical Person:	Kashif Shakeel	Approved

	8, KCHSU, Karachi (ELI-00090) Godown: Shop No. 1, Ground Floor, Plot No. 4-D, 17 th Commercial Street Phase-II (Ex) DHA, Karachi	Faisal Iqbal New Technical Person: Dr. Sana Waseem Pharm D		
27.	M/s A & E Medical, 323-Ata Truk Block New Garden Town, Lahore (ELI-00023)	Ihtsham-ul-Haq B.Pharm	Ihtsham-ul-Haq	Approved
28.	M/s Ontech Corporation, B-154, Block 13-D/2, Gulshan-e-Iqbal, Karachi (ELI-00289)	Old Technical person: Khurram Nawaz New Technical Person: Zahoor Khan Pharm D	Raheel Mirza	Approved
29.	M/s Alam Enterprises, B-22, Sector W-1, Gulshan-e-Maymar, Karachi	Old technical Person: Zumar Saeed Jumani New Technical Person: Hiba Rashid Pharm D	Shah Nawaz Alam	Approved
30.	M/s Aftab Life Care Impex, 1 st Floor AL Fateh Chambers, Tilak Road, Hyderabad (ELI-00357) Godown: Plot No. B-10, HAD Employees Cooperative Housing Society Phase-II, Kohsar, Latifabad, Hyderabad	Old Technical Person: Khurram Shahzad New Technical Person: Maryam Micro Biology	Atique Ahmed Aftab	Approved
31.	M/s Medinostic Healthcare (Pvt) Ltd., B-18, S.I.T.E, Karachi (ELI-00012)	Syed Muhammad Ali Mustafa B.Pharm	Tariq Allawala Syed Waqar Hussain	Approved
32.	M/s Atco Pharma International (Pvt) Ltd., B-18, SITE Karachi (ELI-00106)	Muhammad Nasir Pharm D	Shaikh Mohammad Naseem Allawala Saeed Allawala Aslam Usman Allawala	Approved

33.	M/s Dolphin Care, A-288, Block-15, KDA Scheme-36, Gulistan-e-Johar, Karachi (ELI-00484)	Hamza Zulfiqar B.E Biomedical	Muhammad Asad Ghour Hamza Zulfiqar Muhammad Akbar Khan	Approved
34.	M/s Lab Link Enterprises, Plot No. 221-H, Block-2, PECHS, Karachi (ELI-00007) Godown: B-40, SITE, Karachi	Old Technical Person: Rajesh Kumar New Technical Person: Noman Zaheer Bio Medical Engineer	Muhammad Arshad Awan	Approved
35.	M/s Matrix Pharma, Plot No. 12, Sector No. 15, Korangi Industrial Area, Karachi (ELI-0039)	Ammad Shams Pharm D	Liaqat Ali Malik Sameer Liaqat Ali	Approved
36.	M/s Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-5, Mezzanine Floor, Business Centre, Block-6, PECHS, Main Shahr-e-Faisal, Karachi (ELI-00232)	Old Technical Person: Amar ali New Technical Person: Sobia Meraj Pharm D	Old management: Khalil Ahmed Allahwala Sabih Mohsin Ahsan Mehmood Raza Mehmood New Management: Khalil Ahmed Allahwala Sabih Mohsin Ahsan Mehmood Raza Mehmood Mstateyesha Yousuf	Approved
37.	M/s United Healthcare, Plot No. 330/A, 2 nd Floor, Block-3, DMCHS, Karachi	Tamha Fatima Pharm D	Asad Feroz	Approved
38.	M/s Safe Health Pakistan Bizcon,	Muhammad Kamran Pharm D	Naveed Ur Rizwan Azizi	Approved

	Office No. 25, 2 nd Floor Dilkushan Chamber Marsion Road, Karachi New Address. Rizvi Chamber, 1 st Floor, Plot No. 337, A.M Akbar Road, Karachi			
39.	M/s Keyyani Medical Solutions, 424, Mashrique Centre, Sir Shah Suleman Road, Gulshan-e-Iqbal Block 14, Karachi	Muhammad Arif Khanzada B-Pharm	Saghir Ahmed Mrs. Fozia Saghir	Approved
40.	M/s SY, AH Impex, 1-6/15, Sector-5, Korangi Industrial Area, Karachi (ELI-00440)	Aisha Saleem Pharm D	Syed Omar Ahmed	Approved
41.	M/s Cedar Pharma, A-85, 1 st Floor, S.M.C.H.S, Karachi New Address: Office No. 1, R- 12, Block-F, Gulshan-e-Jamal, Rashid Minhas Road, Karachi (ELI-00499)	Old Technical Person: Tahoora Iqrar New Technical Person: Syeda Waqar Fatima Pharm D	Amin Ul Haq Mrs. Wajiha Atif Mrs. Fatima Haseeb	Approved
42.	M/s Scientific Supplies (Pvt) Ltd., 57-A, Block-2, PECHS, Karachi	Old Technical Person: Dr. Tooba Rauf New Technical Person: Mohammad Haris MPhil Biochemistry	Muhammad Maqsood Khan Muhammad Masroor Khan Mansoor Ahmed Khan Mudassir Maqsood	Approved
43.	M/s Amir Enterprises, 1 st Floor, Plaza No. 55, Opposite Security Check Post Gate No. 1, Gulshan Abad, Adyalla Road, Rawalpindi (ELI-00490)	Old Technical Person: Furqan Aslam Chaudhry New Technical Person: Tehzeen Fatima Pharm D	Muhammad Asim Khan	Deferred for confirmation of change of technical staff and submission of required fee.
44.	M/s Reliance (Pvt). Ltd., 17/3 Maulana Zafar Ali Khan Road, Lahore (ELI-00158)	Ms. Maryam Shabir Pharm D	Waqar Hayee	Deferred for confirmation of change of technical staff and submission of required fee.

45.	M/s Surebio Diagnostic, EE-10, Defense View Phase II, Near Iqra University, Shaheed-e-Millat, Express Way, Karachi	Romana Adil B-Pharm		Deferred for confirmation of change of technical staff and submission of required fee.
46.	M/s Med Art Pakistan, A-175, Block 13-C, KDA Scheme 24, Gulshan-e-Iqbal, Karachi (ELI-0024)	Rida Khalid Pharm D	Gulshad Ali	Deferred for confirmation of change of technical staff and submission of required fee.
47.	M/s Medcraft International, M-1, 107-D, West View Appartment, Khalid Bin Waleed Road, Block 2, PECHS, Karachi	Old Technical Person: Bakht Amir New Technical Person: Muhammad Zakaria Sami Pharm D	Shaikh Haris Hameed	Deferred for confirmation of change of technical staff and submission of required fee.
48.	M/s PharmEvo Pvt. Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055)	Amir Nawaz Pharm D		Deferred for confirmation of change of technical staff and submission of required fee.
49.	M/s Sudais Associates, Madina Centre Kabootar Chowk Ring Road, Peshawar			Deferred for confirmation of change of technical staff and submission of required fee.
50.	M/s Life Care, M-20, Mezzanine Floor, Falak Naz Plaza Near Natha Khan Bridge, Shahr-e-Faisal, Karachi Old Godown: CB-53, Al Falah Society near Sindh Bank Shah Faisal Colony No. 1, Karachi New Godown Address: House No. 104/A-102, Area Asifabad Shah Faisal Town, Karachi	Nasir Ali Qureshi MSC. Microbiology		Deferred for confirmation of change of technical staff and submission of required fee.
51.	M/s Premier Sales (Pvt) Ltd., Plot No. 1-A/15, Sector 15, Korangi Industrial Area, Karachi (ELI-0050)	Maryam Fatima Pharm D		Deferred for confirmation of change of technical staff

	Godown: Plot No. D-3, D-4 & D-5, Sector 6-F, Mehran Town, Korangi, Karachi			and submission of required fee.
52.	M/s Business Medical International, Suit No 203, 2nd Floor Hafeez Center, Shahrah e faisal Karachi. Godown: Plot No. C-16, Block 7/8, K.A.E.C.H.S, Karachi New Office address and godown: Suite 101 & 102, Trade Centre, Plot No. 23/F, Commercial Area, Mohammad Ali Society, Karachi (ELI-00262)	Jamshad Iqbal BS Biotechnology	Muhammad Nadeem	Deferred for confirmation of change of technical staff and submission of required fee.
53.	M/s Al Waali Care Concepts, 86-Allama Iqbal Road, Lahore (ELI-00386)	Old Technical Person: Farwa Majeed New Technical Person: Muhammad Waleed Pharm D	Abdul Waheed M Abu Bakar Siddique	Deferred for confirmation of change of technical staff and submission of required fee.
54.	M/s Ever-X, 1-E Samanberg Johar Town, Lahore (ELI - 00139)	Nabeela Liaqat Pharm D	Muhammad Farooq CEO	Deferred for confirmation of change of technical staff and submission of required fee.
55.	M/s Sial Traders, House No. 156-A, Abubakkar Block New Garden Town, Lahore (ELI-00138)	Ms. Sonia Tariq Pharm D	Muhammad Ashiq CEO	Deferred for confirmation of change of technical staff and submission of required fee.
56.	M/s Surgi World, 303, Muhammdia Plaza, College Road, Rawalpindi (ELI-00212)	Old Technical person: Muhammad Yasir New Technical Person: Maria Murtaza	Muhammad Saeed Iqbal	Deferred for confirmation of change of technical staff and submission of required fee.

		Pharm-D		
57.	M/s Life Elements Private Ltd., Old Office Address: Office No. 5-6, Ground Floor, Nawab Plaza, Range Road, Rawalpindi (ELI-00445) New Address: Basement No. 02, Deen Plaza, Near Misrial Chowk Range Road, Rawalpindi	Muhammad Irfan Azam B. Pharmacy	Muhammad Irfan Azam Shazia Irfan	Deferred for confirmation of change of technical staff and submission of required fee.
58.	M/s Excel Corporation, 435, BYJ Society Bahadurabad, Karachi (ELI-00110)	Amna Aftab Pharm-D	Ather Feroze (CEO)	Deferred for confirmation of change of technical staff and submission of required fee.
59.	M/s FM Health Care, 203, Al Rahman Centre, Block 7/8, KCHS, Shaheed-e-Millat Road, Karachi (ELI-00082)	Faiza Nazir Pharm D		Deferred for confirmation of change of technical staff and submission of required fee.
60.	M/s Nimra Farma, 223/4, Abdul Habib Khan Road, Tariqabad Rawalpindi (ELI-00404)	Old Technical Person: Aneesa Naeem New Technical Person: Khaliq Nawaz Pharm D	Sabir Sohail Mir Babar Mir	Deferred for confirmation of change of technical staff and submission of required fee.
61.	M/s Meximp Technologies, B-62, Block-5, Gulshan-e-Iqbal, Karachi (ELI- 00052)	Muhammad Samiulahaq B-Pharmacy		Deferred for confirmation of change of technical staff and submission of required fee.
62.	M/s A.M Distributors, 4 th Floor, Plot No. 37-C, Bukhari Commercial Lane-8, Phase VI, DHA, Karachi (ELI-00901)	Jawaid Abdul Ghani B-Pharm	Mr Muhammad Rafiq Proprietor	Approved
63.	Tri Tech International, 10-C, 1 st , 2 nd and 3 rd Floor, Sunset Commercial Lane, Phase-II, Ext. DHA, Karachi (ELI-00247)	Mohammad Salman Khan Pharm-D	Sheikh Muhammad Azeem (Partner)	Deferred for confirmation of change of technical staff and submission of required fee.
64.	M/s Labserv, House No. B-165/2, Block -3A, Gulistan-e-Johar, Scheme 36, Karachi	Sumaria Rafiq Pharm-D	Irshad Bano	Deferred for confirmation of change of

				technical staff and submission of required fee.
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AGENDA ITEM NO. II: APPLICATIONS FOR ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22137; 18-Jul-2025 Fee: 6,000/- Slip # 4820308851	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA Type: Copy of Apostille Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 24-06-2025	Brand Name: Dayang Generic Name: Shower Chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model: Not mentioned in LOA and Application form Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form.
2.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22138; 18-Jul-2025	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA	Brand Name: Dayang Generic Name: Rollator Applied as: Single Class: A Models/Code/sizes (as per FSC & application	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin.

	Fee: 6,000/- Slip # 449929875418	Type: Copy of Apostille Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 24-06-2025	Model: Not mentioned in LOA and Application form Shelf Life: 5 years	No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form.
3.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22132; 18-Jul-2025 Fee: 6,000/- Slip # 55359520444	Name of Manufacturer: Qufu Shengde Medical Technology Co., Ltd. Address: Lingcheng Town, Industrial Park, QUFU City, Shangong Province China LOA: Not submitted • FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 • ISO – Certificate: Not submitted	Brand Name: Qufu Generic Name: Motor Driven Operating Table Applied as: Family Class: A Models/Code/sizes (as per FSC & application) Model: Not mentioned in LOA and Application form Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. No details of the product specification and description have been submitted. Differential fee for the application of product as family shall be submitted.
4.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22136; 18-Jul-2025	Name of Manufacturer: Qufu Shengde Medical Technology Co., Ltd. Address: Lingcheng Town, Industrial Park, QUFU City, Shangong Province China LOA Type: Original Notarization: Apostille	Brand Name: Qufu Generic Name: Lead Shadowless Lamp (LED) Applied as: Family Class: A	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin.

	Fee: 6,000/- Slip # 90539029427	Issue Date: 10-02-2025 Validity: 10-02-2030 • FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 • ISO – Certificate: Not submitted	Models/Code/sizes (as per FSC & application Model): STHD-LEDTOSO SMD-LED70170SHD- LEDSOOS0,SHD- LEDB37005S0.SHID LFDET0 SHD- LEDESOSTE&SHD- LEDY0.SHIDLEDSDOR SHID- LED@700SHID- LEDBS00.SHID- LEDY700, SHID- LEDYS00 SHD- LEDSH3HSHD- LEDSH SH.SHD- LEDSHSH SHD- LEDBSH@H, SHD- LEDESTH SH SHD- LEDBSHSH.SHID.LE DSHLSHID-LEDBSH SHD-LEDYSHSHD- LED3SH, SHD- LEDB3H.SHD- LEDY3H.SHD- LEDC700,SHD- LEDC500,SHD- LEDC700/500. SHD- LEDC700/70,SHD- LEDCS00500,SHD- LEDMY100/700SHD- LEDMY5005S00. SHD-LEDK SOO SHD- LEDK700,SHD- LEDK700500,SHD- LEDKS005S00,SHD- LEDK700700, SHD- LEDK YS0050,SHD- LEDK Y700/700.SHD- LEDKY700/S00,SHD- LEDKY50, SHID- LEDKY70.SHD- LEDA70 S00 SHD>- LEDA 70070SHD- LEDA S00/S00.SHD- LEDA70, SHD -LEDA SOO SHD-LEDAY70 S0,SHD-LEDA Y70@.SHD-	No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form. Justification for applying multiple models in single application.
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			L_EDAYS0,SHD- LEDKSHBH, SHD- LEDK SHSH.SHD- LEDK3H3H,SHD- LEDKSH,SHD- LEDK3H,SHD- TBSH,SHD-TBSH, HD-LEDSB.SHD- LEDS <u>SHD-</u> <u>LEDS.SHD.LEDKBSH</u> <u>ISH.SHD-</u> <u>LEDKBSH@3HLSHD-</u> <u>LEDKB5H</u> Shelf Life: 5 years	
5.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22131; 18-Jul-2025 Fee: 6,000/- Slip # 40286298	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA Type: Original Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Original Notarization: Notarized • Validity: 24-06-2025	Brand Name: Dayang Generic Name: Walker Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model: Not mentioned in LOA and Application form Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form.
6.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540)	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA Type: Original Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Original Notarization: Notarized • Validity: 24-06-2025	Brand Name: Dayang Generic Name: Electrical Wheel Chair Applied as: Single Class: A	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant

	R&I No. & Date: 22133; 18-Jul-2025 Fee: 6,000/- Slip # 7483439079	Foshan, Guangdong, China LOA Type: Original Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Original Notarization: Notarized • Validity: 24-06-2025	Models/Code/sizes (as per FSC & application) Model: Not mentioned in LOA and Application form Shelf Life: 5 years	regulatory authority of country of origin. No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form.
7.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22134; 18-Jul-2025 Fee: 6,000/- Slip # 0759219804	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA Type: Original Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Original Notarization: Notarized • Validity: 24-06-2025	Brand Name: Dayang Generic Name: Manual Wheel Chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not mentioned in LOA and Application form Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Submitted FSC has not been issued by the relevant regulatory authority of country of origin. No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form.

8.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22128; 18-Jul-2025 Fee: 6,000/- Slip # 265819468679	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA Type: Original Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Original Notarization: Notarized • Validity: 24-06-2025	Brand Name: Dayang Generic Name: Commode Chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not mentioned in LOA and Application form Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. No details of the product specification and features have been submitted. No details of the applied model have been submitted in Application form.
9.	M/s Medimage Services, Suit No. 5/B, Peshawar Medical Centre, Shoba Bazar, Peshawar (ELI-00540) R&I No. & Date: 22135; 18-Jul-2025 Fee: 6,000/- Slip # 7356514911	Name of Manufacturer: Changdong Dayang Medical Technology Co., Ltd., Address: Changhongling Industrial Park (2nd Phase) Shishan, Nanhai, Foshan, Guangdong, China LOA Type: Original Notarization: Apostille Issue Date: 10-02-2025 Validity: 10-02-2030 FSC Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille	Brand Name: Dayang Generic Name: Crutch Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not mentioned in LOA and Application form Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. No details of the product specification and description have been submitted. No details of the applied model have been submitted in Application form.

		Issue Date: 17-07-2024 Validity: 16-07-2026 • ISO – Certificate: Type: Original Notarization: Notarized • Validity: 24-06-2025		
10.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21492; 15-Jul-2025 Fee: 50,000/- Slip # 86372706672	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamen Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 ISO – Certificate: Legalization: No Validity: 21-06-2026	Brand Name: Anbio Generic Name: Anbio Rapid Test (Cardic Cluster) (HS-CTNL,NT-PRO, BNP, CTNT, CTNL, MYO, CK-MB, SST2, H-FABP) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application Model): -- Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original legalized FSC, notarized LOA & ISO certificate shall be submitted. No details of the product specification and brief description have been submitted. No details of the applied codes have been submitted in Application form. Notarized CE certificate or free sale certificate from any RRA shall be submitted. Justification for applying multiple products as cluster in single application
11.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21493; 15-Jul-2025 Fee: 50,000/- Slip # 52990799669	Name of Manufacturer: Ultra Care diagnostics, Address: 54 Elswesry A, Nasr City, Cairo Egypt LOA: Type: Copy Legalization: No Validity: 21-09-2026 FSC Type: Copy of Legalized Issued By: Ministry of Health, Egypt Legalization: Legalized Validity: 01-01-2025	Brand Name: Ultra Care Generic Name: Ultra Care Lever Rapid Test (ALAT GPT Alakline Phosphatase, Bilirubin total, Bilirubin Direct, Bilirubin DMSO Direct), Gamma GT Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application Model): --	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for applying multiple products in single application.

		ISO – Certificate: Legalization: No Validity: 14-06-2025	(ALAT GPT Alakline Phosphatase, Bilirubin total, Bilirubin Direct, Bilirubin DMSO Direct), Gamma GT Shelf Life: 5 years	Notarized CE certificate or free sale certificate from any RRA shall be submitted.
12.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21482; 15-Jul-2025 Fee: 50,000/- Slip # 53046126478	Name of Manufacturer: Ultra Care diagnostics, Address: 54 Elswesry A, Nasr City, Cairo Egypt LOA: Type: Copy Legalization: No Validity: 21-09-2026 FSC Type: Copy of Legalized Issued By: Ministry of Health, Egypt Legalization: Legalized Validity: 01-01-2025 ISO – Certificate: Legalization: No Validity: 14-06-2025	Brand Name: Ultra Care Generic Name: Ultra Care Rapid Test (Lipid Profile Cluster) Cholestrol, HDL, Direct, LDL Direct, Triglyceride Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: -- Cholestrol, HDL, Direct, LDL Direct, Triglyceride Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for applying multiple products in single application. Notarized CE certificate or free sale certificate from any RRA shall be submitted.
13.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21481; 15-Jul-2025 Fee: 50,000/- Slip # 56418770115	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamrn Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027	Brand Name: Anbio Generic Name: Anbio Rapid Test (Reproductive Cluster) (FSH ,PROG, TES, LH, PRL, E2, B-HCG, AMH) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: FSH ,PROG, TES, LH, PRL, E2, B-HCG, AMH) Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. FSC not issued by concerned regulatory authority.. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for applying multiple products in single application. Notarized CE certificate or free sale certificate from any RRA shall be submitted.

		ISO – Certificate: Legalization: No Validity: 21-06-2026		
14.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21478; 15-Jul-2025 Fee: 25,000/- Slip # 33449116877	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamrn Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 ISO – Certificate: Legalization: No Validity: 21-06-2026	Brand Name: Anbio Generic Name: Anbio Rapid Test (Bone Metabolism Cluster) (Vit D, Vit D3) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application Model: (Vit D, Vit D3) Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for applying multiple products in single application. Notarized CE certificate or free sale certificate from any RRA shall be submitted.
15.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21479; 15-Jul-2025 Fee: 25,000/- Slip # 5431739211	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamrn Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products	Brand Name: Anbio Generic Name: Anbio Rapid Test (Inflammation Cluster) (CEA, CA125, CA15-3, CA 19-9, AFP, PG1, PGH, G-17, PGI/PGII, PSA, FPSA) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application Model: Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for

		Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 ISO – Certificate: Legalization: No Validity: 21-06-2026		applying multiple products in single application. Notarized CE certificate or free sale certificate from any RRA shall be submitted.
16.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21480; 15-Jul-2025 Fee: 50,000/- Slip # 5567556136	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamen Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 ISO – Certificate: Legalization: No Validity: 21-06-2026	Brand Name: Anbio Generic Name: Anbio Rapid Test (Thyroid Hormones Cluster) (T1, T2, T3, T4, TSH, FT3, FT4, KIT) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for applying multiple products in single application. Notarized CE certificate or free sale certificate from any RRA shall be submitted.
17.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21489; 15-Jul-2025 Fee: 25,000/- Slip # 97909348811	Name of Manufacturer: Ultra Care diagnostics, Address: 54 Elswesry A, Nasr City, Cairo Egypt LOA: Type: Copy Legalization: No Validity: 21-09-2026 FSC Type: Copy of Legalized Issued By: Ministry of Health, Egypt Legalization: Legalized Validity: 01-01-2025	Brand Name: Ultra Care Generic Name: Ultra Care Diabetic Cluster (Glucose, Glucose HK, Amylase, HBA1C) Applied as: Cluster Class: A Models/Code/sizes (as per FSC & application Model):	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and description have been submitted. Justification for

		ISO – Certificate: Legalization: No Validity: 14-06-2025	Shelf Life: 5 years	applying multiple products in single application. Notarized CE certificate or free sale certificate from any RRA shall be submitted. Justification of class and differential fee accordingly
18.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21477; 15-Jul-2025 Fee: 6,000/- Slip # 3122718130	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamrn Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 ISO – Certificate: Legalization: No Validity: 21-06-2026	Brand Name: Anbio Generic Name: Anbio Immunofluorescence Analyzer (AF-100C, AF-100) Applied as: Cluster Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original legalized FSC, notarized LOA & ISO certificate shall be submitted. No details of the product specification and features have been submitted. notrized CE certificate or free sale certificate from any RRA shall be submitted. Justification of class Justification of applying multiple models in single application
19.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21483; 15-Jul-2025 Fee: 25,000/- Slip # 8595788041	Name of Manufacturer: Anbio (Xiamen) Biotechnology Co. Ltd., Address: 2016, Wengjiao West Road, Xinyang Street, Haieang District, 361026, Xiamrn Fujian, China LOA: Type: Copy Legalization: Notarized Validity: 29-05-2028 FSC Type: Copy of Apostille	Brand Name: Anbio Generic Name: Anbio Diabatic Profile Hba1C Applied as: Cluster Class: A Models/Code/sizes (as per FSC & application Model): HBA1C, Glucose, AMH	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original legalized FSC, notarized LOA & ISO certificate shall be submitted.

		Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Issue Date: 08-05-2025 Validity: 07-05-2027 ISO – Certificate: Legalization: No Validity: 21-06-2026	Shelf Life: 5 years	No details of the product specification and features have been submitted. No details of the applied model have been submitted in Application form. Justification of class Justification of applying multiple products
20.	Tahir Scientific Supplies, 13-Karachi Market, Khyber Bazaar, Peshawar (ELI-00334) R&I No. & Date: 21493; 15-Jul-2025 Fee: 25,000/- Slip # 52990799669	Name of Manufacturer: Ultra Care diagnostics, Address: 54 Elswesry A, Nasr City, Cairo Egypt LOA: Type: Copy Legalization: No Validity: 21-09-2026 FSC Type: Copy of Legalized Issued By: Ministry of Health, Egypt Legalization: Legalized Validity: 01-01-2025 ISO – Certificate: Legalization: No Validity: 14-06-2025	Brand Name: Ultra Care Generic Name: Ultra Care Liver Test (ALAT (GPT), Alakaline Phosphatase, bilirubin total, Bilirubin Direct, Bilirubin DMSO Direct, Gamma GT) Applied as: Cluster Class: A Models/Code/sizes (as per FSC & application Model: (ALAT (GPT), Alakaline Phosphatase, bilirubin total, Bilirubin Direct, Bilirubin DMSO Direct, Gamma GT) Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Original valid legalized FSC, notarized LOA & valid ISO certificate shall be submitted. No details of the product specification and features have been submitted. Justification of class Justification of applying multiple products
21.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20096; 07-Jul-2025 Fee: 31,000/- Slip # 9109518754	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaia 3, 4006, Plovdiv Bulgaria LOA: Type: Copy	Brand Name: Exomind Generic Name: Transcranial Magnetic Stimulation (TMS) Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: Exomind	Deferred for following observations: The submitted LOA does not include the applied product.

		Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Exomind Applicator (BTL-699-AP-M-2) Shelf Life: 5 years	
22.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20101; 07-Jul-2025 Fee: 31,000/- Slip # 256572022	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-6000 Super Inductive System Generic Name: High-Intensity Electromagnetic Therapy Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model: BTL-6000 Super Inductive System 1. BTL-6000 Super Inductive System Pro 2. Inductive BTL-6000 Super Inductive System Elite 3. Planar field applicator BTL- 299-1 4. Focused field applicator BTL- 299-2 Shelf Life: 5 years	Deferred for justification of applying multiple models in single application.
23.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20087; 07-Jul-2025	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC	Brand Name: BTL-6000 Lymphastim Generic Name: Lymphatic Pressure Unit/Lymphatic Drainage Applied as: Family Class: B	Approved BTL-6000 Lymphastim 6 easy

	Fee: 50,000/- Slip # 5980302002	Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Models/Code/sizes (as per FSC & application Model): BTL-6000 Lymphasm 1. BTL-6000 Lymphastim 6 easy 2. BTL-6000 Lymphatism 12 Easy 3. BTL-6000 Lymphatism 12 Topline Shelf Life: 5 years	
24.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20087; 07-Jul-2025 Fee: 62,000/- Slip # 763875362873	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-6000 FSWT Generic Name: Focused Shockwave Therapy (FSWT) Applied as: Single Class: C Models/Code/sizes (as per FSC & application Model): BTL-6000 FSWT & FSWT applicator BTL-294-1 Shelf Life: 5 years	Approved.
25.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200)	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom	Brand Name: BTL-8 ECG Generic Name: Electorcardiogram (ECG) Machine Applied as: Single Class: B	Approved BTL-078-1 (BTL 8 Smart)

	R&I No. & Date: 20089; 07-Jul-2025 Fee: 50,000/- Slip # 31271945886	Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Models/Code/sizes (as per FSC & application Model: 1. BTL-078-1 (BTL 8 Smart) 2. BTL-078-2 (BTL 8 Pro) 3. BTL-078-3 (BTL 8 Elite) Shelf Life: 5 years	
26.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20088; 07-Jul-2025 Fee: 62,000/- Slip # 40608447205	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-Exilis Generic Name: High Frequency Electromedical Device Applied as: Family Class: C Models/Code/sizes (as per FSC & application Model: Exilis Exilis Elite Exilis Ultra 360 Shelf Life: 5 years	Approved Exilis only.
27.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage,	Brand Name: BTL-Emsella Generic Name: High-Intensity Focused Electromagnetic (HIFEM) Technology	Deferred for clarification for applying as single

	(ELI-01200) R&I No. & Date: 20100; 07-Jul-2025 Fee: 31,000/- Slip # 4261667609	Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: BTL Emsella BTL Chair Applicator BTL 299-3 Esmella Chair Applicator BTL-299-3 Esmella Chair applicator BTL-899- AP-M-3 Shelf Life: 5 years	
28.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e- Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20095; 07-Jul-2025 Fee: 100,000/- Slip # 44900623171	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-6000 High Intensity Laser Generic Name: High Intensity Laser Applied as: Family Class: C Models/Code/sizes (as per FSC & application Model: BTL 6000 High Intensity laser 10 W BTL 6000 High Intensity laser 20 W BTL 6000 High Intensity laser 30 W And scanning system easy and Scanning system elite Shelf Life: 5 years	Approved High Intensity Laser Only. Firm will apply separately for scanning system
29.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd.	Brand Name: BTL-785F Generic Name:	Deferred for justification for applying as family

	Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20097; 07-Jul-2025 Fee: 100,000/- Slip # 5584121690	Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Non-invasive RF Technology Machine Applied as: Family Class: C Models/Code/sizes (as per FSC & application Model): EMFACE, EXION and EMFEMME 1. BTL-785F 2. EXION Body applicator BTL- 785-1 3. EXION Body applicator tip BTL-785-1-1 4. EXION Face applicator BTL- 785-2 5. EXION Face applicator tip BTL- 785-2-1 6. EMFEMME applicator BTL- 785-3 7. EMFEMME V tip BTL-785-3-1 8. EMFEMME V24 tip BTL-785- 3-2 9. EMFEMME V30 tip BTL-785- 3-3 10. EXION Fractional RF applicator BTL-785-4 11. EMFACE controller BTL-785-7 12. EMFACE forehead applicator BTL-785-7-1 13. EMFACE cheek applicator BTL-785-7-2 Shelf Life: 5 years	
30.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200)	Name of Manufacturer: BTL Industries Ltd. Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom	Brand Name: BTL-4 ECG Generic Name: Resting Electrocardiogram (ECG) Machine Applied as: Family	Approved BTL -077-1 (BTL 4 Smart) with single battery pack and without Wifi only

	R&I No. & Date: 20099; 07-Jul-2025 Fee: 50,000/- Slip # 45415702112	Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Copy Legalization: Notareized Validity: 01-03-2027 FSC Type: Copy of Apostille Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Class: B Models/Code/sizes (as per FSC & application Model: 1. BTL -077-1 (BTL 4 Smart) with single battery pack and without Wifi 2. BTL -077-2 (BTL 4 Smart) with single battery pack and with Wifi 3. BTL -077-3 (BTL 4 Smart) with single battery pack and with Wifi Shelf Life: 5 years	
31.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20091; 07-Jul-2025 Fee: 50,000/- Slip # 6327954055	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-08 Holter Generic Name: Holter Monitor or ambulatory electrocardiogram (ECG) monitor Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model: 1. BTL -08 Holter H100 2. BTL -08 Holter H300 3. BTL 08 Holter H600 Shelf Life: 5 years	Approved BTL -08 Holter H100.
32.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage,	Brand Name: BTL-4000 Smart /4000 Premium (Combined Therapy) Generic Name:	Deferred for: Clarification of name of device justification for applying multiple products in single application

	(ELI-01200) R&I No. & Date: 20102; 07-Jul-2025 Fee: 100,000/- Slip # 39390659959	Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Physiotherapy Devices: combination of therapies, including ultrasound, Electrotherapy, Magnetotherapy and laser therapy Applied as: Family Class: C Models/Code/sizes (as per FSC & application Model: BTL-4000 Smart_/4000 Premium [Combination Therapy]" (Models: 1. BTIL -4820S Smart 2. BTL-4820S Premium 3. BTL 4825S Smart 4. BTL-4825S Premium 5. BTL-4820L Smart 6. BTL 48201 Premium 7. BTL-4825L Smart 8. BTL- 4825L Premium 9. BTL-4800SL Smart 10. BTL-4800SL Premium 11. BTL 4820SL Smart 12. BTL- 4820SL Premium 13. BTL-4825SL Smart 14. BTL-4825SL Premium 15. BTL-4800LM2 Smart 16. BTL- 4800LM2 Premium 17. BTL-4820M² Smart 18. BTL 4820M² Premium 19. BTL- 4825M² Smart 20. BTL- 4825M² Premium 21. BTL-4820M4 Smart 22. BTL-4820M4 Premium 23. BTL-4825M4 Smart 24. BTL-4825M4 Premium 25. BTL-4820LM2 Smart 26. BTL- 4820LM2 Premium 27. BTL-4825LM2 Smart 28. and	
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			29. BTL-4825LM2 Premium) Shelf Life: 5 years	
33.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20102; 07-Jul-2025 Fee: 31,000/- Slip # 3019081619	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-Flexi 12 ECG Generic Name: Electocardiograph Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: Shelf Life: 5 years	Approved.
34.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20093; 07-Jul-2025 Fee: 50,000/- Slip # 36622583109	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028	Brand Name: BTL-6000 RSWT Generic Name: Radial Shockwave Therapy (RSWT) Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model: 1. BTL-6000 RSWT Easy 2. BTL-6000 RSWT Pro 3. BTL-6000 RSWT Elite 4. Applicator magnum 5. Applicator Easy Shelf Life: 5 years	Approved BTL-6000 RSWT Easy.

		ISO – Certificate: Legalization: Notarized Validity: 08-04-2027		
35.	BTL Healthcare Supplies Pvt.Ltd., 3rd Floor, Mansoor Plaza, Plot No. 14-E Fazal-e-Haq Road, Blue Area, Islamabad (ELI-01200) R&I No. & Date: 20092; 07-Jul-2025 Fee: 50,000/- Slip # 0098508976	Name of Manufacturer: Legal Manufacturer: BTL Industries Ltd. Address: 161 Cleveland Way, Stevenage, Hertfordshire, SG1 6BU, United Kingdom Manufacturing site: BTL Industries, JSC Address: Vladaya 3, 4006, Plovdiv Bulgaria LOA: Type: Original Legalization: Notareized Validity: 01-03-2027 FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 06-10-2028 ISO – Certificate: Legalization: Notarized Validity: 08-04-2027	Brand Name: BTL-Emsculpt NEO Generic Name: High Intensity Focused Electromagnetic (HIFEM) technology combined with radiofrequency (RF) Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: Emsculpt NEO 1. Large applicator 899-AP-C-1 2. Large applicator 899-AP-C-2 3. Large applicator 899-AP-C-4 4. Large applicator 899-AP-C-5 Shelf Life: 5 years	Justification for applying multiple models in single application.
36.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19304; 01-Jul-2025 Fee: 6,000/- Slip # 16513711435	Name of Manufacturer: As per application form: Sir Trang Gloves (Thailand) Public Company Limited Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand As per FSC: Sir Trang Gloves (Thailand) Public Company Limited Address: 110 Kanjanavanit road, Pahtong, Hat yai, Songkhla 90230, Thailand	Brand Name: Axelis Generic Name: Latex Powdered Examination Gloves, Non Sterile Applied as: -- Class: A Models/Code/sizes (as per FSC & application Model: Shelf Life: 5 years	Deferred for Clarification regarding the legal manufacturer and manufacturing site shall be submitted before issuance of enlistment certificate as application form and FSC mention different manufacturers Sizes/codes Differential fee for family

		LOA: Type: Original Legalization: Legalized Validity: 06-05-2030 FSC: Type: Original Issued By: Food And Drug Administration, Thailand Legalization: Legalized Validity: 01-04-2027 ISO – Certificate: Legalization: Legalized Validity: 31-10-2026		
37.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19302; 01-Jul-2025 Fee: 6,000/- Slip # 69326591	Name of Manufacturer: As per application form: Sir Trang Gloves (Thailand) Public Company Limited Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand As per FSC: Sir Trang Gloves (Thailand) Public Company Limited Address: 110 Kanjanavanit road, Pahtong, Hat yai, Songkhla 90230, Thailand LOA: Type: Copy Legalization: Legalized Validity: 06-05-2030 FSC: Type: Copy Issued By: Food And Drug Administration, Thailand Legalization: Legalized Validity: 01-04-2027 ISO – Certificate: Legalization: Legalized	Brand Name: Axelis Generic Name: Nitrile Powder Free Examination Gloves Applied as: -- Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for Clarification regarding the legal manufacturer and manufacturing site shall be submitted before issuance of enlistment certificate as application form and FSC mention different manufacturers Sizes/codes Differential fee for family

		Validity: 31-10-2026		
38.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19303; 01-Jul-2025 Fee: 6,000/- Slip # 762763089096	Name of Manufacturer: As per application form: Sir Trang Gloves (Thailand) Public Company Limited Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand As per FSC: Sir Trang Gloves (Thailand) Public Company Limited Address: 110 Kanjanavanit road, Pahtong, Hat yai, Songkhla 90230, Thailand LOA: Type: Copy Legalization: Legalized Validity: 06-05-2030 FSC: Type: Copy Issued By: Food And Drug Administration, Thailand Legalization: Legalized Validity: 01-04-2027 ISO – Certificate: Legalization: Legalized Validity: 31-10-2026	Brand Name: Axelis Generic Name: Latex Powder Free Examination Gloves, Non Sterile Applied as: -- Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for Clarification regarding the legal manufacturer and manufacturing site shall be submitted before issuance of enlistment certificate as application form and FSC mention different manufacturers Sizes/codes Differential fee for family
39.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19844; 03-Jul-2025 Fee: 6,000/- Slip # 297666539	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Copy Legalization: Apostille Validity: 30-12-2028 FSC: Type: Copy	Brand Name: C&P Generic Name: Disposable Drape Pack Applied as: -- Class: A Models/Code/sizes (as per FSC & application Model): RG2503GP Shelf Life: 5 years	Deferred for following observations: Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin.

		Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027		
40.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19847; 03-Jul-2025 Fee: 6,000/- Slip # 55895680218	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Copy Legalization: Apostille Validity: 30-12-2028 FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027	Brand Name: C&P Generic Name: Disposable Cap Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Submitted FSC and LOA does not include the applied product. Brief description and intended use Code/sizes
41.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19847; 03-Jul-2025 Fee: 6,000/- Slip # 29120713	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Copy Legalization: Apostille Validity: 30-12-2028 FSC: Type: Copy	Brand Name: C&P Generic Name: Face mask Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Submitted FSC and LOA does not include the applied product Code/sizes

		Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027		
42.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19846; 03-Jul-2025 Fee: 6,000/- Slip # 9773662291	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Copy Legalization: Apostille Validity: 30-12-2028 FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027	Brand Name: C&P Generic Name: Non-woven bed sheets Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Submitted FSC and LOA does not include the applied product Brief description and intended use Code/sizes
43.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19845; 03-Jul-2025 Fee: 6,000/- Slip # 20410129161	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Copy Legalization: Apostille Validity: 30-12-2028 FSC: Type: Copy	Brand Name: C&P Generic Name: Disposable Shoe cover Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Submitted FSC and LOA does not include the applied product Intended use Code /sizes

		Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027		
44.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19849; 03-Jul-2025 Fee: 6,000/- Slip # 56747218441	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Copy Legalization: Apostille Validity: 30-12-2028 FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027	Brand Name: C&P Generic Name: Surgical huck towel Class: A Applied as: Single Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin. Submitted FSC and LOA does not include the applied product Intended use Code /sizes
45.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19843; 03-Jul-2025 Fee: 6,000/- Slip # 12852160607	Name of Manufacturer: Hefei C&P Nonwoven Products Co., Ltd. Address: No. 22 Park Road, Feidong New City Development Area, Hefei, Anhui, China LOA: Type: Original Legalization: Apostille Validity: 30-12-2028 FSC: Type: Original	Brand Name: C&P Generic Name: Surgical gown/Reinforced Surgical Gown Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model): Shelf Life: 5 years	Deferred for following observations: The submitted FSC and LOA only mentions the “Surgical Gown”. Declaration of Conformity shall be submitted. Submitted FSC has not been issued by the relevant regulatory authority of country of origin.

		Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 15-04-2027 ISO – Certificate: Legalization: Apostille Validity: 18-01-2027		Submitted FSC and LOA does not include the applied product Code /sizes
46.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20482; 10-Jul-2025 Fee: 31,000/- Slip # 89015929200	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Three-way stopcocks Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model): ST-01 Shelf Life: 3 years	Deferred for submission of Original Ilegalized FSC, notarized CE, LOA and ISO certificate
47.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20483; 10-Jul-2025 Fee: 31,000/- Slip # 13802338116	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy	Brand Name: Daseon Generic Name: Hemostasis Valve set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model): HV, HV-1, HV-2 Shelf Life: 3 years	Deferred for submission of Original Ilegalized FSC, notarized CE, LOA and ISO certificate

		Legalization: Notarized Validity: 16-11-2026		
48.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20486; 10-Jul-2025 Fee: 31,000/- Slip # 919902280186	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Hemostasis Valve set Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: M02, m03 Shelf Life: 3 years	Deferred for submission of Original lregularized FSC, notarized CE, LOA and ISO certificate.
49.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: 20486; 10-Jul-2025 Fee: 25,000/- Slip # 9432362065	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Balloon Inflation Device Applied as: Kit Class: A Models/Code/sizes (as per FSC & application Model: BID1, BID2 Shelf Life: 3 years	Deferred for submission of Original lregularized FSC, notarized CE, LOA and ISO certificate JUSTIFICATION OF CLASS AND SUBMISSION OF DIFFERENTIAL FEE ACCORDINGLY
50.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531)	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New	Brand Name: Daseon Generic Name: Guide Wires Applied as: Family Class: B	Deferred for submission of Original legalized FSC, notarized CE, LOA and ISO certificate

	R&I No. & Date: District, Shenzhen, 20487; 10-Jul-2025 Fee: 50,000/- Slip # 26189518009	District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Models/Code/sizes (as per FSC & application Model: 0.032/0.035/0.038*150c m, J tip, S tip 0.032/0.035/0.038*180c m, J tip, S tip 0.032/0.035/0.038*260c m, J tip, S tip Shelf Life: 3 years	
51.	S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531) R&I No. & Date: District, Shenzhen, 20484; 10-Jul-2025 Fee: 6,000/- Slip # 5849181988	Name of Manufacturer: Tianck Medical Co., Ltd., Address: 1-2 Floor, Building C, No. 16, Yinkui Road, Kuichong Town, Dapeng New District, Shenzhen, 518119, Guangdong P.R. China LOA: Type: Copy Legalization: Notarized Validity: 28-04-2028 FSC: Type: Copy Issued By: Legalization: Apostille Validity: 01-12-2026 ISO – Certificate: Copy Legalization: Notarized Validity: 16-11-2026	Brand Name: Daseon Generic Name: Radial Artery Closure Band Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model: Shelf Life: 3 years	Deferred for submission of Original Ilegalized FSC, notarized LOA and ISO certificate Code/sizes
52.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 15-07-2025 Fee: 6000/- Slip # 2385125809	Name of Manufacturer: Hefei Mlush Sanitary Products Co., Ltd., Address: West Wei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China LOA Type: Copy Notarization: No Validity: 31-12-2030 • FSC	Brand Name: Hefei Disposable Dental Needle Generic Name: Disposable Dental Needle Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model: Model: Not provided Shelf Life: 3 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required

		Type: Copy Issued By: -- Legalization: No Validity: 01-03-2026 • ISO – Certificate: Type: Copy Notarization: No Validity: 31-07-2026		Submitted FSC mentions the name of product as Dental irrigation needle. clarify Details of the product regrading codes/sizes, shall be submitted
53.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 15-07-2025 Fee: 6000/- Slip # 0937276462	Name of Manufacturer: Hefei Mlush Sanitary Products Co., Ltd., Address: West Wei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China LOA Type: Copy Notarization: No Validity: 31-12-2030 • FSC Type: Copy Issued By: -- Legalization: No Validity: 30-03-2027 • ISO – Certificate: Type: Copy Notarization: No Validity: 31-07-2026	Brand Name: Hefei Non-Woven Sponge Generic Name: Non-Woven Sponge Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not provided Shelf Life: 3 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Codes/sizes
54.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 15-07-2025 Fee: 6000/- Slip # 6139296535	Name of Manufacturer: Hefei Mlush Sanitary Products Co., Ltd., Address: West Wei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China LOA Type: Copy Notarization: No Validity: 31-12-2030 • FSC Type: Copy Issued By: -- Legalization: No	Brand Name: Hefei Micro Brush Generic Name: Micro brush Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not provided Shelf Life: 3 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Intended use Code/sizes

		Validity: 01-03-2026 • ISO – Certificate: Type: Copy Notarization: No Validity: 31-07-2026		
55.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 15-07-2025 Fee: 6000/- Slip # 0653749461	Name of Manufacturer: Hefei Mlush Sanitary Products Co., Ltd., Address: West Wei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China LOA Type: Copy Notarization: No Validity: 31-12-2030 • FSC Type: Copy Issued By: -- Legalization: No Validity: 01-03-2026 • ISO – Certificate: Type: Copy Notarization: No Validity: 31-07-2026	Brand Name: Hefei Barrier film Generic Name: Barrier film Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not provided Shelf Life: 3 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized ISO certificate shall be submitted. Cose/sizes
56.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 15-07-2025 Fee: 6000/- Slip # 787191980232	Name of Manufacturer: Hefei Mlush Sanitary Products Co., Ltd., Address: West Wei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China LOA Type: Copy Notarization: No Validity: 31-12-2030 • FSC Type: Copy Issued By: -- Legalization: No Validity: 04-09-2026 • ISO – Certificate:	Brand Name: Hefei Self healing pouch Generic Name: Self healing pouch Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not provided Shelf Life: 3 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized ISO certificate shall be submitted. The submitted FSC does not mention the name of issuing authority Code/sizes

		Type: Copy Notarization: No Validity: 31-07-2026		
57.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 15-07-2025 Fee: 6000/- Slip # 9071153511	Name of Manufacturer: Hefei Mlush Sanitary Products Co., Ltd., Address: West Wei A Road, Yaohai Industrial Park, Xinzhan District, Hefei City, Anhui Province, China LOA Type: Copy Notarization: No Validity: 31-12-2030 • FSC Type: Copy Issued By: -- Legalization: No Validity: 04-09-2026 • ISO – Certificate: Type: Copy Notarization: No Validity: 31-07-2026	Brand Name: Hefei Saliva Ejector Generic Name: Saliva ejector Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Not provided Shelf Life: 3 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized ISO certificate shall be submitted. The submitted FSC does not mention the name of issuing authority Code/sizes
58.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 18-07-2025 Fee: 31000/- Slip # 37106664597	Name of Manufacturer: Foshan Nanhai Hager Medical Machinery Co., Ltd., Address: F3, No 222 Lijia Industrial Area, Shang'ancun, Qiaojin North Road, Danzao Town, Nanhai District, Foshan China LOA Type: Copy Notarization: No Validity: 07-06-2026 • FSC Type: Copy Issued By: -- Legalization: No Validity: 05-05-2026 • ISO – Certificate: Type: Copy	Brand Name: Hefei Dental unit Generic Name: Dental unit Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: Not provided Shelf Life: 5 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized ISO and CE certificate shall be submitted. The submitted FSC does not mention the name of issuing authority Model/code Clarify whether system or single.

		Notarization: No Validity: 20-10-2026		
59.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 18-07-2025 Fee: 31000/- Slip # 7293654648	Name of Manufacturer: United Dental Changzhou Address: B1 Building No. 9, Chang Yang Rd., Wujin District Changzhou 213145 Jiangsu P.R. China LOA Type: Copy Notarization: No Validity: 07-06-2026 • FSC Type: Copy Issued By: -- Legalization: No Validity: 05-05-2026 • ISO – Certificate: Type: Copy Notarization: No Validity: 22-04-2023	Brand Name: UDG Root Canal Files Generic Name: Root Canal Files Applied as: Single Class: B Models/Code/sizes (as per FSC & application Model: Not provided Shelf Life: 5 years	Deferred for following observations: Original Legalized FSC shall be submitted. Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized ISO and CE certificate shall be submitted. The submitted FSC does not mention the name of issuing authority Code/model
60.	M/s. Mr. Dental Supply (Pvt) Ltd., UG-42, Land Mark Plaza , Jail Road, Lahore (ELI-00306) R&I Date: 27-06-2025 Fee: 6000/- Slip # 3275347348	Name of Manufacturer: Maillefer Instruments Holding Sarl Address: Chemin Du Verger 3, Ch-1338 Ballaigues, Switzerland LOA Type: Copy Notarization: Yes Validity: 31-12-2026 • FSC The submitted Copy of FSC needs to be verified. • ISO – Certificate: Type: Copy Notarization: No Validity: 08-07-2025	Brand Name: Mailefer M-Access K-File Generic Name: M-Access K-File Applied as: Family Class: B Models/Code/sizes (as per FSC & application Model: Not provided Shelf Life: 5 years	Deferred for following observations: Original Legalized FSC shall be submitted . The list of products submitted in attachment of FSC is not readable Original Notarized LOA shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized ISO certificate shall be submitted. Code/model
61.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459	Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning	Brand Name: Lansionbio Generic Name: FSH Test Kit (Dry Fluorescence Immunoassay)	Deferred for following observations: Original Legalized valid FSC shall be submitted.

	R&I Date: 10-07-2025 Fee: 31000/- Slip # 2213299666	District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Yes Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months	Original Notarized LOA & ISO certificate shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notrized CE certificate or free sale form any RRA shall be submitted. Code/model
62.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip # 93556877678	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: TT4 Test Kit (Dry Fluorescence Immunoassay) FT4 Test kit (Dry Fluorescence immunoassay) Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Code / model Clarification for applying as cluster.
63.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: PSP Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.

	R&I Date: 10-07-2025 Fee: 31000/- Slip # 9943353501	District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months	Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Code/model
64.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip # 830202386	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: D-Dimer Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Code/model
65.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: cTnl Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.

	R&I Date: 10-07-2025 Fee: 31000/- Slip # 0450241616	District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months	Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Code/model
66.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip # 5364080180	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: Ferritin Test Kit (Dry) Fluorescence Immunoassay Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Code/model
67.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: Ferritin Test Kit (Dry) Fluorescence Immunoassay Applied as: Cluster	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.

	R&I Date: 10-07-2025 Fee: 6000/- Slip # 78241834831	District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Class: A Models/Code/sizes (as per FSC & application) Model: LS-1100 LS-2100 Shelf Life: 18 months	Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Justification of class and multiple models
68.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip # 8236512591	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: TSH Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: LS-1100 LS-2100 Shelf Life: 18 months	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Justification and confirmation of multiple models
69.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459	Name of Manufacturer: Lanson Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Brand Name: Lansonbio Generic Name: β-HCG Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.

	R&I Date: 10-07-2025 Fee: 31000/- Slip # 338704615	District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Apostille Validity: 07-04-2028 • FSC Type: Copy Issued By: Jiangsu Medical product Administration Legalization: Apostille Validity: 04-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 02-04-2027	Class: B Models/Code/sizes (as per FSC & application) Model: LS-1100 LS-2100 Shelf Life: 18 months	Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or free sale form any RRA shall be submitted. Justification and confirmation of multiple models
70.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/- Slip # 3900893284	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025	Brand Name: Diagreat Generic Name: Diagreat Thyroid Cluster Thyroid Cluster T3, T4, TSH, FREE T3, Free T4, Total TSH Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted along with the details of models etc.. Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted
71.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/-	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA	Brand Name: Diagreat Generic Name: Diagreat Bacterial Cluster PCT, ASO Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application)	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.

	Slip # 620586661	Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025	Model: Shelf Life:	Description of the applied product shall be submitted along with the details of models etc.. Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted
72.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/- Slip # 954597099	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025	Brand Name: Diagreat Generic Name: Diagreat Fertility Cluster LH, FSH, B-HCG, Prolactin, AMH Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted along with the details of models etc.. Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted Justification for applying as cluster
73.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/- Slip # 5308249373	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy	Brand Name: Diagreat Generic Name: Diagreat Hepatology Cluster AMA Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted along with the details of models etc..

		Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025		Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted. Justification for applying as cluster
74.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/- Slip # 385807243458	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025	Brand Name: Diagreat Generic Name: Diagreat Cardio Cluster CNTI, PRO BNP, D-Dimer, MYO, HFABP Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted along with the details of models etc.. Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted. Justification for applying as cluster
75.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/- Slip # 3900893284	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate:	Brand Name: Diagreat Generic Name: Diagreat Cluster IGE, BHAIC, 25-Hydroxy Vit B, Ferritin, AFP Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted along with the details of models etc.. Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted.

		Type: Copy Notarization: No Validity: 26-07-2025		Justification for applying as cluster
76.	Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305 R&I Date: 18-07-2025 Fee: 50000/- Slip # 8902740092	Name of Manufacturer: Beijing Diagtrat Bio Technologies CO., Ltd., Address: Floor 1-3 Building 19, No. 2 Yard, Huane Middle Road, Tongzhou District Beijing China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: -- Legalization: Validity: 17-11-2024 • ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025	Brand Name: Diagreat Generic Name: Diagreat Autoimmune Disorder Cluster CRP, RF Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application) Model: Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted along with the details of models etc.. Data regarding the product shelf life shall be submitted. CE certificate or the FSC from any RRA shall be submitted. Justification for applying as cluster
77.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: 31000/- Slip # 8781383526	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yin Hai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026	Brand Name: Accurate Pregnancy (hCG) Rapid Test Generic Name: Pregnancy (hCG) Rapid Test Applied as: Family Class: B Models/Code/sizes (as per FSC & application) Pregnancy (HCG) test strips Pregnancy (HCG) test Cassette Shelf Life: 3 years	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. CE certificate or the FSC from any RRA shall be submitted Submitted FSC has not been issued by the relevant regulatory authority. Justification for applying as family Code/model

		• ISO – Certificate: Not submitted Type: Notarization		
78.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Not submitted	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yin Hai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Brand Name: Accurate Hepatitis C Virus Test Kit (HCV) Generic Name: Hepatitis C Virus Test Kit (HCV) Applied as: Family Class: C Models/Code/sizes (as per FSC & application Shelf Life: 3 years	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. The submitted LOA has not been signed form the applicant. Submitted FSC has not been issued by the relevant regulatory authority CE certificate or the FSC from any RRA shall be submitted Code/model Evidence of submission of fee shall be provided
79.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Not submitted	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yin Hai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy	Brand Name: Accurate Typhoid Rapid Test Generic Name: Typhoid Rapid Test Applied as: Family Class: B Models/Code/sizes (as per FSC & application Shelf Life: 2 years	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. The submitted LOA has not been signed form the applicant. Submitted FSC has not been issued by the relevant regulatory authority Description of the applied product shall be submitted

		Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization		CE certificate or the FSC from any RRA shall be submitted Code/model Evidence of submission of fee shall be provided
80.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Not submitted	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yin Hai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Brand Name: Accurate Malaria P.f/P.v Rapid Test. Generic Name: Malaria P.f/P.v Rapid Test. Applied as: Family Class: B Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted. The submitted LOA has not been signed form the applicant. Submitted FSC has not been issued by the relevant regulatory authority Description of the applied product shall be submitted CE certificate or the FSC from any RRA shall be submitted Code/model Evidence of submission of fee shall be provided
81.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yin Hai Street, Qiantang New	Brand Name: Accurate Dengue NS1 Rapid Test Generic Name: Dengue NS1 Rapid Test. Applied as: Family	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.

	Fee: Not submitted	Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Class: B Models/Code/sizes (as per FSC & application Shelf Life:	The submitted LOA has not been signed form the applicant. Submitted FSC has not been issued by the relevant regulatory authority Description of the applied product shall be submitted CE certificate or the FSC from any RRA shall be submitted Code/model Evidence of submission of fee shall be provided
82.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpata, Lahore ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 31000 vide deposit slip no. 25501086481	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027	Brand Name: Integral Dental Unit Chair Generic Name: Integral Dental Unit Chair Applied as: Single Class: B Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized valid LOA shall be submitted. The scope of submitted ISO certificate does not include applied product. CE certificate or the FSC from any RRA shall be submitted. Code/model Justification of class
83.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address:	Brand Name: Small Steam Sterilizers Generic Name: Small Steam Sterilizers	Deferred for following observations: Original Legalized valid FSC shall be submitted.

	Industrial Estate, Kot Lakhpat, Lahore ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 6000 vide deposit slip no. 483445897	032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027	Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life:	Original Notarized valid LOA & ISO certificate shall be submitted. Code/model Justification of class
84.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 6000 vide deposit slip no. 294302224950	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027	Brand Name: Oil free air compressor Generic Name: Oil free air compressor Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized valid LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted Code/model Intended use
85.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei	Brand Name: Intra oral scanner Generic Name: Intra oral scanner Applied as: Single Class: A	Deferred for following observations: Original Legalized valid FSC shall be submitted.

	ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 6000 vide deposit slip no. 400823545966	Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027	Models/Code/sizes (as per FSC & application Shelf Life:	Original Notarized valid LOA & ISO certificate shall be submitted. Code/model
86.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 6000 vide deposit slip no. 78946083718	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027	Brand Name: Image plate scanner Generic Name: Image plate scanner Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized valid LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted Intended use Model/code
87.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore ELI-00298 R&I Date: 07-07-2025	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China	Brand Name: Ultrasonic cleaner Generic Name: Ultrasonic cleaner Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized valid LOA & ISO certificate shall be submitted. Code/model

	Fee: Rs. 6000 vide deposit slip no. 386555561690	LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027		
88.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 6000 vide deposit slip no. 69944868	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027	Brand Name: Mobile cart Generic Name: Mobile cart Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized valid LOA & ISO certificate shall be submitted. Code/model
89.	Glow Pak International Lahore, 129/5-M Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore ELI-00298 R&I Date: 07-07-2025 Fee: Rs. 6000 vide deposit slip no. 905275473512	Name of Manufacturer: Ningbo Runyes Medical Instrument Co., Ltd Address: 032 Building #456 Tonghui Road, Jianbei Investment & Pioneering Park C, 315033 Ningbo City. China LOA Type: Copy Notarization: No	Brand Name: Water Distiller Generic Name: Water Distiller Applied as: Single Class: A Models/Code/sizes (as per FSC & application Shelf Life:	Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Notarized valid LOA & ISO certificate shall be submitted. Description of the applied product shall be submitted Intended use Code/model

		Issued: 01-12-2008 • FSC: Not submitted Type: -- Issued By: -- Legalization: -- Validity: -- ISO – Certificate: Type: Copy Notarization: No Validity: 12-07-2027		
90.	Assuza Incorporation, 17-rabbani Road, Old Anarkali, Lahore ELI-00546 R&I Date: 15-07-2025 Fee: Rs. 31,000 vide deposit slip no. 505636883	Name of Manufacturer: Guangdong Econ Medical Co., Ltd. Address: Building 1, NO. 222, Xindu Road, Chengjiao Street, Conghua District Guangzhou City, Guangdong Province, Republic of China LOA Type: Copy Notarization: No Issued: 10-07-2025 • FSC: Not submitted Type: Copy Issued By: -- Legalization: Apostille Validity: 05-08-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 25-11-2025	Brand Name: UNICMED Generic Name: UNICMED SILICON Urethral Catheter 2 Way Applied as: Single Class: B Models/Code/sizes (as per FSC & application 6fr, 8fr, 10fr, 12fr, 15fr, 16fr, 18fr, 20fr, 22fr, 24fr, 226fr, 28fr, 30fr Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Differential fee for the application of product as family shall be submitted since various sizes have been applied. Original Notarized LOA shall be submitted since the submitted LOA has been notarized even before issuance of the LOA and also does not bear name of any signatory Notarized ISO certificate shall be submitted. Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Valid notarized CE certificate shall be submitted
91.	Assuza Incorporation, 17-rabbani Road, Old Anarkali, Lahore ELI-00546 R&I Date: 15-07-2025 Fee: Rs. 31,000 vide deposit slip no. 080577819397	Name of Manufacturer: Guangdong Econ Medical Co., Ltd. Address: Building 1, NO. 222, Xindu Road, Chengjiao Street, Conghua District Guangzhou City, Guangdong Province, Republic of China	Brand Name: UNICMED Generic Name: UNICMED Reinforced Endotechal Tube UnCuffed Applied as: Single Class: B Models/Code/sizes (as per FSC & application	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Differential fee for the application of product as family shall be submitted

		LOA Type: Copy Notarization: No Issued: 10-07-2025 • FSC: Not submitted Type: Copy Issued By: -- Legalization: Apostille Validity: 05-08-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 25-11-2025	6fr, 8fr, 10fr, 12fr, 15fr, 16fr, 18fr, 20fr, 22fr, 24fr, 226fr, 28fr, 30fr Shelf Life: 5 years	since various sizes have been applied. Original Notarized LOA shall be submitted since the submitted LOA has been notarized even before issuance of the LOA and also does not bear name of any signatory Notarized copy of ISO certificate shall be submitted. Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted.
92.	Assuza Incorporation, 17-rabbani Road, Old Anarkali, Lahore ELI-00546 R&I Date: 15-07-2025 Fee: Rs. 31,000 vide deposit slip no. 61160953940	Name of Manufacturer: Guangdong Econ Medical Co., Ltd. Address: Building 1, NO. 222, Xindu Road, Chengjiao Street, Conghua District Guangzhou City, Guangdong Province, Republic of China LOA Type: Copy Notarization: No Issued: 10-07-2025 • FSC: Not submitted Type: Copy Issued By: -- Legalization: Apostille Validity: 05-08-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 25-11-2025	Brand Name: UNICMED Generic Name: UNICMED Reinforced Endotechal Tube Cuffed Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 6fr, 8fr, 10fr, 12fr, 15fr, 16fr, 18fr, 20fr, 22fr, 24fr, 226fr, 28fr, 30fr Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Differential fee for the application of product as family shall be submitted since various models have been applied. Original Notarized LOA shall be submitted since the submitted LOA has been notarized even before issuance of the LOA and also does not bear name of any signatory Notarized copy of ISO certificate shall be submitted. Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted.
93.	M/s. NI Healthcare Products (Pvt.) Ltd., Office # A, Unit 10,	Name of Legal Manufacturer:	Brand name: Coagulation Markers	Deferred due to following deficiencies in the application;

	Survey No. 263, Damlotte Riad, District Malir, Karachi. (ELI- 01028) R&I detail 22-05-2025 Fee: 6,000/- Slip: 343722591	M/s Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building, No. 5158 Shahe West Road, Xili, Nanshan, 518055 Shenzen, Guangdong, China. Manufacturing Site: M/s Medcaptain Medical Technology Co., Ltd., Building C, Jiale Science and Technology Industrial Park, Matian Street, Gunagming, 518106 Shenzen, Guangdong, China. • LOA Type: Original Attested By: CCPIT Validity: 18-11-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Apostilled Validity: 07-04-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 16-02-2026	Generic Name: Coagulation Markers Applied as: Cluster Class: A Model/Codes/Sizes: • D-Dimer (CLIA) (as per form) - MCL02201E (as per form & Label) - MCL02202E (as per form & Label) • FDP (CLIA) (As per form & FSC) - MCL04001E (as per form & Label) - MCL04002E (as per form & Label) • FDP Control (As per form & FSC) - MCL05001E (as per form & Label) Shelf life: • D-Dimer (CLIA)-14 Months (2-8oC) • FDP (CLIA)- 14 Months (2-8oC) • FDP Control-16 Months (2-8oC)	• Justification/Clarification for applying as Class-A Medical Device is required. • Brand name has not been provided. • The Reagent D-Dimer (CLIA), has not been mentioned in FSC. • Differential fee of cluster is required.
94.	M/s. NI Healthcare Products (Pvt.) Ltd., Office # A, Unit 10, Survey No. 263, Damlotte Riad, District Malir, Karachi. (ELI- 01028) R&I detail 22-05-2025 Fee: 6,000/- Slip: 083990493176	Name of Legal Manufacturer: M/s Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building, No. 5158 Shahe West Road, Xili, Nanshan, 518055 Shenzen, Guangdong, China. Manufacturing Site: M/s Medcaptain Medical Technology Co., Ltd., Building C, Jiale Science	Brand name: Thyroid Function Markers Generic Name: Thyroid Function Markers Applied as: Cluster Class: A Model/Codes/Sizes:	Deferred due to following deficiencies in the application; • Justification/Clarification for applying as Class-A Medical Device is required. • Brand name has not been provided. • The Reagents Thyroid Stimulating Hormone (CLIA), Total Thyroxine (CLIA), Free Thyroxine (CLIA), Total Triiodothyronine

		and Technology Industrial Park, Matian Street, Gunagming, 518106 Shenzhen, Guangdong, China. • LOA Type: Original Attested By: CCPIT Validity: 18-11-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Apostilled Validity: 07-04-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 16-02-2026	• Thyroid Stimulating Hormone (CLIA) MCL09401E (as per form & Label) MCL09402E (as per form & Label) MCL09403E (as per form & Label) • Total Thyroxine (CLIA) MCL09501E (as per form & Label) MCL09502E (as per form & Label) MCL09503E (as per form & Label) • Free Thyroxine (CLIA) MCL09601E (as per form & Label) MCL09602E (as per form & Label) MCL09603E (as per form & Label) • Total Triiodothyronine (CLIA) MCL09701E (as per form & Label) MCL09702E (as per form & Label) MCL09703E (as per form & Label) • Free Triiodothyronine (CLIA) MCL09801E (as per form & Label) MCL09802E (as per form & Label) MCL09803E (as per form & Label) • Thyroglobulin (CLIA) MCL09901E (as per form & Label) MCL09902E (as per form & Label) MCL09903E (as per form & Label)	(CLIA), Free Triiodothyronine (CLIA), Thyroglobulin (CLIA), Antithyroglobulin (CLIA) and Antithyroid peroxidase antibody (CLIA), have not been mentioned in FSC. • Differential fee of cluster is required.
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			• Antithyroglobulin (CLIA) MCL10001E (as per form & Label) MCL10002E (as per form & Label) MCL10003E (as per form & Label) • Antithyroid peroxidase antibody (CLIA) MCL10101E (as per form & Label) MCL10102E (as per form & Label) MCL10103E (as per form & Label) • Thyroid Function Control MCL07601E (as per form & Label) • Thyroid Autoantibody Control MCL07701E Shelf life: • Thyroid Stimulating Hormone (CLIA)- 14 Months (2-8oC) • Total Thyroxine (CLIA)- 14 Months (2-8oC) • Free Thyroxine (CLIA)- 14 Months (2-8oC) • Total Triiodothyronine (CLIA)- 14 Months (2-8oC) • Free Triiodothyronine (CLIA)- 14 Months (2-8oC) • Thyroglobulin (CLIA) 14 Months (2-8oC) • Antithyroglobulin (CLIA)- 14 Months (2-8oC) • Antithyroid peroxidase antibody	
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			(CLIA)- 14 Months (2-8oC) • Thyroid Function Control-14 Months (2-8oC) • Thyroid Autoantibody Control-16 Months (2-8oC)	
95.	M/s. NI Healthcare Products (Pvt.) Ltd., Office # A, Unit 10, Survey No. 263, Damlotte Riad, District Malir, Karachi. (ELI- 01028) R&I detail 22-05-2025 Fee: 6,000/- Slip: 8405379450	Name of Legal Manufacturer: M/s Medcaptain Medical Technology Co., Ltd., 12 th Floor, Baiwang Research Building, No. 5158 Shahe West Road, Xili, Nanshan, 518055 Shenzen, Guangdong, China. Manufacturing Site: M/s Medcaptain Medical Technology Co., Ltd., Building C, Jiale Science and Technology Industrial Park, Matian Street, Gunagming, 518106 Shenzen, Guangdong, China. • LOA Type: Original Attested By: CCPIT Validity: 18-11-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Apostilled Validity: 07-04-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 16-02-2026	Brand name: Vitamins Generic Name: Vitamins Assay Reagents Applied as: Cluster Class: A Model/Codes/Sizes: • 25-Hydroxyvitamin D (CLIA) (as per FSC & form) MCL0601E (as per form & Label) MCL0602E (as per form & Label) MCL0603E (as per form & Label) Shelf life: 14 Months (2-8oC)	Deferred due to following deficinecies in the application; • Brand name has not been provided. • Differential fee of cluster is required.
96.	M/s. NI Healthcare Products (Pvt.) Ltd., Office # A, Unit 10, Survey No. 263,	Name of Legal Manufacturer: M/s Medcaptain Medical Technology Co., Ltd.,	Brand name: F6 Analyzer General Reagent/Consumable Pack	Deferred due to following deficinecies in the application;

	Damlotte Riad, District Malir, Karachi. (ELI- 01028) R&I detail 22-05-2025 Fee: 6,000/- Slip: 1932545043	12th Floor, Baiwang Research Building, No. 5158 Shahe West Road, Xili, Nanshan, 518055 Shenzen, Guangdong, China. Manufacturing Site: M/s Medcaptain Medical Technology Co., Ltd., Building C, Jiale Science and Technology Industrial Park, Matian Street, Gunagming, 518106 Shenzen, Guangdong, China. • LOA Type: Original Attested By: CCPIT Validity: 18-11-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Apostilled Validity: 07-04-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 16-02-2026	Generic Name: F6 Analyzer General Reagent/Consumable Pack Applied as: Kit Class: A Model/Codes/Sizes: • Single Use Cartridge (as per form) • Single use Tip • Pre-trigger Solution (as per form & label) MCL01302E • Trigger Solution (as per form & label) MCL01402E • Washing Buffer (as per form & label) MCL02301E Shelf life: 14 Months	• Justification for applying as kit is required. • The single use cartridge, tip & reagents have not been mentioned in FSC. • The codes of Single use tip & cartridge are not clear.
97.	M/s. NI Healthcare Products (Pvt.) Ltd., Office # A, Unit 10, Survey No. 263, Damlotte Riad, District Malir, Karachi. (ELI- 01028) R&I detail 22-05-2025 Fee: 6,000/- Slip: 01482228016	Name of Legal Manufacturer: M/s Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building, No. 5158 Shahe West Road, Xili, Nanshan, 518055 Shenzen, Guangdong, China. Manufacturing Site: M/s Medcaptain Medical Technology Co., Ltd., Building C, Jiale Science and Technology Industrial Park, Matian	Brand name: Tumor Markers Generic Name: Tumor Marker reagents Applied as: Cluster Class: A Model/Codes/Sizes: • Carcinoembryonic antigen (CLIA) (as per FSC & Appl.) MCL08701E (as per form & label)	Deferred due to following deficiencies in the application; • Justification/Clarification for applying as Class-A Medical Device is required • Brand name has not been provided. • Differential fee of cluster is required.

		Street, Gunagming, 518106 Shenzen, Guangdong, China. • LOA Type: Original Attested By: CCPIT Validity: 18-11-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Apostilled Validity: 07-04-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 16-02-2026	MCL08702E MCL08703E • Neuron Specific Enolase (CLIA) (as per FSC & Appl.) MCL05501E (as per form & label) MCL05502E (as per form & label) MCL05503E (as per form & label) • Cancer Antigen 15-3 (CLIA) (as per FSC & Appl.) MCL08601E (as per form & label) MCL08602E (as per form & label) MCL08603E (as per form & label) • Protein S100 (CLIA) (as per FSC & Appl.) MCL05401E (as per form & label) MCL05402E (as per form & label) MCL05403E (as per form & label) Shelf life: 14 Months (2-8oC)	
98.	M/s. NI Healthcare Products (Pvt.) Ltd., Office # A, Unit 10, Survey No. 263, Damlotte Riad, District Malir, Karachi. (ELI- 01028) R&I detail 22-05-2025 Fee: 6,000/- Slip: 63514875840	Name of Legal Manufacturer: M/s Medcaptain Medical Technology Co., Ltd., 12th Floor, Baiwang Research Building, No. 5158 Shahe West Road, Xili, Nanshan, 518055 Shenzen, Guangdong, China. Manufacturing Site: M/s Medcaptain Medical Technology Co., Ltd., Building C, Jiale Science and Technology Industrial Park, Matian Street, Gunagming, 518106 Shenzen,	Brand name: Anemia Merkers Generic Name: Anemia Merkers Reagents Applied as: Cluster Class: A Model/Codes/Sizes: • Ferritin (CLIA) as per FSC & Appl.) MCL05701E (as per FSC & Appl.) MCL05702E (as per FSC & Appl.)	Deferred due to following deficinecies in the application; • Justification/Clarification for applying as Class-A Medical Device is required • Brand name has not been provided. • Differential fee of cluster is required.

		Guangdong, China.	MCL05703E (as per FSC & Appl.) • Vitamin B12 (CLIA) (as per FSC & Appl.) MCL10601E (as per form & label) MCL10602E (as per form & label) MCL10602E (as per form & label) Shelf life: 14 Months (2-8oC)	
		• LOA Type: Original Attested By: CCPIT Validity: 18-11-2027 • FSC Type: Original Issued By: Govt. Body Attested By: CCPIT Legalization: Apostilled Validity: 07-04-2026 • ISO Certificate Type: Original Attested By: CCPIT Validity: 16-02-2026		
99.	M/s. Tru Technology, 297-Tariq Block, New Garden Town, Lahore. (ELI- 01176) R&I detail 26-06-2025 Fee: 31,000/- Slip: 2856937659	Name of Manufacturer: Beijing Goldenlaser Development Co., Ltd., 15-3 Building, Zhongnan Hitech Industrial Park, #4 Liushan Street, Yanjiao, Sanhe, Langfang, Hebei. 065201, China. • LOA Type: Original Attested By: CCPIT Validity: 23-03-2030 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 05-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 20-03-2027 • CE Certificate Type: Original Attested By: CCPIT Validity: 28-03-2027	Brand name: Diode Laser Machine Generic Name: Laser Machine Applied as: Single Class: B Model/Codes/Sizes (as per CE): GLD01, GLD02, GLD03, GLD05, GLD06, GLD07, GLD08, GLD09, GL009, GL010, GL060, GL063, GL065, GL090, GLY01, GLY02, GLY03, GLY05, GLY06. Service life: Not mentioned	Deferred due to following deficiencies in the application; • Justification for consideration as medical device is required. • FSC has been issued by chamber of commerce, not by regulatory body of country of origin. • Multiple models have been mentioned in CE certificate. The applied model has not been specified in application. • Service life has not been mentioned.

100.	M/s. Tru Technology, 297-Tariq Block, New Garden Town, Lahore. (ELI- 01176) R&I detail 26-06-2025 Fee: 31,000/- Slip: 028931589509	Name of Manufacturer: Beijing Goldenlaser Development Co., Ltd., 15-3 Building, Zhongnan Hitech Industrial Park, #4 Liushan Street, Yanjiao, Sanhe, Langfang, Hebei. 065201, China. • LOA Type: Original Attested By: CCPIT Validity: 23-03-2030 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 05-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 20-03-2027 • CE Certificate Type: Original Attested By: CCPIT Validity: 19-12-2028	Brand name: Picosecond Laser Machine Generic Name: Laser Machine Applied as: Single Class: B Model/Codes/Sizes (as per CE): GL015, GL016, GL017, GL018, GL020, GL022, GL025, GL026, GL028 Service life: Not mentioned	Deferred due to following deficiencies in the application; • Justification for consideration as medical device is required • FSC has been issued by chamber of commerce, not by regulatory body of country of origin. • Multiple models have been mentioned in CE certificate. The applied model has not been specified in application. • Service life has not been mentioned.
101.	M/s. Tru Technology, 297-Tariq Block, New Garden Town, Lahore. (ELI- 01176) R&I detail 26-06-2025 Fee: 31,000/- Slip: 14554757	Name of Manufacturer: Beijing Goldenlaser Development Co., Ltd., 15-3 Building, Zhongnan Hitech Industrial Park, #4 Liushan Street, Yanjiao, Sanhe, Langfang, Hebei. 065201, China. • LOA Type: Original Attested By: CCPIT Validity: 23-03-2030 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 05-05-2027	Brand name: CO2 Fractional Laser Machine Generic Name: Laser Machine Applied as: Single Class: B Model/Codes/Sizes (as per CE): GL05, GL06, GL012, GL060, GL063, GL065, GL080 Service life: Not mentioned	Deferred due to following deficiencies in the application; • Justification for consideration as medical device is required • FSC has been issued by chamber of commerce, not by regulatory body of country of origin. • Multiple models have been mentioned in CE certificate. The applied model has not been specified in application. • Service life has not been mentioned.

		• ISO Certificate Type: Original Attested By: CCPIT Validity: 20-03-2027 • CE Certificate Type: Original Attested By: CCPIT Validity: 19-12-2028		
102.	M/s. Tru Technology, 297-Tariq Block, New Garden Town, Lahore. (ELI- 01176) R&I detail 26-06-2025 Fee: 31,000/- Slip: 0990821259	Name of Manufacturer: Beijing Goldenlaser Development Co., Ltd., 15-3 Building, Zhongnan Hitech Industrial Park, #4 Liushan Street, Yanjiao, Sanhe, Langfang, Hebei. 065201, China. • LOA Type: Original Attested By: CCPIT Validity: 23-03-2030 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 05-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 20-03-2027 • CE Certificate Type: Original Attested By: CCPIT Validity: 19-12-2028	Brand name: HIFU Machine Generic Name: High Energy Focussed Ultrasound Machine Applied as: Single Class: B Model/Codes/Sizes (as per CE: GLC01, GLC02, GLC03, GLC05, GLC06, GLC07, GLC08, GLC09, GLC10 Service life: Not mentioned	Deferred due to following deficiencies in the application; • FSC has been issued by chamber of commerce, not by regulatory body of country of origin. • Multiple models have been mentioned in CE certificate. The applied model has not been specified in application. • Service life has not been mentioned.
103.	M/s. Tru Technology, 297-Tariq Block, New Garden Town, Lahore. (ELI- 01176) R&I detail 26-06-2025 Fee: 31,000/-	Name of Manufacturer: Beijing Goldenlaser Development Co., Ltd., 15-3 Building, Zhongnan Hitech Industrial Park, #4 Liushan Street, Yanjiao, Sanhe, Langfang, Hebei. 065201, China.	Brand name: Hydra Facial Machine Generic Name: Hydra Facial Machine Applied as: Single	Deferred due to following deficiencies in the application; • Justification for consideration as medical device is required • FSC has been issued by chamber of commerce, not by regulatory body of country of origin.

	Slip: 2681739148	• LOA Type: Original Attested By: CCPIT Validity: 23-03-2030 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 05-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 20-03-2027 • CE Certificate Type: Original Attested By: CCPIT Validity: 19-12-2028	Class: B Model/Codes/Sizes (as per CE): GLQ01, GLQ02, GLQ03, GLQ05, GLQ06, GLQ07, GLQ08, GLQ09, GLQ10 Service life: Not mentioned	• Multiple models have been mentioned in CE certificate. The applied model has not been specified in application. • Service life has not been mentioned.
104.	M/s. Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. (ELI- 00183) R&I detail 20-06-2025 Fee: 38,000/- Slip: 385805908790 Fee: 62,000/- Slip: 2870872457	Name of Manufacturer: Huizhou Foryou Medical Devices Co., Ltd., North Shangxia Rd., Dongjiang Hitech Industry Park, 516005 Huizhou, China. • LOA Type: Original Attested By: CCPIT Validity: 30-03-2028 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 06-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 31-01-2026 • CE Certificate or FSC of reference country Not submitted	Brand name: Luofucon Extra Silver Gelling Fiber Dressing Generic Name: Wound Dressing Applied as: Family Class: C Model/Codes/Sizes (as per FSC & application): • SD100100R (100x100mm) • SD150150R (150x150mm) • SD300200R (300x200mm) • SD1000230R (1000x230mm) • SD54040R (540x450mm) Shelf life: 3 Years	Deferred due to following deficiencies in the application; • FSC has been issued by chamber of commerce, not by regulatory body of country of origin. • CE certificate of FSC of reference country has not been submitted.

105.	M/s. Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad. (ELI- 00183) R&I detail 20-06-2025 Fee: 38,000/- Slip: 7702892492 Fee: 62,000/- Slip: 83809649	Name of Manufacturer: Huizhou Foryou Medical Devices Co., Ltd., North Shangxia Rd., Dongjiang Hitech Industry Park, 516005 Huizhou, China. • LOA Type: Original Attested By: CCPIT Validity: 30-03-2028 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 06-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 31-01-2026 • EU QMS country Type: Original Attested By: CCPIT Validity: 04-09-2027	Brand name: Suntouch Soluble Hemostatic Gauze Generic Name: Wound Dressing Applied as: Family Class: C Model/Codes/Sizes (as per FSC & application): • SG030030P (30x30mm) • SG050030P (50x30mm) • SG050050P (50x50mm) • SG100050P (100x50mm) • SG100100P (100x100mm) • SG200100P (200x100mm) • SG220100PA (220x100cm) • SG011011p4 (11x11mm) • SG015015P4 (15x15mm) • SG015015P2 (15x15mm) • SG019019PA (19x19mm) • SG50007R (φ5x7mm) • SG50012R (φ5x12mm) Shelf life: 3 Years	Deferred due to following deficiencies in the application; • FSC has been issued by chamber of commerce, not by regulatory body of country of origin.
106.	M/s. Biowel Sciences, Office No. B-9, Basement, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area, Islamabad.	Name of Manufacturer: Huizhou Foryou Medical Devices Co., Ltd., North Shangxia Rd., Dongjiang Hitech Industry Park, 516005 Huizhou, China.	Brand name: Luofucon Silicon Postoperative Dressing Generic Name: Wound Dressing	Deferred due to following deficiencies in the application; • FSC has been issued by chamber of commerce, not by regulatory body of country of origin.

	(ELI- 00183) R&I detail 20-06-2025 Fee: 38,000/- Slip: 876041728 Fee: 62,000/- Slip: 31705284371	• LOA Type: Original Attested By: CCPIT Validity: 30-03-2028 • FSC Type: Original Issued By: CCCIEMHP Legalization: Apostilled Validity: 06-05-2027 • ISO Certificate Type: Original Attested By: CCPIT Validity: 31-01-2026 • EU QMS country Type: Original Attested By: CCPIT Validity: 04-09-2027	Applied as: Family Class: C Model/Codes/Sizes (as per FSC & application): • OP150090A (150x90mm) • OP100100A (100x100mm) • OP150100A (150x100mm) • OP200100A (200x100mm) • OP300100A (300x100mm) • OP350100A (350x100mm) • OP250200A (250x200mm) • OP500200A (500x200mm) Shelf life: 3 Years	
107.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 6186940167	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application): • GM700 • GM700/7000 • GM700/500 • GM700D Applied as: Family Service life: 5 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

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

	Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 26704699806	• LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Models/Codes/Sizes (as per FSC & Application: • GM500 • GM500D Applied as: Family Service life: 5 Years	
110.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 4969679121	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application: • STARRY500/700 Applied as: Single Service life: 5 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

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

	Fee: PKR 25,000/- Slip No. 4128868263	Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Models/Codes/Sizes (as per FSC & Application: • GM300 • GM300D Applied as: Family Service life: 5 Years	
113.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 751115544	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate	Brand name: Grand Generic Name: Operating Light (Include Medical Examination Lamp) Class: A Models/Codes/Sizes (as per FSC & Application: • GM200 • GM200D Applied as: Family Service life: 5 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

		Type: Original Notarization: By CCPIT Validity: 25-03-2027		
114.	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 4582242953	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • HyGrand700T Applied as: Single Service life: 10 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.
115.	M/s Tri Tech International, 10-C, 1 st , 2 nd , 3 rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 2495401336	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-III Applied as: Single	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

		• FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Service life: 10 Years	
116.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 7890249774	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application: • HyGrand-III Applied as: Single Service life: 10 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

		Validity: 25-03-2027		
117.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 1360367031	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-IV Applied as: Single Service life: 10 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.
118.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 67757463199	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-1A Applied as: Single Service life: 10 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

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

	2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 25,000/- Slip No. 63158488	Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application: • GM-700 • GM-700A • GM-700G • GM-700Q • GM-700I • GM-700T Applied as: Family Service life: 10 Years	by regulatory body of country of origin.
121.	M/s Tri Tech International, 10-C, 1st, 2nd, 3rd Floor, Sunset Commercial Lane, Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 8653230085	Name of Manufacturer: Shandong Grand Medical Equipment Co., Ltd., No. 8, Ziwei Road, Xinyan Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled	Brand name: Grand Generic Name: Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application: • GM-V Applied as: Single Service life: 10 Years	Deferred for submission of Valid Legalized FSC issued by regulatory body of country of origin.

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

	Phase-II EXT., DHA, Karachi. ELI-00247 Date of R& I 10-07-2025 Fee: PKR 6,000/- Slip No. 9858269079	Town, Yanzhou District, Jining City, Shandong Province, China. • LOA Type: Original Notarization: By CCPIT Validity: 05-05-2035 • FSC (China Chamber of Commerce) Type: Original Issued By: CCCMHPIE Legalization: Apostilled Validity: 06-05-2027 • FSC (MPA) Type: Copy Issued By: MPA Legalization: Apostilled Issue Date: 29-08-2024 Validity: 2 Years • ISO Certificate Type: Original Notarization: By CCPIT Validity: 25-03-2027	Electric Operating Table Class: A Models/Codes/Sizes (as per FSC & Application): • GM-800A Applied as: Single Service life: 10 Years											
124.	M/s Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. ELI-00091 Date of R& I 02-06-2025 Fee: 62,000/- Slip 169920796831 Fee: 42,500/- Slip No. 27224060	Name of Manufacturer: VSY Biotechnology GmbH, Esslinger Strabe 7 70771 Leinfelden-Echterdingen, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 24-04-2025 Validity: Not mentioned • ISO Certificate Type: Original	Brand name: Enova Generic Name: Hydrophobic Intraocular Lense Class: C Models/Codes/Sizes (as per FSC, DOC & Application): <table><tr><th>Model</th><th>Model No.</th></tr><tr><td>ENOVA GF3</td><td>M055 G</td></tr><tr><td>ENOVA T GF3</td><td>M085 G</td></tr><tr><td>ENOVA ADC</td><td>M088 G</td></tr><tr><td>ENOVA T ADC</td><td>M089 G</td></tr></table>	Model	Model No.	ENOVA GF3	M055 G	ENOVA T GF3	M085 G	ENOVA ADC	M088 G	ENOVA T ADC	M089 G	Deferred for justification for applying multiple models in single application.
Model	Model No.													
ENOVA GF3	M055 G													
ENOVA T GF3	M085 G													
ENOVA ADC	M088 G													
ENOVA T ADC	M089 G													

		Notarization: Notarized Validity: 25-07-2026	<table><tr><td>ENOVA MAESTR O C</td><td>M0109 G</td></tr><tr><td>ENOVA MAESTR O T C</td><td>M0110 G</td></tr><tr><td colspan="2">Preloaded</td></tr><tr><td>ENOVA PGF3</td><td>M059 G</td></tr><tr><td>ENOVA T PGF3</td><td>M0115 G</td></tr><tr><td>ENOVA PADC</td><td>M0119 G</td></tr><tr><td>ENOVA T PADC</td><td>M0120 G</td></tr><tr><td>ENOVA MAESTR O CP</td><td>M0131 G</td></tr><tr><td>ENOVA MAESTR O T CP</td><td>M0132 G</td></tr></table> Applied as: Family Shelf life: 4 Years	ENOVA MAESTR O C	M0109 G	ENOVA MAESTR O T C	M0110 G	Preloaded		ENOVA PGF3	M059 G	ENOVA T PGF3	M0115 G	ENOVA PADC	M0119 G	ENOVA T PADC	M0120 G	ENOVA MAESTR O CP	M0131 G	ENOVA MAESTR O T CP	M0132 G	
ENOVA MAESTR O C	M0109 G																					
ENOVA MAESTR O T C	M0110 G																					
Preloaded																						
ENOVA PGF3	M059 G																					
ENOVA T PGF3	M0115 G																					
ENOVA PADC	M0119 G																					
ENOVA T PADC	M0120 G																					
ENOVA MAESTR O CP	M0131 G																					
ENOVA MAESTR O T CP	M0132 G																					
125.	M/s Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. ELI-00091 Date of R& I 02-06-2025 Fee: 62,000/- Slip No. 4974244278 Fee: 42,500/- Slip No. 61620350132	Name of Manufacturer: VSY Biotechnology GmbH, Esslinger Strabe 7 70771 Leinfelden-Echterdingen, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 24-04-2025 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 25-07-2026	Brand name: Acrida Generic Name: Hydrophobic Intraocular Lense Class: C Models/Codes/Sizes (as per FSC, DOC & Application): <table><tr><th>Model</th><th>Model No.</th></tr><tr><td>ACRIVA UD 613</td><td>M003 G</td></tr><tr><td>ACRIVA BB UD 613</td><td>M025 G</td></tr><tr><td>ACRIVA BB UDM 611</td><td>M031 G</td></tr><tr><td>ACRIVA BB T UDM 611</td><td>M029 G</td></tr><tr><td>ACRIVA TRINOVA PRO</td><td>M0220 G</td></tr></table>	Model	Model No.	ACRIVA UD 613	M003 G	ACRIVA BB UD 613	M025 G	ACRIVA BB UDM 611	M031 G	ACRIVA BB T UDM 611	M029 G	ACRIVA TRINOVA PRO	M0220 G	Deferred for justification for applying multiple models in single application. Shelf life.						
Model	Model No.																					
ACRIVA UD 613	M003 G																					
ACRIVA BB UD 613	M025 G																					
ACRIVA BB UDM 611	M031 G																					
ACRIVA BB T UDM 611	M029 G																					
ACRIVA TRINOVA PRO	M0220 G																					

			<table><tr><td>ACRIVA TRINOVA PRO TORIC</td><td>M0221 G</td></tr><tr><td>ACRIVA TRINOVA PRO C</td><td>M077 G</td></tr></table> Applied as: Family Shelf life: <table><tr><th>Model</th><th>Shelf life.</th></tr><tr><td>ACRIVA UD 613</td><td>5 Years</td></tr><tr><td>ACRIVA BB UD 613</td><td>3 Years</td></tr><tr><td>ACRIVA BB UDM 611</td><td>3 Years</td></tr><tr><td>ACRIVA BB T UDM 611</td><td></td></tr><tr><td>ACRIVA TRINOVA PRO</td><td></td></tr><tr><td>ACRIVA TRINOVA PRO TORIC</td><td></td></tr><tr><td>ACRIVA TRINOVA PRO C</td><td>5 Years</td></tr></table>	ACRIVA TRINOVA PRO TORIC	M0221 G	ACRIVA TRINOVA PRO C	M077 G	Model	Shelf life.	ACRIVA UD 613	5 Years	ACRIVA BB UD 613	3 Years	ACRIVA BB UDM 611	3 Years	ACRIVA BB T UDM 611		ACRIVA TRINOVA PRO		ACRIVA TRINOVA PRO TORIC		ACRIVA TRINOVA PRO C	5 Years	
ACRIVA TRINOVA PRO TORIC	M0221 G																							
ACRIVA TRINOVA PRO C	M077 G																							
Model	Shelf life.																							
ACRIVA UD 613	5 Years																							
ACRIVA BB UD 613	3 Years																							
ACRIVA BB UDM 611	3 Years																							
ACRIVA BB T UDM 611																								
ACRIVA TRINOVA PRO																								
ACRIVA TRINOVA PRO TORIC																								
ACRIVA TRINOVA PRO C	5 Years																							
126.	M/s Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. ELI-00091 Date of R& I 02-06-2025 Fee: 62,000/- Slip No. 7570621121 Fee: 42,500/- Slip No. 684922490	Name of Manufacturer: VSY Biotechnology GmbH, Esslinger Strabe 7 70771 Leinfredlen-Echterdingen, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized	Brand name: Reviscon Generic Name: Intrarticular Viscosupplement Class: C Models/Codes/Sizes (as per FSC, DOC & Application): <table><tr><th>Model</th><th>Ref No.</th></tr><tr><td>Reviscon 1%</td><td>MV01 5G</td></tr><tr><td>Reviscon Plus 1.6%</td><td>MV01 6G</td></tr></table>	Model	Ref No.	Reviscon 1%	MV01 5G	Reviscon Plus 1.6%	MV01 6G	Deferred for justification for applying multiple models in single application.														
Model	Ref No.																							
Reviscon 1%	MV01 5G																							
Reviscon Plus 1.6%	MV01 6G																							

		Issue Date: 24-04-2025 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 25-07-2026	<table><tr><td>Reviscon Mono 2%</td><td>MV04 4G</td></tr></table> Applied as: Single Shelf life: 3 Years	Reviscon Mono 2%	MV04 4G			
Reviscon Mono 2%	MV04 4G							
127.	M/s Popular International (Pvt.) Ltd., 141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi. ELI-00091 Date of R& I 02-06-2025 Fee: PKR 62,000/- Slip No. 62014267211	Name of Manufacturer: VSY Biotechnology GmbH, Esslinger Strabe 7 70771 Leinfelden-Echterdingen, Germany. • LOA Type: Original Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC (Germany) Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 24-04-2025 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 25-07-2026	Brand name: Recross by Reviscon Generic Name: Intrarticular Viscosupplement Class: C Models/Codes/Sizes (as per FSC, DOC & Application): <table><tr><td>Model</td><td>Ref No.</td></tr><tr><td>Recross by Reviscon</td><td>MV12 8G</td></tr></table> Applied as: Single Shelf life: 3 Years	Model	Ref No.	Recross by Reviscon	MV12 8G	Approved
Model	Ref No.							
Recross by Reviscon	MV12 8G							

Agenda Item No. III: APPLICATIONS FOR ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT DEFERRED BY MDB IN ITS VARIOUS MEETINGS

DEFERRED IMPORT CASES

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
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1.	Medzntech Pvt.Ltd., D-21 Sector 16-A Govt. Teachers CO-operative Housing Society, KDA Scheme 33, Karachi (ELI-00657) Fees: Rs 62000 Challan # 99957955755 Fees: Rs 42,500 Challan # 08447214379 dated 02-10-2025 Rs 104,500 Challan # 2637643201 dated 02-10-2025 Rs 104,500 Challan # 49869401 dated 02-10-2025 Date of R& I	<u>Legal Manufacturer:</u> Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX, USA 76134 <u>Other Sites:</u> PT CIBA Vision Batam, Jl. Berinjin Lot # 204, Batamindo Industrial Park, Muka Kuning, Batam Islamabd, Indonesia <u>LOA:</u> Sole Agency Agreement Issue date: 09-01-2024 (Original notarized) <u>FSC: USA</u> Valid Until: 08-05-2025 (Original Notarized) EC Certificate valid until:23-06-2027 (Original Notarized) <u>ISO:</u> Valid till: 24-04-2025 (Original Notarized)	Laser Probes 8065750978-25 GA Straight Laser Probe w/RFID Shelf Life. 36 m 8065750985-20 GA Curved Illuminated Laser Probe w/RFID SMA/RFID-ACMI Shelf Life. 24 m 8065750989 – 20 GA Curved Laser Probe w/RFID Shelf Life. 36 m 8065750990 – 20 GA Straight Laser Probe w/RFID Shelf Life. 36 m Newly applied codes. 8065750991 – 23 GA Straight Laser Probe W/RFID Applied as: Set Shelf Life. 36 m 8065751113 – 23 GA Flexible Tip Laser Probe W/RFID Shelf Life. 36 m 80865751114 – 25 GA Flexible Tip Laser Probe W/RFID Shelf Life. 36 m 8065751592 – 23 GA Illuminated Flexible Curved Laser Probe W/RFID Shelf Life. 24 m	The MDB approved the following three (03) medical devices, firm will submit valid ISO and FSC before issuance of Form 8; 1. Straight Laser Probes Codes/Sizes 8065750990 20 GA 8065750991 23 GA 8065750978 25 GA Shelf Life 36 months 2. Illuminated Flexible Curved Laser Probes; 8065751592 23 GA 8065751593 25 GA Shelf Life 24 Months 3. Flexible Tip Laser Probes; 8065751113 23 GA 8065751114 25 GA 8065751709 27+ Shelf Life 36 Months
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	05-05-2025			8065751593 – 25 GA Illuminated Flexible Curved Laser Probe W/RFID Shelf Life. 24 m 8065751709 – 27 + Flexible Tip Laser Probe W/RFID Shelf Life. 36 m 8065751020 – Constellation 20 GA UltraVit Anterior Vit Pak 5000 CPM W/RFID Shelf Life. 24 m 8065751561 – Constellation 23 GA UltraVit Anterior Vit Pak 5000 CPM W/RFID Shelf Life. 24 m Class C Shelf Life: Codes/Sizes: 8065750978-25 GA Straight Laser Probe w/RFID 8065750985-20 GA Curved Illuminated Laser Probe w/RFID SMA/RFID-ACMI 8065750989 – 20 GA Curved Laser Probe w/RFID 8065750990 – 20 GA Straight Laser Probe w/RFID	
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2.	Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi ELI-0000471 Date of R&I 28-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 0535848999	<u>Legal Manufacturer:</u> Jiangsu Kanghua Medical Equipment Co. Ltd., Sanhekou Changzhou Jiangsu 213115, China LOA Validity: 18-03-2030 FSC: China Validity: 21-12-2025 ISO Validity: 30-04-2026 EU QA Certificate Validity: 26-05-2024 with extension notification letter	Tirzi Disposable Syringe Class-B Shelf life: 5 Years Models/ Specification; Syringe specification: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100 ml, with Hypodermic needle specification: Hypodermic needle specification 0.30×9 RW LB, 0.30×13RW LB, 0.33×9RW LB, 0.33×13RW LB, 0.36×9RW LB, 0.36×13RW LB, 0.4×13RW LB, 0.4×16RW LB, 0.45×13RW LB, 0.45×16RW LB, 0.5×16RW LB, 0.5×25RW LB, 0.55×16RW LB, 0.55×25RW LB, 0.6×25TW LB, 0.6×32TW LB, 0.6×38TW	The MDB approved Tirzi disposable insulin syringe with 31 G x 6mm needle only.
3.	M/s. Royal Enterprises, Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi. (ELI- 00062) R&I detail 14-05-2025 Fee: 6,000/- Slip: 58042971572	<u>Name of Manufacturer:</u> M/s. Zhejiang Hand in Hand Intelligent Health Technology Co., Ltd., Second Floor, No. 12, Xiayantou Nature Country, Jiuzhou Town, East City Street, Yongkang, Jinhua, Zhejiang, China.	<u>Brand name:</u> Nebicare Plus <u>Generic Name:</u> Electric Wheelchair <u>Class:</u> A <u>Models/Sizes:</u> XSW001-B, XSW002-H, XSW002-C,	Deferred for submission of; 1. Catalogue that describe each model/size applied. 2. shelf life data.

		• LOA Type: Original Notarization: By CCPIT Validity: 13-04-2035 • FSC Type: Original Legalization: Appostilled Validity: 20-11-2025 • ISO Certificate Type: Original Notarization: By CCPIT Validity: 30-10-2026	XSW003-D, XSW003-K, XSW001-B Series, XSW002-H Series, XSW002-C Series, XSW003-D Series, XSW003-K Series Shelf life: Not mentioned	
4.	M/s Intek Corporation Office # 30, AL Amin Plaza, the Mall, Rawalpindi. ELI-00034 943-P Evaluator AD-III	<u>Legal Manufacturer:</u> TERUMO CORPORATION 44-1, 2-Chome, Hatagaya, Shibuya-Ku, Tokyo 151-0072 JAPAN <u>Manufacturing Sites</u> TERUMO CORPORATION ASHITAKA FACTORY Address: 150, Maimaigi-Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan. TERUMO VIETNAM CO., LTD. Lot 44a-44b-44c Quang Minh Industrial Zone, Me Linh District, Hanoi CITY, VIETNAM FSC Japan issuance 18-02-2020	Radifocus Guide Wire M (Catheter Guide Wire) Class-D Shelf life: 3 years Codes as per FSC	Deferred for; 1. Justification that how products of different manufacturers fall under family. 2. submission of valid, notarized DE certificate.
5.	Applicant Name: Ferozsons Laboratories Limited, P.O. Ferozsons Amangarh, Nowshera (KPKP)	Name of Manufacturer: CenterPoint Systems, LLC 3338 Parkway	Brand name: Site Selective Pacing Catheters Generic Name:	Deferred for submission of; 1. details of codes/models.

	(ELI-00120) Date of R&I 18-04-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 22661968775	Blvd West Valley City UT 84119 USA Manufacturing Site: CenterPoint Systems, LLC 3338 Parkway Blvd West Valley City UT 84119 USA LOA exp date: 31-12-2025(Copy) FSC: USA Expiry date: 09-08- 2025(Original Notarized) ISO Validity: 28-12-2024 (Notarized) EU QA Certificate Validity: 26-05- 2024(Notarized)	Intravascular Guiding Catheters Class-D Shelf life: 24 months Applied as: System Models/ Specification	2. fee (differential) for family of class D.
6.	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 4050-KP Submission date: 02/08/2023 Fee submitted: 50,000/-PKR Challan# 471846030515 Evaluator: DD-II	Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland. FSC: USA Valid till: 12/10/2024	Inogen X4 CRT-D (Cardiac Resynchronization Therapy Defibrillator) Models: G146, G148 (Mentioned in FSC) Class-D Shelf life: 2 years	Approved subject to submission of valid, notarized LOA. The firm will submit the LOA within ninety (90) days, otherwise case will be again placed before MDB for decision.
7.	Feroszons Laboratorries Limited, P.O Ferozsons, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 4054-KP Submission date: 02/08/2023	Legal Manufacturer: Boston scientific Corporation 4100 Hamline Ave N Saint Paul, MN, USA 55112 Manufacturing Site: Boston Scientific Limited Cashel Road	Inogen EL ICD (Implantable cardioverter Defibrillator) Model: D140, D141,D142,D143 (Mentioned in FSC) Class-D	Approved subject to submission of valid, notarized LOA. The firm will submit the LOA within ninety (90) days, otherwise case will be again placed before MDB for decision.

	Fee submitted: 50,000/-PKR Challan# 1471030631 Evaluator: DD-II	Clonmel, Tipperary Ireland FSC: USA Date of Issue: 12/10/2024	Shelf life: 2 years	
8.	Ferozsans Laboratorries Limited, P.O Ferozsans, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 4328-KP Submission date: 02/08/2023 Fee submitted: 50,000/-PKR Challan# 6316286338 Evaluator: DD-II	Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland FSC: U.S.A Valid till: 12/10/2024	INOGEN CRT-D (Cardiac Resynchronization Therapy Defibrillator) Models: G140, G141 (Mentioned in FSC) Class-D Shelf Life: 2 years	Approved subject to submission of valid, notarized LOA. The firm will submit the LOA within ninety (90) days, otherwise case will be again placed before MDB for decision.
9.	Applicant Name: M/s. Ferozsans Laboratories Limited, P.O Ferozsans, Amangarh, Nowshera. (ELI- 00120) R&I detail 07-04-2025 Fee: 6000 Slip: 91862081893 Dated: 25-03-2025	Name of Manufacturer: M/s. Boston Scientific Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA M/s Boston Scientific Corporation, 302 Parkway Global Park, Heredia Costa Rica Agency Agreement Validity: 31-12-2025 FSC Validity (FDA): 25-06-2025 ISO Validity: 18-10-2027	Brand name: Electrophysiology Cables Generic Name: Medical Device Electrical Cable, Reusable Class: A Codes/Sizes: M0045441S0, M0045454S0, M004626S0, M00420S0, M0046130, M0046510, M004603S0, M004653S0, M0046200, M0046270, M0046210, M0046710 Shelf life: 03 Years	Approved the codes/models M0046710, M0046210, M0046130 & M0046510 subject to submission of; valid, notarized LOA. The firm will submit the LOA within ninety (90) days, otherwise case will be again placed before MDB for decision and Fee (differential) for family.

10.	Ferozsans Laboratories Limited P.O. Ferozsans, Amangarh, Nowshera, KPK (ELI-00120)	Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA Manufacturing Boston Scientific Limited Business and Technology Park Model Farm Road CORK, IRELAND	Extractor Pro RX-S Retrieval Balloon Catheter M00547300 M00547310 M00547320 M00547330 M00547340 M00547350	Approved in Class B subject to submission of DOC.
11.	M/s Ferozsans Laboratories Limited , P.O Ferozsans, Amangarh, Nowshera (KPK) ELI: 00120 Evaluator: AD – II (3548-P)	Legal Manufacturer: M/s Apollo Endosurgery , 1120 South Capital of Texas Highway, Building 1, Suite 300, Austin, Texas 78746 USA. FSC: USA Valid till: 25.05.2023	OverStitch & OverStitch Sx Endoscopic Suturing System Codes & Sizes: As per FSC Class-C Shelf Life: 03 years	Deferred for submission of; 1. Original, notarized and valid LOA issued by Apollo Endosurgery, USA instead of Boston Scientific International, Netherlands. 2. original, embassy attested and valid FSC. 3. valid, notarized ISO13485. 4. Fee for the system. 5. Firm will apply OverStitch Sx Endoscopic Suturing System separately.
12.	Feroszons Laboratorries Limited, P.O Ferozsans, Amangarh, Nowshera (KPK), Pakistan ELI: 00120 Dossier# 4049-KP Submission date: 02/08/2023 Fee submitted: 50,000/-PKR Challan# 4307057199 Evaluator: DD-II	Legal Manufacturer: Boston Scientific Corporation 4100 Hamline Ave N Saint Paul, MN USA 55112 Manufacturing Site: Boston Scientific Limited Cashel Road Clonmel, Tipperary Ireland. Original FSC: USA Valid till: 12/10/2024	Essential MRI Model: L131 (Pulse Generator: Implantable Pacemaker) Codes & Sizes: Model: L131 Class-D Shelf life: 2 years	Approved subject to submission of valid, notarized LOA. The firm will submit the LOA within ninety (90) days, otherwise case will be again placed before MDB for decision.

13.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK)-Pakistan. ELI-00120	M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA M/s Boston Scientific Corporation 302 Parkway, Global Park, Heredia, Costa Rica Copy of FSC of USFDA valid till 05.11.2025. Copy of 3 FSC of Ireland two issued on 10.06.2024 Third FSC issued on 15.7.2024 EU technical documentation 2.09.2027 EU QMS valid till 2.09.2027 ISO 13485 Valid till 01.09.2026	Farapulse™ Pulsed Field Ablation System Pulse Field Ablation Catheter Catheter Connection Cable Class D 24 Months(2) N/A FARASTAR Pulsed Field Ablation Generator M004PFCE61M401 M004PFCE61M407 Electronic Components- Shelf Life Not Applicable FARAWAVE Catheter M004PFCE41M401 M004PFCE41M402 24 months FARASTAR Connection Cable M004PF41M434 24 months ACCESSORIES M004PF61M404 M004PF61M405 M004PF61M409 M004PF61M408 M004PF61M410	Approved FARASTAR Pulsed Field Ablation Generator (M004PFCE61M401) Farastar Recording System Module (RSM & Component) (M004PFCE61M407) FARASTAR Catheter Connection Cable, Gen1 (M004PF41M434) subject to submission of fee for the system.
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			M004PF61M411 M004PF61M412 M004PF61M413 M004PF61M415 M004PF61M416 M004PF61M417 M004PF61M420 M004PF61M421 Electronic Components- Shelf Life Not Applicable (Attached as annexure: 04) Fee 100000/-	
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14.	Name & Address of Importer	Contraceptives Pakistan (Pvt.) Ltd. Address of Importer Office No. 4A, Street No. 1, 116 Apartments Shah Jamal, Lahore.
	Detail of ELM/ELI	ELI-01178
	Name Address of Manufacturer	Corporate Channels India Pvt. Ltd. 1590-1600, Village Paldi, Post Loyara, P.O. Badgaon, Udaipur 313001 Rajasthan, INDIA
	Brand Name Generic Name	EVE'S TCu380A IUCD
	Country of origin FSC	FSC: FSC No.: FSC/MD/2021/000227
	Whether the product is applied on CE certificate basis or free sale in reference countries	UNFPA Prequalified List provided
	Date of application received along with Fee	Date of R& I 22 February, 2024 Fee Rs. 50,000/= through slip no. 994535732648
	Class of medical device	D

Brief Description of the Medical Device with intended use	The TCu380A IUD consists of a T-shaped frame made from low-density polyethylene with barium sulphate added for X-ray opacity. T
Stability data/ service life	Shelf Life: 5 years
Documents submitted	
Marketing Authorization Letter:	Marketing Authorization Letter (LOA): Valid till: March-2028
Production Quality Management System Certificate (ISO 13485)	Production Quality Management System Certificate (ISO 13485) International Certification Services Pvt. Ltd. Accredited by National Accreditation Board For Certification bodies, India Valid Date: 09.03.2024
Full Quality Assurance Certificate or Equivalent:	EU Quality Management System Certificate (MDR): UNFPA Prequalified TCu380A IUD List provided
Design Examination	Design Examination Certificate: N/A. UNFPA Prequalified TCu380A IUD provided which obsolete requirement of Design examination certificate that is under MDD.
Declaration of Conformity (Doc) provided/not provided	Declaration of Conformity (Doc) Provided
Codes/ sizes	As per FSC
Remarks	ISO 13485 is expired but valid upon submission. The brand name on FSC is EVES T10 whereas on Form-7A it is EVES.
Decision	Deferred for the clarification of Brand name and provision of valid ISO 13485 certificate.
Remarks	Firm has submitted ISO 13485 valid till 9 th March 2027, copy of termination letter issued by the manufacturer for K.M. Enterprises Lahore and UNFPA prequalification list dated 21.10.2022. The copy of ISO and Termination letter are notarized.
Decision	Approved. MDB authorized the Chairman to give showcase and personal hearing to K.M. Enterprises for cancellation of its restartion before issuance of registration letter/ Form 8 to applicant.

Agenda Item No. IV: Misc. Cases

Case No. 1 ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES – INVALID

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

Following Establishment License for Imports has become invalid (cease to exist) due to late submission of renewal application after expiry of validity of license, the relevant clause Rule 7(5) of Medical Devices Rules 2017 is reproduced as under:

“If an application for renewal is made after expiry of the period of validity of licence, the applicant shall deposit an additional fee equivalent to applicable renewal fee for each month till one year of the expiry of the establishment licence and after one year the establishment licence shall cease to exist and the application shall be treated as a fresh application for grant of establishment licence.”

S.NO.	Name of Firm	Renewal Due Date	Date of Renewal Application	Decision
1.	M/s K.R International, H No. 210 (CB No. 988) St.No.5 (East) Shabbir lane, Peshawar road, Pir Wadhai Mor, Rawalpindi. (ELI-00331)	25-02-2024	02-09-2025	The board observed that the firm has applied for renewal of license after expiry of one-year grace period given in the Medical Devices Rules, 2017 (Rule 7(5) of Medical Devices Rules 2017), therefore, it was decided to issue show cause notice to the firm.

MINUTES OF ADDITIONAL AGENDA

AGENDA ITEM NO. I: APPLICATIONS FOR ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025 Fee: Rs. 6,000 vide deposit slip no. 4006843269	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	Brand Name: Secure Ages Generic Name: Shower Chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY03790,DY03791,DY03792,DY03791S,DY03794LL, DY037935, DY03797L, DY03798L, DY0379911, DY0398LQ, DDY03795L,DY03796 L, DY03780L, DY03782L, DY033782L(2),DY03781L,DY03783L,DY03784L, DY03785L. Shelf Life: --	Deferred for following observations: Justification for applying various models. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority as submitted FSC has not been issued by the relevant regulatory authority.
2.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	Brand Name: Secure Ages Generic Name: Rollator Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY049142,DY049143, DY049145L, DY049146L(2),DYO49	Deferred for following observations: Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted.

	Fee: Rs. 6,000 vide deposit slip no. 99926889	Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	144L, DY049146L,DY049151L,DY049147L, DY049148L,DY049149L,DY049150L Shelf Life: --	Original Legalized FSC shall be submitted issued by the relevant regulatory authority Submitted FSC has not been issued by the relevant regulatory authority.
3.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025 Fee: Rs. 6,000 vide deposit slip no. 381437537508	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No	Brand Name: Secure Ages Generic Name: Electric Wheel Chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY01101LA, DYO1101, DY01102, DY01105, DY01106, DY01107, DY01108, DY01109, DY01117L, DY01131LA, DY01121C, DY01114LA, DY01112A, DY01111A,DY01110A, DY01120, DY01123LA(2), DY01122, DY01108L(2), DY01105L(3)A, Y01101(3)LA, DYO1106(L), DY01102LA, DY01109LA, DY01122(2),	Deferred for following observations: Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Submitted FSC has not been issued by the relevant regulatory authority.

		Validity: 23-06-2028	DY01107(6)LAGC, DY0110733LAGC, DY01112(4)LA, DY01112(6)A, DY01112(7)A. Shelf Life: --	
4.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025 Fee: Rs. 6,000 vide deposit slip no. 45999321	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	Brand Name: Secure Ages Generic Name: Walker Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY04912L-5, DY04912L-2.5, DY04919L, DY04913L, DY04915L, DY04962L. DY04916L, DY04917L, DY04918L, DY04963L, DY04914L, DY04961L. DY04964L. DY04965L-5. DY04965L, DY04912L(S)-5, DY04913L(S), DY04966L(S)-2.5, DY04966L(S) Shelf Life: --	Deferred for following observations: Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Submitted FSC has not been issued by the relevant regulatory authority.
5.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025 Fee: Rs. 6,000 vide deposit slip no. 53650067	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA	Brand Name: Secure Ages Generic Name: Stick Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY059201L-M1. DY059201L-M2, DY059201L-M3, DY059201L-M4, DY059201L-M5,	Deferred for following observations: Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority

		Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	DY059201L-M6, Y059201L-M7, DY059201L-M10, DY05927L-M2, DY05927L-M1, DY05927L-M3, DY05927L-M9, DY0591OL, DY05920L, DY059201LB, Y05927LB, DY05939L, DY05929L, DY0593OL, DY05928L, DY059281L, DY05938L, DY05938LB, DY05911L, DY05911LB, DY059282L, DY05936L, DY05936L(S), DY05921, DY05922, DY05924, DY05926, DY05932, DY05934, DY05931, DY05941, DY05944, DY05947, DY05940L, DY05927L-M4, DY05927L -M5, DY05927L-M6, DY05927L-M7, DY05927L-M8, DY05927L-M10 Shelf Life: --	Submitted FSC has not been issued by the relevant regulatory authority.
6.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025 Fee: Rs. 6,000 vide deposit slip no. 91688988729	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy	Brand Name: Secure Ages Generic Name: Manual Wheel Chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY01201LO, DY01700LQ, Y01958LBCJ, DY01959LB, DY01953LQ, DY01953LCQ,	Deferred for following observations: Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority

		Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	DY01903LB, DY01903LABQ, DY01954LGC, DY01950LBQ, DY01955LB, DY01973LAH, DY01980LA-46, DY01980LA-35, DY01908LAJ, DY01200LABJQ, DY01983L, DY01869L (2)AJ, DY01869LAJ, DY01869L(3)AJ, DY01864LDJ, DY01864L, DY01864L(4) J-46, DY01872LAJ, DY01868LJ, DY01868L, DY01910LAJ, DY01863L3AJ, DYO19 0GLDI, DY01907LAI,DY01984 LI,DY019003LABJ,DY 01871LBJ,DY01805LA BJ,DY01801LABJ,DY0 1863LABJ,DY019001L BJ-40, DY01905A(2)J, DY01904BD, DY01976A(2)BEJ, DY01976A(2)J, DY01809SW,DY01990 ,DY01903GC, DY01903BGC- 35,DY01902GC, DY01951B- 56,DY01951AC-56, DY01974- 51,DY01909B,DY0190 8, DY01903,DY01902C,D Y01901, DY01980AC- 35,DY01972BDE, DY01972BDEC,1 DY01983, DY01802E- 35,DY01874- 46,DY01868DY01809, DY01875D,DY01871,D Y01873, DY01906DJ,DY02609	Submitted FSC has not been issued by the relevant regulatory authority.
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			GC, DY02608GC, DY02608L,DY026609, DY02608, DY02681,DY02683Q, DY02608LGC,DY0268 1C-511 DY01908LABI,DY021 51L466 DY01216LA- 46,DY01213LAJ-46, DY01408LA466,DY01 409L1, DY01303LQ- 36, DY01303LQ-41, DY01303LQ- 44,DY01303LQ-46 Shelf Life: --	
7.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07- 2025 Fee: Rs. 6,000 vide deposit slip no. 0330602171	Name of Manufacturer: Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	Brand Name: Secure Ages Generic Name: Crutch Applied as: Single Class: A Models/Code/sizes (as per FSC & application DY05925L(L), DY05925L(M), DY05925L(S), DY05935L, DY0593SM, DY05935S, DY05933L(S), DY05933L, DY059331L, DY05923L, DY05937L, DY05937L-RD, DY05937L-BK Shelf Life: --	Deferred for following observations: Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Submitted FSC has not been issued by the relevant regulatory authority..
8.	Hussan Trader, Shop No. G-25 A, Quetta Wala Market Kutchi	Name of Manufacturer:	Brand Name: Secure Ages Generic Name:	Deferred for following observations:

	Gali No. 1 1/2 Marriot Road, Saddar Town, Karachi ELI-00729 R&I Date: 11-07-2025 Fee: Rs. 6,000 vide deposit slip no. 861242029	Guangdong Dayang Medical Technology CO., Ltd Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, People's Republic of China LOA Type: Copy Notarization: No Validity: 10-06-2030 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 16-07-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 23-06-2028	Commode chair Applied as: Single Class: A Models/Code/sizes (as per FSC & application) DY02691,D Y02692E, DY 02695, DY02692(2), DY028191, DY 02819L, DY02699L, DY 02696(5), DY02696(2).DY02697(2),DY02894(2). DY02894(5), DY02896(2)I, DY02894L(2), DY02895L,DY02893,D Y 02815,DY02817, DY02800, DY02810,DY 02899(3),DY02899(2), DY02899U DY02898,DY 02890:DY02897, >Y02897(2),DY0281 1,DY028 16L,DY0281 8L, DY02897L,DY 02899L,DY077600-06, DY077600- 51,DY077600(2),DY02 695-51, DY02695C751,DY0281 7U,DY02805,DY02820 L, DY02894,DY02894(5) E,DY02696(5)E, DY02804,DY074006,D Y074006,DY02823(2), DY01118,DY01118(3), DY01118(4), DY01118(5)L,DY0111 8(6),DY01118(8), DY0 1118(9) Shelf Life: --	Justification for applying various models in single application. Original Notarized LOA shall be submitted Notarized copy of ISO certificate shall be submitted. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Submitted FSC has not been issued by the relevant regulatory authority.
9.	I-Care, Shop No. 21 Basement No. 1, Marium Tower, Near Bhatti Chowk, Lahore ELI-01019	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd Address:	Brand Name: Dr Trust Blood Lancet Generic Name: Blood Lancet Applied as: Single	Deferred for following observations: Change of brand name The submitted FSC has not been issued by the relevant

	R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 562669625	Dingtao (Yantai) Industrial Park, Heze City, Shandong 274100, P.R. China LOA Type: Copy Notarization: Yes Validity: 02-06-2030 • FSC: Type: Copy Issued By: Shandonhg Association for Medical Device Industry Legalization: No Validity: 08-06-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025	Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years	regulatory authority and also does not endorse the free sale status in country of origin. Original Notarized LOA & valid Iso certificate shall be submitted Original Legalized FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted. Codes/model
10.	I-Care, Shop No. 21 Basement No. 1, Marium Tower, Near Bhatti Chowk, Lahore ELI-01019 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 64511850	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd Address: Dingtao (Yantai) Industrial Park, Heze City, Shandong 274100, P.R. China LOA Type: Copy Notarization: Yes Validity: 02-06-2030 • FSC: Type: Copy Issued By: Shandonhg Association for Medical Device Industry Legalization: No Validity: 08-06-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025	Brand Name: Dr Trust Intravenous Infusion set with Burette 100ml Generic Name: Intravenous Infusion Set with Burette 100ml Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years	Deferred for following observations: Change of brand name The submitted FSC has not been issued by the relevant regulatory authority and also does not endorse the free sale status in country of origin. Original Notarized LOA & valid Iso certificate shall be submitted Original Legalized FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted. Codes/model
11.	I-Care, Shop No. 21 Basement No. 1,	Name of Manufacturer:	Brand Name:	Deferred for following observations: Change of brand name

	Marium Tower, Near Bhatti Chowk, Lahore ELI-01019 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 63683046790	Shandong Wuzhou Medical Equipment Co., Ltd Address: Dingtao (Yantai) Industrial Park, Heze City, Shandong 274100, P.R. China LOA Type: Copy Notarization: Yes Validity: 02-06-2030 • FSC: Type: Copy Issued By: Shandonhg Association for Medical Device Industry Legalization: No Validity: 08-06-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025	Dr Trust Disposable Sterile Blood Transfusion Set Generic Name: Disposable Sterile Blood Transfusion Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years	Codes/model The submitted FSC has not been issued by the relevant regulatory authority and also does not endorse the free sale status in country of origin. Original Notarized LOA & valid Iso certificate shall be submitted Original Legalized FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted.
12.	I-Care, Shop No. 21 Basement No. 1, Marium Tower, Near Bhatti Chowk, Lahore ELI-01019 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 1348346021	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd Address: Dingtao (Yantai) Industrial Park, Heze City, Shandong 274100, P.R. China LOA Type: Copy Notarization: Yes Validity: 02-06-2030 • FSC: Type: Copy Issued By: Shandonhg Association for Medical Device Industry Legalization: No Validity: 08-06-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025	Brand Name: Dr Trust Disposable sterile Intravenous Needle Generic Name: Butterfly Needle Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years	Deferred for following observations: Change of brand name Codes/model The submitted FSC has not been issued by the relevant regulatory authority and also does not endorse the free sale status in country of origin. Original Notarized LOA & valid Iso certificate shall be submitted Original Legalized FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted.

13.	I-Care, Shop No. 21 Basement No. 1, Marium Tower, Near Bhatti Chowk, Lahore ELI-01019 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 3685372557	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd Address: Dingtao (Yantai) Industrial Park, Heze City, Shandong 274100, P.R. China LOA Type: Copy Notarization: Yes Validity: 02-06-2030 • FSC: Type: Copy Issued By: Shandonhg Association for Medical Device Industry Legalization: No Validity: 08-06-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-09-2025	Brand Name: Dr Trust Disposable sterile Infusion set (Normal) Generic Name: Disposable sterile Infusion set (Normal) Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years	Deferred for following observations: Change of brand name Codes/model The submitted FSC has not been issued by the relevant regulatory authority and also does not endorse the free sale status in country of origin. Original Notarized LOA & valid Iso certificate shall be submitted Original Legalized FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted.
14.	I-Care, Shop No. 21 Basement No. 1, Marium Tower, Near Bhatti Chowk, Lahore ELI-01019 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 2559113614	Name of Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd Address: Dingtao (Yantai) Industrial Park, Heze City, Shandong 274100, P.R. China LOA Type: Copy Notarization: Yes Validity: 02-06-2030 • FSC: Type: Copy Issued By: Shandonhg Association for Medical Device Industry Legalization: No Validity: 08-06-2027 ISO – Certificate: Type: Copy	Brand Name: Dr Trust Disposable Sterile Infusion Set (Y-Port Type) Generic Name: Disposable Sterile Infusion Set (Y-port type) Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years	Deferred for following observations: Change of brand name Codes/model The submitted FSC has not been issued by the relevant regulatory authority and also does not endorse the free sale status in country of origin. Original Notarized LOA & valid Iso certificate shall be submitted Original Legalized FSC shall be submitted issued by the relevant regulatory authority Valid CE certificate shall be submitted

		Notarization: Notarized Validity: 04-09-2025		
15.	AAIR Medicals, Office No. 201, Khattak Plaza, Gordon College Road, Rawalpindi ELI-01131 R&I Date: 14-07-2025 Fee: Rs. 6,000 vide deposit slip no. 7109065853	Name of Manufacturer: Anqing Yipak Packaging Material Co., Ltd. Address: Intersection of Fangxing Road, and Huangpu Road, Development Zone, Anqing, 246008` Anhui, P.R.China LOA Type: Copy Notarization: Notarized Issued date: 05-05-2025 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Notarized Validity: 14-05-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 03-08-2027	Brand Name: Astra Med Generic Name: Medical Crepe paper Applied as: Family Class: A Models/Code/sizes (as per FSC & application 1) Model: YCP-30 Size: 30cm x 30cm, 2) Model: YCP-40 Size: 40cm x 40cm, 3) Model: YCP-50 Size: 50cm x 50cm, 4) Model: YCP-60 Size: 60cm x 60cm, 5) Model: YCP-75 Size: 75cm x 75cm, 6) Model: YCP-90 Size: 90cm x 90cm, 7) Model: YCP-100 Size: 100cm x 100cm 8) Model: YCP-120 Size: 120cm x 120 cm Shelf Life: 5 years	Deferred for following observations: The submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Differential fee for the application of product as family shall be submitted since various models have been applied.
16.	AAIR Medicals, Office No. 201, Khattak Plaza, Gordon College Road, Rawalpindi ELI-01131 R&I Date: 14-07-2025 Fee: Rs. 6,000 vide deposit slip no. 694258704	Name of Manufacturer: Anqing Yipak Packaging Material Co., Ltd. Address: Intersection of Fangxing Road, and Huangpu Road, Development Zone, Anqing, 246008` Anhui, P.R.China LOA Type: Copy Notarization: Notarized Issued date: 05-05-2025 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products	Brand Name: Astra Med Generic Name: Flat sterilization roll Applied as: Family Class: A Models/Code/sizes (as per FSC & application	Deferred for following observations: The submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Differential fee for the application of product as family shall be submitted since various models have been applied.

		Legalization: Notarized Validity: 14-05-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 03-08-2027		
			Shelf Life: 5 years	
17.	AAIR Medicals, Office No. 201, Khattak Plaza, Gordon College Road, Rawalpindi ELI-01131 R&I Date: 14-07-2025 Fee: Rs. 6,000 vide deposit slip no. 6210604336	Name of Manufacturer: Anqing Yipak Packaging Material Co., Ltd. Address: Intersection of Fangxing Road, and Huangpu Road, Development Zone, Anqing, 246008` Anhui, P.R.China LOA Type: Copy Notarization: Notarized Issued date: 05-05-2025 • FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Notarized Validity: 14-05-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 03-08-2027	Brand Name: Astra Med Generic Name: Sterilization Indicator Strips Applied as: Family Class: A Models/Code/sizes (as per FSC & application) 1. Model: YSIS-2075 2. Model: YEIS-18105 3. Model: YHIS-18105 4. Model: YSIS-2075 5. Model: YSIS15100 6. Model: YEIS-15160 7. Model: YPIS-15160 Shelf Life: 5 years	Deferred for following observations: The submitted FSC has not been issued by the relevant regulatory authority of country of origin. Original Legalized FSC shall be submitted issued by the relevant regulatory authority Differential fee for the application of product as family shall be submitted since various models have been applied.
18.	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade,	Name of Manufacturer: Innovex Medical Co., Ltd., Address:	Brand Name: Innovex Urological Sampler Sets	Deferred for following observations:

	Main University Road, Karachi ELI-0382 R&I Date: 09-07-2025 Fee: Rs. 6,000 vide deposit slip no. 448108026709	2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Copy Notarization: Apostille Validity: 20-05-2028 • FSC: Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 04-11-2027	Generic Name: Urological Sampler Sets Applied as: Single Class: A Models/Code/sizes (as per FSC & application) IVX-NB-150 Shelf Life: 3 years	Original Valid Legalized FSC shall be submitted issued by the relevant regulatory authority Original Notarized LOA and ISO certificate shall be submitted.
19.	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09-07-2025 Fee: Rs. 31,000 vide deposit slip no. 155273695	Name of Manufacturer: Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Copy Notarization: Apostille Validity: 20-05-2028 • FSC: Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 04-11-2027	Brand Name: Innovex Ureteral Stents Generic Name: Urological Ureteral Stents Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Several models have been applied in FSC Shelf Life: 3 years	Deferred for following observations: Legalized FSC shall be submitted issued by the relevant regulatory authority Original Notarized LOA and ISO certificate shall be submitted. Differential fee shall be submitted for applied product as Family since various models have been applied. Justification of class
20.	Kingston Health Crafts (Pvt.) Ltd Building 5C, Mezzanine Floor 10th Commercial Lane Kh-e-Sehar Phase 7 DHA Karachi ELI-00422	Name of Manufacturer: Yangzhou Jindu Sporting Goods Co, Ltd. Add: 228 Fandong Rd, Ind. Zone, Fanchuan Town, Jiangdu District, Yangzhou, Jiangsu, China Exporter:	Brand Name: Smart Flamingo Orthopedic Arm Sling Generic Name: Arm Sling Applied as: Single Class: A Models/Code/sizes (as per FSC & application)	Approved Differential fee for the application of product as family shall be submitted , before issuance of enlistment certificate, since various models have been applied.

	R&I Date: 27-06-2025 Fee: Rs. 6,000	1.Shanghai Real-Tech New Material Co Ltd Room 1811No. 42 Lane 2626 Gongji Rd Shanghai China 2.Star Midas Middle East General Trading LLC PO Box 123611 Dubai UAE LOA Type: Copy Notarization: Notarized Issued: 01-07-2024 • FSC: Type: Original Issued By: CCPIT Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Validity: 03-11-2027	S,M,L,XL,XXL.XX XL Shelf Life: N/A	
21.	Kingston Health Crafts (Pvt.) Ltd Building 5C, Mezzanine Floor 10 th Commercial Lane Kh-e-Sehar Phase 7 DHA Karachi ELI-00422 R&I Date: 27-06-2025 Fee: Rs. 6,000	Name of Manufacturer: Yangzhou Jindu Sporting Goods Co, Ltd. Add: 228 Fandong Rd, Ind. Zone, Fanchuan Town, Jiangdu District, Yangzhou, Jiangsu, China Exporter: 1.Shanghai Real-Tech New Material Co Ltd Room 1811No. 42 Lane 2626 Gongji Rd Shanghai China 2.Star Midas Middle East General Trading LLC PO Box 123611 Dubai UAE LOA Type: Copy Notarization: Notarized Issued: 01-07-2024 • FSC: Type: Original Issued By: CCPIT Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy	Brand Name: Smart Flamingo Orthopedic Elastic Wrist Splint Generic Name: Elastic Wrist Splint Applied as: Single Class: A Models/Code/sizes (as per FSC & application) S,M,L,XL,XXL.XX XL Shelf Life: N/A	Approved Differential fee for the application of product as family shall be submitted , before issuance of enlistment certificate, since various models have been applied.

		Validity: 03-11-2027		
22.	Kingston Health Crafts (Pvt.) Ltd Building 5C, Mezzanine Floor 10th Commercial Lane Kh-e-Sehar Phase 7 DHA Karachi ELI-00422 R&I Date: 27-06-2025 Fee: Rs. 6,000	Name of Manufacturer: Yangzhou Jindu Sporting Goods Co, Ltd. Add: 228 Fandong Rd, Ind. Zone, Fanchuan Town, Jiangdu District, Yangzhou, Jiangsu, China Exporter: 1.Shanghai Real-Tech New Material Co Ltd Room 1811No. 42 Lane 2626 Gongji Rd Shanghai China 2.Star Midas Middle East General Trading LLC PO Box 123611 Dubai UAE LOA Type: Copy Notarization: Notarized Issued: 01-07-2024 • FSC: Type: Original Issued By: CCPIT Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Validity: 03-11-2027	Brand Name: Smart Flamingo Orthopedic Soft Collar Generic Name: Soft Collar Applied as: Single Class: A Models/Code/sizes (as per FSC & application) S,M,L,XL,XXL.XX XL Shelf Life: N/A	Approved Differential fee for the application of product as family shall be submitted , before issuance of enlistment certificate, since various models have been applied.
23.	Kingston Health Crafts (Pvt.) Ltd Building 5C, Mezzanine Floor 10th Commercial Lane Kh-e-Sehar Phase 7 DHA Karachi ELI-00422 R&I Date: 27-06-2025 Fee: Rs. 6,000	Name of Manufacturer: Yangzhou Jindu Sporting Goods Co, Ltd. Add: 228 Fandong Rd, Ind. Zone, Fanchuan Town, Jiangdu District, Yangzhou, Jiangsu, China Exporter: 1.Shanghai Real-Tech New Material Co Ltd Room 1811No. 42 Lane 2626 Gongji Rd Shanghai China 2.Star Midas Middle East General Trading LLC PO Box 123611 Dubai UAE LOA	Brand Name: Smart Flamingo Thumb Spica Splint Generic Name: Thumb Spica Splint Applied as: Single Class: A Models/Code/sizes (as per FSC & application) S,M,L,XL,XXL.XX XL Shelf Life: N/A	Approved Differential fee for the application of product as family shall be submitted , before issuance of enlistment certificate, since various models have been applied.

		Type: Copy Notarization: Notarized Issued: 01-07-2024 • FSC: Type: Original Issued By: CCPIT Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Validity: 03-11-2027		
24.	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 93546341262	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	Brand Name: Dental Plaque Indicator Generic Name: Dental Plaque Indicator Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LLR-II 2ml, 5ml, 10ml, 15ml Shelf Life: --	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Original Notarized LOA and ISO certificate shall be submitted. Description of the drug product sha; be submitted including specifications, intended use, shelf life studies
25.	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad ELI-00542 R&I Date: 03-07-2025	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA	Brand Name: Temporary Filling Material Generic Name: Temporary Filling Material Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LLR-VIII-B	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority

	Fee: Rs. 6,000 vide deposit slip no. 023028028	Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	2g, 5g, 10g, 15g, 30g, 50g Shelf Life: --	Original Notarized LOA and ISO certificate shall be submitted. Description of the drug product sha; be submitted including specifications, intended use, shelf life studies
26.	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 832026559	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park, Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	Brand Name: Temporary LC Resin Generic Name: Light Cured, Temporary Crown and Bridge Material Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LLF-I-A2, LLF-I-A3, LLF-I-A3.5, LLF-I-A4 Specification: 5g/tube, 10g/tube, 15g/tube, 30g/tube Shelf Life: --	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Original Notarized LOA and ISO certificate shall be submitted. Description of the drug product sha; be submitted including specifications, intended use, shelf life studies. Differential fee shall be submitted as family since several model have been applied.;
27.	Medident Supplies & Services, 4th Floor, Plaza No. 20 Orchard Road, Near Lignum Tower, Gate No. 02, DHA, Phase 2 Islamabad	Name of Manufacturer: Longly Biotechnology (Wuhan) Co. Ltd. Address: No. 02 of 2nd Floor, Building A2-2, Optics Valley Biomedical Park,	Brand Name: Caries indicator Generic Name: Caries indicator Applied as: Single	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required

	ELI-00542 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 7249810847	Gaoxin Avenue No. 858, East Lake High Tech Development Zone, Wuhan, China LOA Type: Copy Notarization: No Issued date: Not mentioned • FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 26-03-2026	Class: A Models/Code/sizes (as per FSC & application) LLR-III 2ml, 5ml, 10ml, 15ml Specification: 5g/tube, 10g/tube, 15g/tube, 30g/tube Shelf Life: --	Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Original Notarized LOA and ISO certificate shall be submitted. Description of the drug product sha; be submitted including specifications, intended use, shelf life studies. Differential fee shall be submitted as family since several model have been applied.;
28.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 966703506	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detro Pro Activ Generic Name: %55 (w/w) Pentapotassium bis (peroxymonosulphate) bis (Sulphate) Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority. Intended use and justification as medical device
29.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3	Brand Name: Akaclean Rust Generic Name: Phosphoric acid, complexing agents, corrosion inhibitors	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority

	R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 098085184238	Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 2 years	Intended use and justification as medical device
30.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 41181481	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detro Aspiradent Generic Name: Nonionic active agent, amphoteric active agent, 2-aminoethanol, n-alkyl dimethyl benzyl ammonium chloride Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 2 years	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Intended use and justification as medical device
31.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025	Name of Manufacturer: Detro Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye	Brand Name: Detro Matic A Generic Name: Potassium Hydroxide, Surfactants, Silicates, Complexing agents, corrosion inhibitors Applied as: Single	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority

	Fee: Rs. 6,000 vide deposit slip no. 5635563313	LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Intended use and justification as medical device
32.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 3566956499	Name of Manufacturer: Detrol Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detrol Matic Enzym Generic Name: Enzymes (Protease, amylase, Lipase), anionic surfactant Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority
33.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 17388696	Name of Manufacturer: Detrol Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes	Brand Name: Detrol Lube Generic Name: White paraffin oils, butane, propane Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Intended use and justification as medical device

		Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026		
34.	4A International, Plot No. 7, Street 11, Lawyers Society, Chaklala, Rawalpindi ELI-00099 R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 822505514802	Name of Manufacturer: Detrol Healthcare Kimya Sanayi A.S Address: Ataturk Mah. Cemal Gursel Cad. No:8/3 Esenyurt/Istanbul-Turkiye LOA Type: Copy Notarization: Yes Validity: 02-01-2030 • FSC: Type: Copy Issued By: Istanbul Chamber of Commerce Legalization: Legalized Validity: 20-05-2026 ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-11-2026	Brand Name: Detrol Instruclean Generic Name: Non ionic surfactants, corrosion inhibitors, complexing agents. Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	Deferred for following observations: Original Legalized valid FSC shall be submitted issued by the relevant regulatory authority Intended use and justification as medical device
35.	Bay-G Pharma, House No. 103-A A Block Satellite Town Rawalpindi ELI-00016 R&I Date: 09-07-2025 Fee: Rs. 62,000 vide deposit slip no. 01523899	Name of Manufacturer: Jiangue Yuyue Medical Equipment and Supply Co., Ltd., Address: Baisheng Road No. 1, Yuwell Industrial Park, Dan Yang, Jiangsu Province P.R. China LOA Type: Original Notarization: Notarized Issued date: 03-06-2025 • FSC: Type: Copy	Brand Name: Believita Oxygen Concentrator OXC-10 Generic Name: Believita Oxygen Concentrator OXC-10 Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: --	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Firm has submitted that original documents have been provided along with application of Believita Oxygen Concentrator OXC-05, submitted vide R&I diary no.20464 dated 09-07-2025, which need to be verified.

		Issued By: Jiangsu Medical Product Administration Legalization: No Validity: 13-07-2025 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-01-2027 EU Quality management certificate submitted.		Submitted FSC and LOA does not include the name/model of applied product CE certificate shall be submitted
36.	Ghazali Brothers, 1st Floor Azzainab Court, Campbell Street, Karachi ELI-00240 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 330013271178	Name of Manufacturer: Hospital & HomeCare Imp. & EXP, Co., Ltd, Address: No. 12 Plant, Phase II, Standard Plant Gaochun Economic Development Zone, 211300 Nanjing, Jiangsu Province, People's Republic of China LOA Type: Copy Notarization: Notarized Issued date: 24-03-2035 • FSC: Type: Copy Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 26-07-2026 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 07-12-2025 Full Quality Assurance certificate submitted	Brand Name: Hospital & Homecare Generic Name: Silicone Stomach Tube Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 2mm, 2.7mm, 3.3mm, 4.0mm, 5.3mm, 6.0mm, 6.7mm, 7.3mm, 8.0mm Shelf Life: 5year	Approved subject to differential fee for family.
37.	Ghazali Brothers, 1st Floor Azzainab Court, Campbell Street, Karachi	Name of Manufacturer: Hospital & HomeCare Imp. & EXP, Co., Ltd, Address:	Brand Name: Hospital & Homecare Generic Name: Silicone Foley Catheters Applied as: Single	Approved subject to differential fee for family.

	ELI-00240 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 321349003	No. 12 Plant, Phase II, Standard Plant Gaochun Economic Development Zone, 211300 Nanjing, Jiangsu Province, People's Republic of China LOA Type: Original Notarization: Notarized Issued date: 24-03-2035 • FSC: Type: Original Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 26-07-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 07-12-2025 Full Quality Assurance certificate submitted	Class: B Models/Code/sizes (as per FSC & application) 2mm, 2.7mm, 3.3mm, 4.0mm, 4.7mm, 5.3mm, 6.0mm, 6.7mm, 7.7mm, 8.0mm Shelf Life: 5year	
38.	K.S Agencies, Suit No. 210, 2nd Floor, Business Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09-07-2025 Fee: Rs. 31,000 vide deposit slip no. 7103137035	Name of Manufacturer: Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Copy Notarization: Apostille Validity: 20-05-2028 • FSC: Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 04-11-2027	Brand Name: Innovex Urological Stone extraction baskets Generic Name: Urological Stone extraction baskets Applied as: Single Class: B Models/Code/sizes (as per FSC & application)	Deferred for following observations: Original Valid Legalized FSC shall be submitted issued by the relevant regulatory authority Original Notarized LOA and ISO certificate shall be submitted. Justification for applying several models.

		EU certificate for Quality management system has been submitted	IVX-US-T0810, IVX-US-T0815, IVX-US-T1110, IVX-US-T1115, IVX-US-T1410, IVX-US-T1415, IVX-US-T1710, IVX-US-T1715, IVX-US-T2010, IVX-US-T2015, IVX-US-F0810, IVX-US-F0815, IVX-US-F1110, IVX-US-F1115, IVX-US-F1410, IVX-US-F1415, IVX-US-F1710, IVX-US-F1715, IVX-US-F2010, IVX-US-F2015	
			Shelf Life: 3 years	
39.	Ayyan Molecular Products, 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town ELI-00240 R&I Date: 02-07-2025 Fee: Rs. 6,000 vide deposit slip no. 383350124	Name of Manufacturer: Ustar Biotechnologies (Hangzhou) Ltd. Address: 6/F, Bldg 2, 611 Dongguan Road, Binjiang District 310053 Hangzhou Zhejiang Province, People's Republic of China LOA Type: Original Notarization: Notarized Issued date: 24-03-2035 • FSC: Type: Original Issued By: Zhejiang Medical Product Administration Legalization: Apostille Validity: 31-10-2026	Brand Name: Ustar Nucleic Acid Amplification and Detection Analyzer Generic Name: Nucleic Acid Amplification and Detection Analyzer Applied as: Single Class: A Models/Code/sizes (as per FSC & application) UC0204 UC0208 UC0216 Shelf Life: 5year	Approved UC0204.

		Copy of Apostille FSC issued by AEMPS of Spain ahs also been submitted. ISO – Certificate: Type: Copy Notarization: Notarized Validity: 10-07-2026 EU certificate for Quality management system has been submitted		
40.	Ayyan Molecular Products, 43/11, FCC Villas Muratib Ali Road, Gulberg-IV, Lahore Gulberg Town ELI-00240 R&I Date: 02-07-2025 Fee: Rs. 6,000 vide deposit slip no. 12768871	Name of Manufacturer: Ustar Biotechnologies (Hangzhou) Ltd. Address: 6/F, Bldg 2, 611 Dongguan Road, Binjiang District 310053 Hangzhou Zhejiang Province, People's Republic of China LOA Type: Copy Notarization: No Issued date: 25-05-2025 • FSC: Not submitted ISO – Certificate: Not submitted	Brand Name: PortNAT Molecular Analyzer Generic Name: Molecular Analyzer Applied as: Single Class: A Models/Code/sizes (as per FSC & application) PN0102 Shelf Life: 5year	Deferred for following observations: Original Legalized FSC shall be submitted. Valid Notarized LOA & ISO certificate shall be submitted
41.	M/S Global Marketing Services (ELI- 00109) R&I: 30-04-2025 Fee 62000/-	Legal Manufacturer: Abbott Medical, Also known ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION 15900 Valley View Court, Sylmar, California- 91342, USA Manufacturing Site: 1. Abbott Medical, also known as ST. JUDE MEDICAL OPERATIONS (M) SDN BHD Plot 102, Lebuhraya	Brand Name UltiPace Generic Name: Pacing Lead Class: D Shelf life: 3 Years Codes as per FSC: • LPA1231 (Lead Length (cm) 46, 52, 58, 65)	Approved subget to differential fee for family

		Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia, Country: Malaysia 2.Abbott Medical, 15900 Valley View Court, Sylmar, California- 91342, USA Free Sale Certificate (FSC) eCFG is attached Valid Till March 31, 2027. ISO 13485: 2016 Attached Valid till 31-03-2028 CE Certificate DoC is attached EU QMS Certificate is attached, validity: 14-08-2027 Design Examination: EU TDAC is attached Validity: 04-06-2028		
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