

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

DECISIONS OF 104TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 16-10-2025 (PART-II MANUAL APPLICATIONS)

104th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 16th October, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S.No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr Ijaz Alvi, Director DTL Punjab, Rawalpindi.	Member (attended meeting through videolink)
3.	Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore	Member (attended meeting through videolink)
4.	Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
6.	Prof. Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	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.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
13.	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.	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): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017
(Evaluator: Mr. Muhammad Amin, Deputy Director-IX)

TRANSFER OF LICENSE FROM DRUG MANUFACTURING LICENCE (DML) TO ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES (ELM):

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1.	M/s Zafa Surgitex, Plot No. A/421, SITE, Nooriabad District Dadu, Sindh.	Muhammad Usman Pharm-D Experience: 15 years	Muhammad Danish Pharm-D Experience: 15 years	The Medical Devices Board considered the application of the firm regarding transfer of Drug Manufacturing License (DML) to Establishment License to Manufacture Medical Devices (ELM) under Medical Devices Rules 2017 and following decision was taken: 1. The firm was initially granted Drug Manufacturing License (DML No. 000553) by Central Licensing Board at the premises Plot No. A/421, SITE, Nooriabad, Dadu, Sindh on 03-11-2004. 2. After promulgation of Medical Devices Rules 2017, the firm applied for transfer of <u>DML</u> into ELM on 24-06-2022. Under Rule 6 of Drugs (L, R&A) Rules, 1976 the license of the firm was valid for the period

				<p>02-11-2019 to 03-11-2024 at the time of this application.</p> <p>3. Accordingly, a panel was constituted and inspection of the facility was conducted by a panel of experts. The board considered the report and approved transfer of license from Drug Manufacturing License to Establishment License to Manufacture Medical Devices w.e.f. 02-11-2024 under Medical Devices Rules 2017 for the following sections:</p> <ul style="list-style-type: none"> • Crepe Bandages Section • Folded Gauze Section • Cut Gauze Section • Bandages Section
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(FRESH CASES-ELM)

S.#	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	decision
2.	M/s Turbo Surgical Solution (Pvt.) Ltd, Plot No. A-83, SITE-II, Super Highway, Karachi.	Abiha Waheed Pharm-D Experiecn: 2Years	Abdul Khaliq Msc Microbiology Experience 7 Years	The Borad observed that the work experience of both the production and QC incharge is not relevant therefore it was decided to defer the case for reconsideration of the board upon provision/ appointment of qualified persons with relevant experience as required under Medical Devices Rules 2017.

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-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Abdul Munim & Co, F-67, Ghorī Street, Block F, North Nazimabad, Karachi.	Muhammad Ismail Pharm-D	Approved

	Godown: W-402, 4 th Floor, AL Najeebi Bazar, Aga Khan III road, Saddar ,Karachi.		
2.	M/s EHMA pharmaceuticals, Godown / office:House#562, Wah Model Town phase 1, Wah cantt, Tehsil Taxila, District Rawalpindi Wah Cantonment	Abdullah Sakhi Pharm-D Daud Masih Pharm-D	Approved subject to submission of undertaking by applicant on stamp paper that the premises shall not be used for residential purpose and the applicant shall allow drug inspectors to visit the premises without any hinderance as per existing policy of MDB.
3.	M/s Reliance Medical (Pvt) Ltd., Office / Godown: Office No. 11, 1 st Floor, 14 C-1, Civic Center, Faisal Town, Lahore	Ms. Ain Zahra Biomedical Engineering	Approved

Item No. I(C): DEFERRED CASES IMPORT MEDICAL DEVICES LICENSE.

S.#	Name of Establishment	Name of Qualified Technical	Decision of MDB
1.	M/s Trade International Private Limited, Office/ godown: 269-D, St. No. 53, Sector F-10/4, Islamabad	Previous Technical Person: Amed Umar B.E. Electrical New Technical Person: Waseem Abbas Bs Bio-Medical Engineering Technology	Approved

Item No. I(D): 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-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s The Holy Green International, Office / Godown: Office No.8 & 9 First Floor Fatima Center Queens Road, Lahore ELI-00165	Waqas Anwar B Pharmacy	Waqar Ahmed Butt	Approved
2.	M/s Merlin International,	Maryam Murtaza	Muhammad Qasim	Approved

	Office/Godown: 3rd Floor, 41 Office, Jail Road, Landmark Plaza, Lahore. ELI-00569	B Pharmacy		
3.	M/s MUAZ MEDICAL TRADERS, OFFICE NO. 401-402, 6TH FLOOR SAITH CENTER 10 SYED MOJ DARYA ROAD LAHORE Godown 12 , Lower Ground Saith Centre Mouj Darya Road, Lahore ELI-00574	Asma Sohail Doctor of Medical Laboratory Science	Muhammad Ghulam Rasol	Approved
4.	M/s Mr Dental Supply Pvt Ltd, Office/Godown: LG-41, 42, 43 Land Mark Plaza, Jail Road, Lahore ELI-00306	Irzam Kainat Rana Bs Biotechnology	Qaisar Naveed	Approved
5.	M/s MOON ENTERPRISES, Office/Godown: 324 – Rewaz Garden, Lahore ELI-00356	Abdul Rafay Majid Pharm D	Muhammad Afzal Muhammad Murslin Zaeema Murslin	Deferred till finalization of the case regarding submission of forged documents in portal applications.
6.	M/s Azad Scientific Office/Godown: 3-B/2 Mouj Darya Road,Lahore (54010) ELI-00349	Maiza Sidiqi Pharm D	Khalid Mehmood Malik	Approved
7.	M/s Genus, 220, Block# 3, S. Abdul Tawwab Road, D.M.C.H.S, Karachi, Pakistan New Warehouse Address: Plot No. 43, Sector-27, Korangi Industrial Area ELI-00038	Nadia Muhammd Yaseen Pharm D	Haseeb Qamar	Approved
8.	M/s GHAZALI BROTHERS, 1st Floor Azzainab Court Campbell Street Karachi Godown 1: Ground Floor Karimjee Building North Napier Road	Alishan Arbani Pharm D	AHMED GHAZALI	Approved

	Godown 2: Second Floor Karimjee Building North Napier Road			
9.	M/s Global Health Care, Office/Godown address: Midway Commercial Plaza no 20 Backside Prism Arcade 2 Bahria Town Phase 7 Rawalpindi ELI-00086	Habiba Shaikh Pharm D	Asif Mehmood	Approved
10	M/s Hasnain Scientific, Plot No. 276, Office/Godown: Khawaja Food Industries Area, Street No. 1 , I-9/3, Islamabad. ELI-00197	Khurram Shahzad Saqlain B Pharm	Hassan Nawaz Lalee	Approved
11	M/s Alpha Evolution Enterprises Pvt Ltd, Office: Plot No.42, 1st Floor, Tech Tower, FECHS, E-11/2, North Commercial, Islamabad Godown: Shop 1& 2, lower ground floor, Secon hills, E11/2, Islamabad ELI-00278	Komal Sundas Pharm D	Ahsan Abbas Kazmi Mr. Muhammad Ehtisham Mr Khaqan Babar Mr Usman Rasheed Butt	Approved
12	M/s Elite Traders, F-825/19, Block-F, Satellite Town, Rawalpindi Godown: B-699, B Block Satellite Town Rawalpindi ELI-00193	Qurat Ul Ain Pharm D	Muhammad Imran	Approved
13	M/s Kantech Medical System, Office/Godown: Office # R-820 Ground Floor,BLoxk-1, Federal B Area Karachi ELI-00460	Hina Saleem Pharm D	Anwer Baig	Approved
14	M/s KAIN Medical, Ali Bhai Center Plot No 233/A/2 PECHS Office no 35, 3rd Floor Karachi Pakistan	Areej Aslam Ansari Pharma D	Kashif Saleem	Approved

	<p>Godown: Office No.35, 3rd Floor, Plot No.233-A, Bhai Center.PECHS Block No.2, Karachi ELI-00506</p>			
15	<p>M/s Universal Enterprises, Office/Godown: 29 Block 3 Overseas Cooperative Housing Society Stadium Road Karachi ELI-00079</p>	<p>Azmat Waseem MSC Physics</p>	<p>Muhammad Aleem Mirza</p>	<p>Deferred for change of technical person along with applicable fee.</p>
16	<p>M/s Trans Angio System, Office: 507 Progressive Square Block-6 P.E.C.H.S Shahra-e-Faisal Karachi Godown: 35-B/1, Protion C, Block 6, P.E.C.H.S. Karachi. ELI-00172</p>	<p>Zahid Ahmed Msc Biochemistry</p>	<p>Zahid Ahmed</p>	<p>Approved</p>
17	<p>M/s Samerian's Enterprise, Office: 4-First Floor, H.J.Centre, Kutchi Gali No.2, Karachi Godown: Suit No. 01, Ground Floor, Cambel Street, SR-7, Shahrah-e-Liaquat Eli- 00425</p>	<p>Khawaja Muhammad Osama Pharm D</p>	<p>Muhammad Hanif Soomro</p>	<p>Approved</p>
18	<p>M/s RHS International Office address: 34 Mozang Road, Lahore Godown: 2nd floor 34-Mozang Road Lahore Opposite Total Petrol Pump ELI-00354</p>	<p>Fatima Sadaqat Pharm D</p>	<p>Dr Shoaib Rafi</p>	<p>Approved</p>
19	<p>M/s RECH INTERNATIONAL Office / godown address: office No.247-B, Block-6, near Hotel Faran , Yaseen Suleman street , Karachi. ELI-00257</p>	<p>Saad Ahmed B.E Bio-medical Amber Siddiqui B.E Bio-medical</p>	<p>Alia Shafiq</p>	<p>Approved</p>
20	<p>M/s Pakistan Marketing Services,</p>	<p>Shakeel Akhtar Pharm D</p>	<p>Khawaja Seemab Nasir</p>	<p>Approved</p>

	Office/godown:house No. 40, Near Fauji foundation university, new lalazar, near rose lane no. 02, jehlum road, Rawalpindi. ELI-00198			
21	M/s Oasis Medical Systems, Office/Godown: House No A-86, Block C, Ground Floor, Gulshan-e- Jamal, Karachi Karachi ELI-00495	Aleena Hamid Pharm D	Muhammad Naeem	Approved
22	M/s Muslim Medical Services, 3 Syed Moj Darya Road, Lahore Godown: basement of Building 34, Mozang Road, Opposite Petrol Pump Lahore ELI-00373	Rida Sultan Pharm D	Haroon Rafi	Approved
23	M/s Molecular Products Co. Office No. 208, 2nd Floor, Nafees Arcade, Plot No. SC- 14, Opp. Askari Park, University Road, Karachi Godown: Office No. 513, 5 th Floor Nafees Arcade, ELI-00261	Hafiz Muhammad Bilal M.sc Biotechnology	Riaz Ahmed	Approved
24	M/s Melamine Emporium 804 Starcity mall, Karachi Godown: Suite 1404 14TH Floor Al- Najeebi Bazar Aga Khan III Road,Saddar Karachi ELI-00414	Muhammand Moiz Azam Pharm D	Abdul Munim akif	Approved
25	M/s Life-Tec Unit B & C, 1st Floor, Block 20-D, G-8 Markaz, Islamabad Godown: Plot no 117, Street no 08, I- 10/3 Industrial Area Islamabad	Muhammad Aqib Pharm D	Khalid mehmoood zia	Approved

	ELI-00155			
26	M/s Life Elements Private Limited Office/Godown: Basement No. 2, Deen Plaza, Near Misrial Chowk, Range Road, Rawalpindi ELI-00445	MUHAMMAD IRFAN AZAM B Pharm	MUHAMMAD IRFAN AZAM – CEO	Approved
27	M/s Kokab Enterprise Office/Godown: A-406, Billy's Shopper's Galleria & Residency, Gulistan-e-Jauhar Block 18, Karachi ELI-00544	Bushara Zehra Pharm D	Muhammad Azam	Approved
28	M/s Diagnostic Systems Office: 1st Floor, A-21, bLOCK-13D-1 Ruffi Cottages, Sehba Akhtar Rd, Gulshan-e- Iqbal Karachi Godown: Ground floor A-21, bLOCK-13D-1 Ruffi Cottages, Sehba Akhtar Rd, Gulshan-e- Iqbal Karachi ELI-00343	Makiya Aqeel Pharm D	Ayaz Alim	Approved
29	M/s Intek Corporation Office 517, Kohistan Towers, Mehfooz Road, Saddar Rawalpindi-46000. Godown 1: 25-A , Nagi Road, Westridge 1, Rawalpindi Godown 2: 22-C, Green Wood Homes, New Muslim Town, Lahore ELI-00794	Muhammad Farrukh Tariq Pharmacist (Godown 1) Adnan Maqsood Pharm D (Godown 2)	Irfan ul Azeem Arain	Deferred for provision of fee and application for approval of technical staff.
30	M/s Akram brothers & Co, Office/Godown: 89-D, jail Road, Lahore ELI-00324	Amina Saeed Pharm D	Rana Muhammad Akram Khan	Deferred for provision of fee and application for approval of technical staff.

31	M/s MUSLIM SCIENTIFIC CORPORATION, 2nd Floor. 03 Syed Mouj Darya Road Lahore Godown: 57B PAF Colony Zarrar Shaheed Road Lahore Cantt ELI-00431	Muhammad Faisal Samee Pharm D	Sami Ullah Shaikh	The board deliberated on the matter and decided to put a hold on the renewal application and shall grant the firm 06 months time for shifting of premises to a new location. The board shall conduct the inspection and shall decide renewal application in the light of new findings at new location.
32	M/s Transheal Pharma (Pvt) Limited, Office/Godown: 301-A, Jofa Tower, Plot No. SB-23-24, Main University Road, Gulshan-e-Iqbal, Karachi ELI-00513	Wajiha Syed B pharmacy	Muhammad Shariq Muhammad Imran Yousaf Seema Imran	The board considered the report and findings of the inspector and decided to issue show cause notice to the firm.
33	M/s TheCure first floor office#6 capri center firdous market gulberg 111 Godown: First Floor, House 77, Block XX, DHA Phase III ELI-0000567	Fariha intikhab Pharm D	Umair Mughees	The board deliberated on the matter and decided to put a hold on the renewal application and shall grant the firm 06 months time for shifting of premises to a new location. The board shall conduct the inspection and shall decide renewal application in the light of new findings at new location.
34	M/s Pak Glorious Enterprises, Office/Godown: Flat # 304A/305, 3rd Floor Muhammadia Plaza Gordon College Road ELI-00329	Not availbale	Shabbir Ahmed	The board considered the report and findings of the inspector and decided to issue show cause notice to the firm.

Agenda Item No.II. ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Mr. Ammar Ashraf Awan (Deputy Director-X)

S. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Ghazali Brothers, 1st Floor Azzainab Court, Campbell Street, Karachi ELI-00240 R&I Date: 18-07-2025 Fee: Rs. 6,000 vide deposit slip no. 5201468013	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: 03-05-2035 • FSC: Not submitted ISO – Certificate: Not submitted	Brand Name: Hospital & Homecare Generic Name: IV Canula Fixation Applied as: Single Class: B Models/Code/sizes (as per FSC & application) MC179 (Non-Woven & PU & PVC): 5x7cm, 6x8cm, 9x6cm,10x10cm,10x12 cm,10x15cm, 10x20cm, 10x25cm MC192 (Non-woven): 10cmx10m, 12cmx10m,15cmx10m, 20cmx10m,125cmx10m ,30cmx10m Shelf Life: 5year	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required Original Legalized FSC shall be submitted. Notarized ISO & CE certificate shall be submitted. Justification for applying multiple types in single application. Which type to be considered for this application. Differential fee for family.
2.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 16-06-2025 Fee: 31000/- Slip # 364017301671	Name of Manufacturer: Zhuhai DL Biotech Co., Ltd., Address: No. 59, Ding Wan 10th Road, Jinwan District, Zhuhai, Guangdong Province, 519040, P.R. China LOA Type: Copy Notarization: No Validity: 31-12-2026 • FSC Type: Copy Issued By: Not mentioned Legalization: No Validity: 18-04-2026	Brand Name: DL Biotech Strep. IST Card (DL-120Strep) Generic Name: Strep. IST Card Applied as: Single Class: B Models/Code/sizes (as per FSC & application) DL-120STREP Shelf Life: 12 months	Deferred for following observations: <i>The submitted ISO certificate was valid till 15-07-2025.</i> <i>Submitted FSC does not declare the name of issuing authority and is also not legalized.</i> <i>Original FSC, LOA, CE and ISO certificate shall be submitted for applied product</i>

		<p>Free sale: Type: Copy Issued By: Ministry of Justice & Consumer Protection Germany Legalization: No Issue Date: 31-03-2025 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 15-07-2025</p>		
3.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 16-06-2025 Fee: 31000/- Slip # 93068735222</p>	<p>Name of Manufacturer: Zhuhai DL Biotech Co., Ltd., Address: No. 59, Ding Wan 10th Road, Jinwan District, Zhuhai, Guangdong Province, 519040, P.R. China LOA Type: Copy Notarization: No Validity: 31-12-2026</p> <p>• FSC Type: Copy Issued By: Not mentioned Legalization: No Validity: 18-04-2026</p> <p>Free sale: Type: Copy Issued By: Ministry of Justice & Consumer Protection Germany Legalization: No Issue Date: 31-03-2025 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 15-07-2025</p>	<p>Brand Name: DL Biotech IST Card (DL-96 Fungs) Generic Name: IST Card (DL-96Fungus) Applied as: Single Class: B Models/Code/sizes (as per FSC & application) DL-120STREP Shelf Life: 12 months</p>	<p>Deferred for following observations: <i>The submitted ISO certificate was valid till 15-07-2025.</i></p> <p><i>Submitted FSC does not declare the name of issuing authority and is also not legalized. Original FSC, LOA, CE and ISO certificate shall be submitted for applied product.</i></p>
4.	<p>AAIR Medicals, Office No. 201, Khattak Plaza, Gordon College Road, Rawalpindi</p> <p>ELI-01131</p>	<p>Name of Manufacturer: Anqing Yipak Packaging Material Co., Ltd. Address: Intersection of Fangxing Road, and Huangpu</p>	<p>Brand Name: Astra Med Generic Name: Gusseted Sterilization Rolls Applied as: Family</p>	<p>Deferred for following observations: <i>The submitted FSC has not been issued by the relevant regulatory authority of country of origin.</i></p>

	<p>R&I Date: 14-07-2025 Fee: Rs. 6,000 vide deposit slip no. 8587042538</p>	<p>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</p>	<p>Class: A Models/Code/sizes (as per FSC & application) 1. Model: YGSR-075 Size: 75mmx100mm 2. Model: YGSR-150 Size: 150mm x 100mm 3. Model: YGSR-150 Size: 150mm x 100mm 4. Model: YGSR-200 Size: 200mm x 100mm 5. Model: YGSR-250 Size: 250mm x 100mm 6. Model: YGSR-300 Size: 300mm x 100mm 7. Model: YGSR-350 Size: 350mm x 100mm 8. Model: YGSR-400 Size: 350mm x 100mm 9. Model: YGSR-450 Size: 450mm x 100mm 10. Model: YGSR-500 Size: 500mm x 100mm Shelf Life: 5 years</p>	<p><i>Original Legalized FSC shall be submitted issued by the relevant regulatory authority</i> <i>Original Notarized documents for LOA, ISO shall be submitted</i> <i>Differential fee for the application of product as family shall be submitted since various models have been applied.</i></p>
5.	<p>M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046) R&I Date: 03-06-2025 Fee: 31000/- Slip # 942907471209</p>	<p>Name of Manufacturer: Head office: Ultra Med A/S Address:64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt Manufacturer: Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab E1 Awamer-Abnoub-Assiut-Egypt), LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year • FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025</p>	<p>Brand Name: HT-Endotracheal tube Generic Name: Endotracheal tube Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Model: FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. Shelf Life: 5 years (Room temperature)</p>	<p>Deferred for submission of manufacturer address as per FSC and size/model as per DoC.</p>

		<p>Validity: 07-04-2027</p> <p>ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A</p> <p>• ISO – Certificate: Type: Original Notarization: Legalized Validity: 26-05-2024</p>		
6.	<p>M/s. Health Tec, H. No. 10-B, Valley Road, St. 24, Opposite Rehmania Masjid, Westridge 1, Rawalpindi, Pakistan. (ELI-00046)</p> <p>R&I Date: 03-06-2025 Fee: 31000/- Slip # 07765173565</p>	<p>Name of Manufacturer: Ultra Med A/S Head office: 64, Nakhla El-Motaiy Triomphe Square, Heliopolis Cairo, Egypt Manufacturer: Ultra for medical products co. ((ULTRAMED)) U.M.I.C) S.A.E, Paret No. (304:310) & Part No. (312 – Industrial Area, Arab El Awamer-Abnoub-Assiut-Egypt), LOA Type: Original Notarization: Legalized Issue Date: 27-03-2025 Validity: 1 year</p> <p>• FSC Type: Original i. Issued By: Egyptian Drug Authority Legalization: Legalized Issue Date: 07-04-2025 Validity: 07-04-2027</p> <p>ii. Issued by: AEMPS of Spain Type: Copy Legalization: Legalized Issue Date: 06-11-2019 Validity: N/A</p> <p>• ISO – Certificate: Type: Original</p>	<p>Brand Name: HT-IV Infusion set Generic Name: IV infusion set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Model): FSC issued by Egyptian Drug Authority does not declare any Model or Sizes. Shelf Life: 5 years (Room temperature)</p>	<p>Deferred for submission of manufacturer address as per FSC and size/model as per DoC.</p>

		Notarization: Legalized Validity: 26-05-2024		
7.	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. 09018126287	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 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	Brand Name: MultNATM Molecular Diagnostic Testing System Generic Name: Molecular Diagnostic Testing System Applied as: Single Class: A Models/Code/sizes (as per FSC & application) UP0102/UP0104 Shelf Life: 5year	Approved UP0102 subject to submission of Differential fee for system.
8.	M/s Batla Impex, Shop No. 40 Namco Center Cambell Street Karachi (ELI-00170) R&I Date: 22-05-2025 Fee: 6,000/- Slip # 385248884717	Name of Manufacturer: Hebei Tianshou Medical Products Co., Ltd., Address: Dabu Village, Xiong County Hebei Province, China LOA Type: Copy Notarization: No Issue Date: 05-11-2024 Validity: Not mentioned • FSC Type: Copy Issued By: Not mentioned	Brand Name: Bcare Latex Surgical Gloves Generic Name: Latex Surgical Gloves Applied as: N/A Class: A Models/Code/sizes (as per FSC & application) Model; Not mentioned Shelf Life: 5 years	Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required The submitted copy of LOA does not bear any sign/stamp. The submitted copy of FSC does not include the applied product

		<p>Legalization: No Validity: 02-11-2025</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 01-11-2026</p>		<p>Original Legalized FSC for applied product shall be submitted.</p> <p>Notarized LOA & ISO certificate shall be submitted</p> <p>Submitted declaration of conformity is neither signed nor stamped</p> <p>None of the document pertaining to specification, shelf life studies, product description etc.. bear the stamp/sign from manufacturer</p> <p>The application form and fee shall be submitted for class B product along with details of intended model/sizes. Type of product</p>
9.	<p>AL Madina International Co., Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi</p> <p>ELI-00661 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 19482864</p>	<p>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: Not submitted FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 27-11-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 17-06-2027</p>	<p>Brand Name: Comfort Care Pregnancy (hCG) Rapid Test Generic Name: Pregnancy (hCG) Rapid Test Applied as: Family Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 3 years</p>	<p>Deferred for following observations: <i>Differential fee for the submission of application as Family shall be submitted</i></p> <p><i>Original Valid Legalized FSC shall be submitted issued by the relevant regulatory authority of country of origin, since the submitted FSC has been issued by the China Chamber of Commerce. Valid Notarized LOA & ISO certificate shall be submitted.</i></p> <p><i>Declaration of conformity shall be submitted along with details of intended mode.</i></p> <p><i>Class of applied product</i></p>
10.	<p>AL Madina International Co., Office No. 306/II, Trade Tower, Altaf</p>	<p>Name of Manufacturer: Ningbo Unimed Medical Instrument Co., Ltd.,</p>	<p>Brand Name: Stethoscope Generic Name:</p>	<p>Deferred for following observations:</p>

	Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Rs. 6,000 vide deposit slip no. 61226129698	Address: 26, Laoshan Road, Beilun, Ningbo, China LOA: Copy Legalization: No Validity: 14-07-2035 FSC: Type: Copy Issued By: Zheijiang Medical Product Administration Legalization: No Validity: 24-09-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 12-09-2025	Stethoscope Applied as: Family Class: A Models/Code/sizes (as per FSC & application) Single head Dual head Sprague Rappaport Shelf Life: 5 years	<i>Justification for applying multiple types, Original Valid Legalized FSC shall be submitted issued by the relevant regulatory authority of country of origin, Valid Notarized LOA & ISO certificate shall be submitted.</i> <i>Copy of import establishment license shall be submitted</i>
11.	Shahid Surgical Basement, Abdul Market , Shop No. 14 Namak Mandi, Peshawar ELI-00492 R&I Date: 15-07-2025 Fee: Rs. 6,000 vide deposit slip no. 02260065	Name of Manufacturer: Wuhan Sitaili Medical Apparatus Development Co., Ltd Address: Room No. 01, Part of South Area, 3rd Floor No. 2 Electronic Plant No. 777 Guanggu Third Road, East Lake New Technology Development Zone, Wuhan Zone, Wuhan City, Hubai Province, P.R. China. LOA: Original Legalization: Apostille Validity: 04-06-2030 FSC: Type: Original Issued By: -- Legalization: Apostille Validity: 14-01-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 19-05-2026	Brand Name: Great Med Generic Name: Ostomy Paste Applied as: Single Class: A Models/Code/sizes (as per FSC & application) 7001,7002,7011,7012,7521,A004,1301/7001,7002,7011,7012,7521,A004,1301 Shelf Life: 5 years	Approved subject to submission of . <i>Differential fee for Family.</i>
12.	Shahid Surgical Basement, Abdul Market , Shop No. 14 Namak Mandi, Peshawar ELI-00492 R&I Date: 15-07-2025	Name of Manufacturer: Wuhan Sitaili Medical Apparatus Development Co., Ltd Address:	Brand Name: Great Med Generic Name: Colostomy bag Applied as: Single Class: A	Deferred for following observations: <i>Original documents of FSC, ISO certificate and</i>

	<p>Fee: Rs. 6,000 vide deposit slip no. 655897940</p>	<p>Room No. 01, Part of South Area, 3rd Floor No. 2 Electronic Plant No. 777 Guanggu Third Road, East Lake New Technology Development Zone, Wuhan Zone, Wuhan City, Hubai Province, P.R. China. LOA: Original Legalization: Apostille Validity: 04-06-2030 FSC: Type: Original Issued By: -- Legalization: Apostille Validity: 14-01-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 19-05-2026</p>	<p>Models/Code/sizes (as per FSC & application) Shelf Life: 5 years</p>	<p><i>LOA have been submitted along with application of Ostomy paste.</i></p> <p><i>Details of the intended models to be marketed shall be submitted.</i></p>
13.	<p>Shahid Surgical Basement, Abdul Market , Shop No. 14 Namak Mandi, Peshawar ELI-00492 R&I Date: 15-07-2025 Fee: Rs. 6,000 vide deposit slip no. 4111378085</p>	<p>Name of Manufacturer: Wuhan Sitaili Medical Apparatus Development Co., Ltd Address: Room No. 01, Part of South Area, 3rd Floor No. 2 Electronic Plant No. 777 Guanggu Third Road, East Lake New Technology Development Zone, Wuhan Zone, Wuhan City, Hubai Province, P.R. China. LOA: Original Legalization: Apostille Validity: 04-06-2030 FSC: Type: Original Issued By: -- Legalization: Apostille Validity: 14-01-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 19-05-2026</p>	<p>Brand Name: Great Med Generic Name: Urostomy bag Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 5 years</p>	<p>Deferred for following observations:</p> <p><i>Original documents of FSC, ISO certificate and LOA have been submitted along with application of Ostomy paste.</i></p> <p><i>Details of the intended models to be marketed shall be submitted.</i></p>

14.	<p>Labe Mehran Enterprises, Suit No. 211, Sunny Plaza Hasrat Mohani Road, Karachi ELI-01213 R&I Date: 14-07-2025 Fee: Rs. 31,000 vide deposit slip no. 3560399308</p>	<p>Name of Manufacturer: Beijing Ruicheng Medical Supplies Co., Ltd. Address: No. 13 Yanqi Ave, Yanqi Economic Development Zone, Huairou District Beijing China LOA: Original Legalization: Notarized Validity: 06-05-2027 FSC: Type: Original Issued By: Not mentioned Legalization: Notarized Validity: 08-09-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 17-08-2026</p> <p>Notarized copy of CE certificate has been submitted.</p>	<p>Brand Name: Doctor X Blood Lancet Generic Name: Blood Lancet Applied as: Kit Class: A Models/Code/sizes (as per FSC & application)</p> <p>Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>The submitted FSC does not bear any sign or stamp of the issuing authority.</i></p> <p><i>Details of the intended product codes to be marketed shall be submitted in the application form.</i></p>
15.	<p>Labe Mehran Enterprises, Suit No. 211, Sunny Plaza Hasrat Mohani Road, Karachi ELI-01213 R&I Date: 14-07-2025 Fee: Rs.6,000 vide deposit slip no. 07569440</p>	<p>Name of Manufacturer: Beijing Ruicheng Medical Supplies Co., Ltd. Address: No. 13 Yanqi Ave, Yanqi Economic Development Zone, Huairou District Beijing China LOA: Original Legalization: Notarized Validity: 18-04-2030 FSC: Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Notarized Validity: 04-03-2027 ISO – Certificate: Type: Original Notarization: Notarized</p>	<p>Brand Name: Eurocare Unine Bag Generic Name: Urine Bag Applied as: Single Class: A Models/Code/sizes (as per FSC & application)</p> <p>Shelf Life: 5 years</p>	<p>Deferred for following observations: Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted. The submitted FSC, ISO and LOA mention the name of manufacturer as M/s Changzhou Shuangma Medical Devices Co., Ltd, 220 Sanhe Road, Zhenglu, Tianning, 213115 Changzhou, China while the application form declares the name of manufacturer as Beijing Ruicheng Medical Supplies Co., Ltd. No. 13 Yanqi Ave, Yanqi Economic Development Zone, Huairou District</p>

		Validity: 01-02-2026		Beijing China. Clarification shall be submitted in this regard. Details of intended models shall be submitted
16.	ASSU Healthcare, House No. 186-C Pak Arab Housing Society Feroz Pur Road, Lahore ELI-00867 R&I Date: 12-06-2025 Fee: Rs. 6,000 vide deposit slip no. 1015681176	Name of Manufacturer: Hebei Houde Hanfang Medical Devices Group Co., Ltd., Address: Beisun Village, Zhengding County, Shijiazhuang City, Hebei Province China LOA Type: Copy Notarization: Notarized validity date: 21-04-2030 • FSC: Type: Copy Issued By: Hebei Houde Hanfang Medical Devices Group Co., Ltd. Legalization: Apostille Validity: Not mentioned ISO – Certificate: Type: Copy Notarization: No Validity: 27-01-2028	Brand Name: Easy Save Fever Generic Name: Hydro Gel Patch Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 2year (2 – 8°C)	Deferred for following observations: <i>The submitted FSC has been issued by the manufacturer itself.</i> <i>Original legalized and valid FSC shall be submitted from the relevant regulatory authority of country of origin.</i> <i>Notarized copy of ISO certificate shall be submitted.</i> <i>The intended codes/sizes not mentioned.</i> <i>Approved Cold Storage facility for applied product</i>
17.	Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road Rawalpindi <i>ELI-01172</i> R&I Date: 15-07-2025 Fee: Rs. 6,000 vide deposit slip no. 21121666296	Name of Manufacturer: Xilan Friendship Ivledical Electronics Co., Ltd., Address: No. 9 Gao Xin 1st Road, High-Tech Developer Tlent Zone, IXI an, 710075 Shaanxi, P.R. China LOA Type: Copy Notarization: No Validity date: 01-01-2028 • FSC: Type: Copy	Brand Name: Cables for EMG Concentric needle Electrodes Generic Name: EMG (EEG) Cables Applied as: Single Class: A Models/Code/sizes (as per FSC & application) CCN 400 3000 Shelf Life: 5 years	Deferred for following observations: <i>The LOA has been issued by the “M/s Future Europe ApS”, while the manufacturer mentioned on application form is “M/s Xilan Friendship Ivledical Electronics Co., Ltd.,”</i> <i>Original legalized and valid FSC shall be submitted from the relevant regulatory authority of country of origin.</i>

		<p>Issued By: -- Legalization: No Validity: 24-03-2026</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 17-11-2025</p>		<p><i>Notarized copy of ISO certificate & LOA shall be submitted.</i></p> <p><i>The details of applied codes/models of applied product shall be submitted as per FSC</i></p>
18.	<p>Mabtech Karachi, Mezzanine 2, 10-C 33rd Street Tauheed Commercial, Phase VI, DHA, Karachi</p> <p><i>ELI-00751</i></p> <p>R&I Date: 01-07-2025 Fee: Rs. 6,000 vide deposit slip no. 852091351</p>	<p>Name of Manufacturer: Chin Kou Medical Instrument Co., LTd Address: 2F NO. Sec 2, Guo Dao Road, Luzhou District, New Taipei City 24766, Taiwan, China LOA Type: Copy Notarization: No Validity date: 31-12-2028</p> <p>• FSC: Type: Copy Issued By: FDA Taiwan Legalization: No Issue date: 11-12-2024</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 14-02-2028</p>	<p>Brand Name: Spirit Generic Name: Stethoscope Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Original legalized and valid FSC shall be submitted from the relevant regulatory authority of country of origin.</i></p> <p><i>Notarized copy of ISO certificate & LOA shall be submitted.</i></p> <p><i>The intended sizes/models of applied product shall be submitted as per FSC</i></p>
19.	<p>Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar Niaz Town Multan</p> <p><i>ELI-00879</i></p> <p>R&I Date: 03-07-2025 Fee: Rs. 31,000 vide deposit slip no. 266515567633</p>	<p>Name of Manufacturer: Hangzhou Bosure Biotech Co., Ltd. Address: 18 Baiyang Street, Wuyi, Jinhua City, Zhejiang, China LOA Type: Copy Notarization: Notarized Issue date: 19-06-2025</p> <p>• FSC: Type: Copy Issued By: Zheiiang Medical Product Admnistration</p>	<p>Brand Name: BioAid Hemoglobin Test Strip BC-101 Generic Name: Hemoglobin Test Strip Applied as: Single Class: B Models/Code/sizes (as per FSC & application) BC-101 Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Submitted FSC is expired.</i></p> <p><i>Original legalized and valid FSC shall be submitted from the relevant regulatory authority of country of origin</i></p>

		<p>Legalization: Notarized Validity: 13-07-2025</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 09-10-2026</p>		
20.	<p>Khan Muhammad Enterprises, Street No. 1, Near Dera Saleem Ladhar Niaz Town Multan</p> <p>ELI-00879</p> <p>R&I Date: 03-07-2025 Fee: Rs. 31,000 vide deposit slip no. 611954738512</p>	<p>Name of Manufacturer: Hangzhou Bosure Biotech Co., Ltd. Address: 18 Baiyang Street, Wuyi, Jinhua City, Zhejiang, China LOA Type: Original Notarization: Notarized Issue date: 19-06-2025 • FSC: Type: Copy Issued By: CIBG of Netherland Legalization: Notarized Issue date: 10-04-2020 2nd FSC Type: Original Issued By: Zheiiang Medical Product Administration Legalization: Notarized Validity: 13-07-2025</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 09-10-2026</p>	<p>Brand Name: BioAid Hemoglobin Testing System BC-101, Generic Name: Hemoglobin Testing System Applied as: Single Class: B Models/Code/sizes (as per FSC & application) BC-101 Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Submitted FSC is expired. Original legalized and valid FSC shall be submitted from the relevant regulatory authority of country of origin.</i></p> <p><i>Original Notarized ISO, CE certificate & LOA shall be submitted.</i></p> <p><i>Free sale certificate from any reference agency or CE certificate shall be submitted.</i></p> <p><i>Differential fee for system</i></p>
21.	<p>AA Traders P871B, Basemt Chen One Road, Peoples Colony No. 1 District Faisalabad</p> <p>ELI-00839</p> <p>R&I Date: 01-07-2025 Fee: Rs. 31,000 vide deposit slip no. 111525282</p>	<p>Name of Manufacturer: Shenzhen As Tec Technology Co., Ltd, Address: 808, Xinbaoyi Industrial and Trade Building No. 29 Third Industrial Zone, Houting Community, Shajing Street, Shenzhen, Guangdong, China LOA: Not submitted FSC: Not submitted</p>	<p>Brand Name: Leader Tense+Ems Generic Name: Tens and Muscle Stimulator Applied as: Single Class: B Models/Code/sizes (as per FSC & application) BC-101 Shelf Life:--</p>	<p>Deferred for following observations: <i>LOA, FSC, CE and ISO certificate have not been submitted.</i></p> <p><i>No details regarding the product description, specifications and intended use have been submitted</i></p>

		ISO – Certificate: Not submitted		
22.	<p>Business Medical International, Suite 101/102 Trade Centre, Plot 23/F Commercial Area M.A.C.H.S Karachi</p> <p>ELI-00262</p> <p>R&I Date: 14-07-2025 Fee: Not submitted</p>	<p>Name of Manufacturer: DoalMed Co., Ltd., Address: 53, Hwigyeong-ro, Dongdaemun-gu, Seoul, Republic of Korea LOA: Type: Copy Notarization: No Issue date: 19-02-2024 FSC: Type: Copy Notarization: No Issued by: Ministry of Food and Drug Safety. Issue Date: 05-02-2025</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 20-6-2027</p>	<p>Brand Name: DoalMed Beauty Equipment (Inno Plus RF system, Purecel CO2 fractional & Surgical laser, Cellina RF Micro needling, Laser Surgical Unit, Koolio Air Cooling device) Generic Name: RF System, Co2 Laser, RF Micro needling, Air Cooling Device Applied as: Family Class: B Models/Code/sizes (as per FSC & application)</p> <p>Shelf Life:--</p>	<p>Deferred for following observations: <i>Evidence of submission of fee shall be submitted.</i> <i>Evidence of submission of application for renewal of Import Establishment License shall be submitted.</i> <i>Submitted LOA is not issued by the manufacturer itself.</i> <i>Legalized FSC shall be submitted</i> <i>Clarification for the address of manufacturer mentioned on FSC is different from that mentioned in the application form.</i> <i>Original Notarized LOA shall be submitted</i> <i>Original Notarized CE certificate and ISO certificate shall be submitted</i> Details of intended models shall be submitted. Clarification of name of device. Justification as medical device</p>
23.	<p>M.Yousaf & Co 79 M Block Gulberg III, Lahore,</p> <p>ELI-00302</p> <p>R&I Date: 17-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 62204844209</p>	<p>Name of Manufacturer: Grena Ltd., Address: 1000 Great West Road, Brent Ford/MiddleSex, TW8, 9DW, UK LOA: Type: Copy Notarization: No Valid date: 14-01-2025 FSC: Type: Copy Notarization: No Issued by: MHRA of UK</p>	<p>Brand Name: Disposable Wound Protector/Retractor Generic Name: Disposable Wound Protector Applied as: -- Class: B Models/Code/sizes (as per FSC & application)</p> <p>Shelf Life:</p>	<p>Deferred for following observations: <i>Evidence of submission of application for renewal of Import Establishment License shall be submitted.</i> <i>Submitted LOA is not issued by the manufacturer itself.</i> <i>Original Legalized valid FSC shall be submitted</i> <i>The address of manufacturer mentioned on.</i> <i>Original valid Notarized LOA shall be submitted</i></p>

		<p>Validity Date: 26-05-2025</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 13-04-2027</p> <p>Copy of CE certificate also submitted.</p>		<p><i>Original Notarized CE certificate and ISO certificate shall be submitted.</i></p> <p><i>Data regarding the shelf life of the applied product shall be submitted.</i></p> <p><i>Intended Models/Sizes shall be submitted.</i></p>
24.	<p>AA Traders P871B, Basemt Chen One Road, Peoples Colony No. 1 District Faisalabad</p> <p>ELI-00839</p> <p>R&I Date: 01-07-2025 Fee: Rs. 31,000 vide deposit slip no. 30747298635</p>	<p>Name of Manufacturer: Guangzhou AXD Electronic Co., Ltd., Address: Factory 3, No. 9 Changxin Road, Changshapu Zhongluotan Town, Baiyun District, Guangzhoy City, Guangdong Province, China LOA: Type: Original Notarization: Apostille Valid date: 16-04-2030 FSC: Type: Original Notarization: Apostille Issued by: Provincial Supervision Body Validity Date: 10-09-2025</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 25-03-2028</p> <p>Notarized Copy of CE certificate also submitted.</p>	<p>Brand Name: Easy-Chek Generic Name: Easy-Chek Digital Arm Blood, Pressure Monitor (AXD-806,808,809) Applied as: Single Class: B Models/Code/sizes (as per FSC & application) AXD-808 AXD-809 AXD-806</p> <p>Shelf Life:--</p>	<p>Deferred for following observations: <i>Original Valid FSC shall be submitted.</i> Justification for applying multiple models in single application. Which model to be considered for this application. Shelf life</p>
25.	<p>Business Medical International, Suite 101/102 Trade Centre, Plot 23/F Commercial Area M.A.C.H.S Karachi</p> <p>ELI-00262</p> <p>R&I Date: 14-07-2025</p>	<p>Name of Manufacturer: Beijing LaserTell Medical Co. Address: Block 1, No. 12, Jingsheng South 2nd Rd., JQ Science Park, Tongzhou District, Beijing, China LOA:</p>	<p>Brand Name: Beijing Lasertell Beauty Machines Generic Name: Beauty Machines (Diode laser, CO2 Laser, Multi-Laser Platform, Q Switch Nd Yag Laser, IPL, RF, Pico Laser) Applied as: Family</p>	<p>Deferred for following observations: <i>Intended models of the applied product shall be submitted</i> <i>Evidence of submission of application for renewal of Import Establishment License shall be submitted.</i></p>

	<p>Fee: Rs. 31,000/- vide deposit slip no. 225653330132</p>	<p>Type: Copy Notarization: No Issue date: 16-04-2024 FSC: The submitted FSC has been issued by the Company itself</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 20-6-2027</p>	<p>Class: B Models/Code/sizes (as per FSC & application) Shelf Life:--</p>	<p><i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted</i> <i>Notarized LOA shall be submitted</i> <i>Original Notarized CE certificate and ISO certificate shall be submitted.</i> <i>Details of intended models shall be submitted</i> Clarification of name of device. Justification as medical device</p>
26.	<p>M.A Tech, 18-G, Upper Basement Memona Centre Mouj Darya Road, Fareed Court Lahore</p> <p>ELI-00593</p> <p>R&I Date: 15-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 42756570</p>	<p>Name of Manufacturer: Joytech Healthcare Co. Ltd., Address: Wuzhou Road, Yuhang Economic Development Zone, 311100, Hangzhou, China</p> <p>LOA: Type: Copy Notarization: Notarized Valid date: 23-06-2030 FSC: Type: Copy Notarization: Apostille Issued by: Zhejiang Medical product Administration Validity Date: 09-05-2026</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 27-04-2028</p> <p>Notarized Copy of EU Quality Management Certificate also submitted</p>	<p>Brand Name: dr-core DMT-4236 Generic Name: Digital Thermometer Applied as: Single Class: B Models/Code/sizes (as per FSC & application) DMT-4236 Shelf Life:--</p>	<p>Deferred for following observations: <i>Evidence of submission of application for renewal of Import Establishment License shall be submitted.</i></p> <p><i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted</i> <i>Notarized LOA shall be submitted</i> <i>Original Notarized CE certificate and ISO certificate shall be submitted.</i></p>
27.	<p>M.A Tech, 18-G, Upper Basement Memona</p>	<p>Name of Manufacturer: Joytech Healthcare Co. Ltd.,</p>	<p>Brand Name:</p>	<p>Deferred for following observations:</p>

	<p>Centre Mouj Darya Road, Fareed Court Lahore</p> <p>ELI-00593</p> <p>R&I Date: 15-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 5219606347</p>	<p>Address: No. 365 Wuzhou Road, Yuhang Economic Development Zone, 311100, Hangzhou, China</p> <p>LOA: Type: Copy Notarization: Notarized Valid date: 23-06-2030 FSC: Only list of products attached.</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 27-04-2028</p> <p>Notarized Copy of EU Quality Management Certificate also submitted</p>	<p>dr-core DBP-123 Digital Blood Pressure Monitor dr-core DBP-6191 Digital Blood Pressure Monitor</p> <p>Generic Name: Digital Blood Pressure Monitor Applied as: System Class: B Models/Code/sizes (as per FSC & application) DBP-1231 DBP-6191 Shelf Life:--</p>	<p>Justification for applying multiple models in single application. Which model to be considered for this application.</p> <p><i>Evidence of submission of application for renewal of Import Establishment License shall be submitted.</i></p> <p><i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted</i> <i>Notarized LOA shall be submitted</i> <i>Original Notarized CE certificate and ISO certificate shall be submitted.</i></p>
28.	<p>Absolute Health Care Systems (SMC-Pvt) Ltd., Unit 6, 2F Khyber 3 G-15 Markaz Islamabad</p> <p>ELI-00593</p> <p>R&I Date: 15-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 5317822353</p>	<p>Name of Manufacturer: Ultra For Medical Products Co., (Ultramed), Address: Head Office: 64 Nakhla EL Motaay St, Triumph Square, Cairo, Egypt Factory : Part (No. 304:310) & (312) - Industrial Area Arab El-Awamer - Assiut – Egypt</p> <p>LOA: Type: Copy Notarization: Legalized Valid date: 31-12-2026 FSC: Type: Copy Notarization: Legalized Issued by: EDA of Egypt Validity Date: 09-05-2026</p> <p>ISO – Certificate: Type: Copy</p>	<p>Brand Name: Ultramed Generic Name: Digital Thermometer Applied as: Family Class: B Models/Code/sizes (as per FSC & application) 2 way balloon foley catheter 3 way balloon foley catheter</p> <p>Shelf Life:- 5 years</p>	<p>Deferred for following observations: <i>The applied product has also been applied by another firm from the same manufacturer.</i></p> <p>Original Legalized FSC, shall be submitted Notarized LOA shall be submitted Sizes/codes and Differential fee family</p>

		<p>Notarization: Notarized Validity: 20-05-2026</p> <p>Copy of EC Certificate also submitted</p>		
29.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 04-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 7892247671</p>	<p>Name of Manufacturer: Jiangsu Webest Medical Prouduct Co., Ltd. Address: No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China LOA: Type: Copy Notarization: Apostille Valid date: 15-12-2029 FSC: Type: Copy Notarization: Apostille Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 06-12- 2026</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille Validity: 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p>Brand Name: Surgi + Pulse Scalp Vein Set Generic Name: Scalp Vein Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Scalp vein set 16G, 17G,18G,19G,20G,21G ,22G,23G,24G,25G,26 G,27G</p> <p>Shelf Life:- 5 years</p>	<p>Deferred for following observations: <i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i></p> <p><i>Original documents for LOA and ISO certificate shall be submitted.</i></p> <p>Differential fee for family</p>
30.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 26-06-2025 Fee: Rs. 31,000/- vide deposit slip no. 42344534574</p>	<p>Name of Manufacturer: Tianchang City Anrui Medical Equipment Co., Ltd., Address: Renhe Industrial District, TianChang City, Anhui Province China LOA: Type: Original Notarization: Apostille Valid date: 14-03-2030 FSC: Type: Original Notarization: Apostille</p>	<p>Brand Name: Surgi+ Pulse Surgical Gloves Powder Free Generic Name: Surgical Gloves Powder Free Applied as: Family Class: B Models/Code/sizes (as per FSC & application Scalp vein set 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5</p> <p>Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i></p> <p><i>Original documents for, CE and ISO certificate shall be submitted.</i></p> <p>Differential fee for family</p>

		<p>Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 27-03-2027</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille Validity: 19-07-2027</p> <p>Copy of EC Certificate also submitted</p>		
31.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 04-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 5007838901</p>	<p>Name of Manufacturer: Tianchang City Anrui Medical Equipment Co., Ltd., Address: Renhe Industrial District, TianChang City, Anhui Province China LOA: Type: Copy Notarization: Apostille Valid date: 14-03-2030 FSC: Type: Copy Notarization: Apostille Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 27-03- 2027</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille Validity: 19-07-2027</p> <p>Copy of EC Certificate also submitted</p>	<p>Brand Name: Surgi+ Pulse Surgical Gloves Powdered Generic Name: Surgical Gloves Powdered Applied as: Family Class: B Models/Code/sizes (as per FSC & application Scalp vein set 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5 Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i></p> <p><i>Original documents for LOA, CE and ISO certificate shall be submitted.</i> Differential fee for family</p>
32.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA</p>	<p>Name of Manufacturer: Jiangsu Webest Medical Prouduct Co., Lts. Address:</p>	<p>Brand Name: Surgi + Pulse Infusion Set with Burette Generic Name:</p>	<p>Deferred for following observations: <i>Original Legalized FSC, issued by the relevant regulatory authority of</i></p>

	<p>EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 04-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 7555347581</p>	<p>No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China</p> <p>LOA: Type: Original Notarization: Apostille Valid date: 15-12-2029 FSC: Type: Copy Notarization: Apostille Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 10-12-2026</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille Validity: 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p>Infusion Set with Burette</p> <p>Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Infusion set with Burette-100ml, 120ml, 150ml Y-port type, Burette type all infusion types</p> <p>Shelf Life:- 5 years</p>	<p><i>country of origin shall be submitted.</i></p> <p><i>Original documents for LOA and ISO certificate shall be submitted.</i></p> <p><i>Multiple types applied, which type to be considered for this application</i></p> <p><i>Differential fee for family shall be submitted</i></p>
33.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 04-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 7892247671</p>	<p>Name of Manufacturer: Jiangsu Webest Medical Prouduct Co., Lts.</p> <p>Address: No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China</p> <p>LOA: Type: Copy Notarization: Apostille Valid date: 15-12-2029 FSC: Type: Copy Notarization: Apostille Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 06-12-2026</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille</p>	<p>Brand Name: Surgi + Pulse Scalp Vein Set</p> <p>Generic Name: Scalp Vein Set</p> <p>Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Scalp vein set 16G, 17G,18G,19G,20G,21G ,22G,23G,24G,25G,26 G,27G</p> <p>Shelf Life:- 5 years</p>	<p>Deferred for following observations:</p> <p><i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i></p> <p><i>Original documents for LOA, CE and ISO certificate shall be submitted.</i></p>

		Validity: 31-05-2026 Copy of EC Certificate also submitted		
34.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 04-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 1196376801</p>	<p>Name of Manufacturer: Jiangsu Webest Medical Prouduct Co., Lts. Address: No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China LOA: Type: Copy Notarization: Apostille Valid date: 15-12-2029 FSC: Type: Copy Notarization: Apostille Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 10-12- 2026 ISO – Certificate: Type: Copy Notarization: Apostille Validity: 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p>Brand Name: Surgi + Pulse Blood Transfusion Set Generic Name: Blood Transfusion Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Shelf Life:- 5 years</p>	<p>Deferred for following observations: <i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i></p> <p><i>Original documents for LOA, CE and ISO certificate shall be submitted Codes/sizes</i></p>
35.	<p>Bio Safe Diagnostic SMC (Pvt) Limited, Karachi Market, Khyber Bazar, Peshawar ELI-01305</p> <p>R&I Date: 18-07-2025 Fee: 50000/- Slip # 308419502185</p>	<p>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</p>	<p>Brand Name: Diagreat Generic Name: Diagreat Hormones Testosterone Progestrone Applied as: Cluster Class: B Models/Code/sizes (as per FSC & application Model: Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.</i></p> <p><i>Description of the applied product shall be submitted along with the details of models etc..</i> <i>Data regarding the product shelf life shall be submitted.</i></p>

		<p>• ISO – Certificate: Type: Copy Notarization: No Validity: 26-07-2025</p>		<p><i>CE certificate or the FSC from any RRA shall be submitted</i></p>
36.	<p>Maher Apparels, 182-Platinum Block, Park View Villas River Edge Society, Opp DHA EME, Multan Road, Lahore.</p> <p>ELI-01330</p> <p>R&I Date: 04-07-2025 Fee: Rs. 31,000/- vide deposit slip no. 7892247671</p>	<p>Name of Manufacturer: Jiangsu Webest Medical Prouduct Co., Ltd. Address: No. 5 Yingchum Rd. Industrial Park 211700 Xuyi, Jiangsu China LOA: Type: Copy Notarization: Apostille Valid date: 15-12-2029 FSC: Type: Copy Notarization: Apostille Issued by: China Chamber of Commerce for Import & Export of Medicines and Health Products Validity Date: 06-12- 2026</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille Validity: 31-05-2026</p> <p>Copy of EC Certificate also submitted</p>	<p>Brand Name: Surgi + Pulse Scalp Vein Set Generic Name: Scalp Vein Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application Scalp vein set 16G, 17G,18G,19G,20G,21G ,22G,23G,24G,25G,26 G,27G</p> <p>Shelf Life:- 5 years</p>	<p>Deferred for following observations: <i>Original Legalized FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i></p> <p><i>Original documents for LOA and ISO certificate shall be submitted.</i> <i>Differential fee for family</i></p>
37.	<p>Reliable Medical Supply, Office No. 204, 2nd Floor, Makkah Tower, Namak Mandi Peshawar</p> <p>ELI-00618</p> <p>R&I Date: 03-07-2025 Fee: 31,000/- Slip # 1721550483</p>	<p>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: No Validity: 25-05-2028</p> <p>• FSC Type: Copy</p>	<p>Brand Name: Disposable Dental Needles Generic Name:</p> <p>Applied as: Set Class: B Models/Code/sizes (as per FSC & application 30Gx(8mm ~ 30mm): 30Gx8MM. 30G% 11mM 30Gx21MM. 306x25MM, 30G* 30MM. 27Gx(12mm ~40mm): 27Gx12MM 27Gx 21MM.</p>	<p>Deferred for following observations: <i>Original Legalized valid FSC, issued by the relevant regulatory authority of country of origin shall be submitted.</i> <i>Original Notarized LOA & valid ISO & CE certificate shall be submitted.</i></p> <p><i>Sizes mentioned in the application form are not as per FSC. differential fee for multiple sizes</i></p>

		<p>Issued By: Shandong Association for Medical Device Industry Legalization: No Validity: 08-06-2027</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 04-09-2025</p> <p>Copy of EC certificate valid till 26-05-2024 has been submitted.</p>	<p>27Gx25MM. 27G x30MM 27Gx 35MM. 27G x38MM 27G x40 MM</p> <p>Model: Shelf Life: 5 years</p>	
38.	<p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>R&I Date: 17-07-2025 Fee: 31000/- Slip # 86723542</p>	<p>Name of Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Address: Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: Copy Notarization: Yes Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 12-01-2026 Free sale: Type: Copy Issued By: TGA Australia Legalization: Legalized Issue Date: 21-01-2025 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028</p>	<p>Brand Name: iFlash-CenpB IgG Generic Name: Chemiluminescent Immunoassay (2 x 50 tests/kit) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) 2 x 50 tests/kit</p> <p>Shelf Life: 18 months (2 – 8°C)</p>	Approved
39.	<p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6,</p>	<p>Name of Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Address:</p>	<p>Brand Name: iFlash-Rib-P0 IgG Generic Name:</p>	Approved

	<p>PECHS, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>R&I Date: 17-07-2025 Fee: 31000/- Slip # 789680978</p>	<p>Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China</p> <p>LOA Type: Copy Notarization: Yes Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 12-01-2026</p> <p>Free sale: Type: Copy Issued By: TGA Australia Legalization: Legalized Issue Date: 21-01-2025 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028</p>	<p>Chemiluminescent Immunoassay (2 x 50 tests/kit)</p> <p>Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) 2 x 50 tests/kit</p> <p>Shelf Life: 18 months (2 – 8°C)</p>	
40.	<p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>R&I Date: 17-07-2025 Fee: 31000/- Slip # 741919035181</p>	<p>Name of Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Address: Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China</p> <p>LOA Type: Copy Notarization: Yes Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 12-01-2026</p> <p>Free sale: Type: Copy</p>	<p>Brand Name: iFlash-Vitamin B12 II Generic Name: Chemiluminescent Immunoassay (2 x 50 tests/kit)</p> <p>Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) 2 x 50 tests/kit</p> <p>Shelf Life: 18 months (2 – 8°C)</p>	Approved

		<p>Issued By: TGA Australia Legalization: Legalized Issue Date: 21-01-2025 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028</p>		
41.	<p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p> <p>R&I Date: 17-07-2025 Fee: 62000/- Slip # 62035405</p>	<p>Name of Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Address: Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: Copy Notarization: Yes Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 12-01-2026 Free sale: Type: Copy Issued By: TGA Australia Legalization: Legalized Issue Date: 21-01-2025 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028</p>	<p>Brand Name: iFlash-ProGRP Generic Name: Chemiluminescent Immunoassay (2 x 50 tests/kit) Applied as: Kit Class: C Models/Code/sizes (as per FSC & application) 2 x 50 tests/kit</p> <p>Shelf Life: 18 months (2 – 8°C)</p>	Approved
42.	<p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi</p> <p>(ELI-00160)</p>	<p>Name of Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Address: Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang</p>	<p>Brand Name: iFlash-PM-Scl IgG Generic Name: Chemiluminescent Immunoassay (2 x 50 tests/kit) Applied as: Kit Class: B</p>	Approved

	<p>R&I Date: 17-07-2025 Fee: 31000/- Slip # 367606471472</p>	<p>District, Shenzhen, Guangdong, China LOA Type: Copy Notarization: Yes Validity: 31-12-2025</p> <ul style="list-style-type: none"> • FSC Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 12-01-2026 Free sale: Type: Copy Issued By: TGA Australia Legalization: Legalized Issue Date: 21-01-2025 Validity: Not mentioned. <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: No Validity: 09-06-2028 	<p>Models/Code/sizes (as per FSC & application) 2 x 50 tests/kit</p> <p>Shelf Life: 18 months (2 – 8°C)</p>	
43.	<p>SBK International, 23, Valley Road, St. No. 3 Westridge 1, Rawalpindi</p> <p>(ELI-00100)</p> <p>R&I Date: 03-07-2025 Fee: 6000/- Slip # 54480250</p>	<p>Name of Manufacturer: Hubei Qianjiang Kingphar Medical Material co., Ltd. Address: Yuanguang Road 433100 Qianjiang, China LOA Type: Original Notarization: Yes Validity: 30-12-2029</p> <ul style="list-style-type: none"> • FSC Type: Original Issued By: Provincial Supervision Body Legalization: Apostille Validity: 11-11-2026 <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Yes Validity: 15-06-2026 	<p>Brand Name: Healthcare Sterile Cotton Ball</p> <p>Generic Name: Asorbent Cotton Ball (Sterile)</p> <p>Applied as: -- Class: A</p> <p>Models/Code/sizes (as per FSC & application) Type A, Type B: \$size: 0,055、 0.18" 0, 15g. 0. 2g, 0, 25g- 0.3g- 0, 35g. 0. 45. 0. 45g 0. 5g 0. 6g. 0. 7g. 0.8g, 0.9g 1. 0g 1.1g、 1.2g、 1.3g、 1.358、 1,48、 1.58、 1.68、 1. 7g- 1. 8g. 1. 9g. 2.0g- 2, 45- 2. 58. 3 0g. 3, 5g, 4. 0g. 4, 5g- 5,0g. 6 0g</p> <p>Shelf Life:</p>	<p>Approved.</p> <p><i>Differential fee for the application as family shall be submitted as different sizes have been applied with same application</i></p>

44.	<p>Kashif Traders, GF-48, Pak Medical Center, Karachi Market, Khyber Bazar, Peshawar</p> <p>(ELI-01040)</p> <p>R&I Date: 07-07-2025 Fee: 6000/- Slip # 0125837296</p>	<p>Name of Manufacturer: Zhejiang Xinke Medical Technology Co., Ltd., Address: No. 133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Type: Copy Notarization: Yes Validity: 09-04-2030</p> <ul style="list-style-type: none"> • FSC Type: Original Issued By: Zhejiang Medical Product Administration Legalization: Apostille Validity: 18-09-2026 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 20-11-2026 	<p>Brand Name: Xkivd Generic Name: DF-Lyse Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LD5H-Lyse</p> <p>Shelf Life: 2years</p>	Approved.
45.	<p>Kashif Traders, GF-48, Pak Medical Center, Karachi Market, Khyber Bazar, Peshawar</p> <p>(ELI-01040)</p> <p>R&I Date: 07-07-2025 Fee: 6000/- Slip # 7062271975</p>	<p>Name of Manufacturer: Zhejiang Xinke Medical Technology Co., Ltd., Address: No. 133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Type: Copy Notarization: Yes Validity: 09-04-2030</p> <ul style="list-style-type: none"> • FSC Type: Original Issued By: Zhejiang Medical Product Administration Legalization: Apostille Validity: 18-09-2026 • ISO – Certificate: Type: Copy Notarization: Apostille Validity: 20-11-2026 	<p>Brand Name: Xkivd Generic Name: DIFF52-Lyse Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LD5H-Lyse</p> <p>Shelf Life: 2years</p>	Approved.
46.	<p>Kashif Traders, GF-48, Pak Medical Center,</p>	<p>Name of Manufacturer:</p>	<p>Brand Name: Xkivd</p>	Approved.

	<p>Karachi Market, Khyber Bazar, Peshawar</p> <p>(ELI-01040)</p> <p>R&I Date: 07-07-2025 Fee: 6000/- Slip # 0206724198</p>	<p>Zhejiang Xinke Medical Technology Co., Ltd., Address: No. 133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA Type: Copy Notarization: Yes Validity: 09-04-2030</p> <p>• FSC Type: Original Issued By: Zhejiang Medical Product Administration Legalization: Apostille Validity: 18-09-2026</p> <p>• ISO – Certificate: Type: Copy Notarization: Apostille Validity: 20-11-2026</p>	<p>Generic Name: LH52-Lyse Applied as: Single Class: A Models/Code/sizes (as per FSC & application) LD5H-Lyse</p> <p>Shelf Life: 2years</p>	
47.	<p>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. 88088515470</p>	<p>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: 20-03-2028</p> <p>• FSC: Type: Copy Issued By: Legalization: Apostille Validity: 20-07-2025</p> <p>ISO – Certificate: Type: Copy Notarization: Apostille Validity: 04-11-2027</p> <p>Copy of Apostille EU QMS certificate also submitted</p>	<p>Brand Name: Innovex Ureteral Dilation Balloon Catheters Generic Name: Ureteral Dilation Balloon Catheters Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 3 years</p>	<p>Approved subject to differential fee for family.</p>
48.	<p>K.S Agencies, Suit No. 210, 2nd Floor, Business</p>	<p>Name of Manufacturer:</p>	<p>Brand Name:</p>	<p>Approved subject to Differential fee for Family</p>

	<p>Arcade, Main University Road, Karachi ELI-0382 R&I Date: 09-07-2025 Fee: Rs. 31,000 vide deposit slip no. 29516711719</p>	<p>Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Original Notarization: Apostille Validity: 20-03-2028 • FSC: Type: Original Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Original Notarization: Apostille Validity: 04-11-2027 Original of Apostille EU QMS certificate also submitted</p>	<p>Innovex Urological Guidewires Generic Name: Urological Guidewires Applied as: Single Class: B Models/Code/sizes (as per FSC & application Shelf Life: 3 years</p>	
49.	<p>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. 358758628024</p>	<p>Name of Manufacturer: Innovex Medical Co., Ltd., Address: 2nd Floor, No.17 Building, 315 Qingda Rd, Pudong, 201201 Shanghai, P.R. China LOA Type: Original Notarization: Apostille Validity: 20-03-2028 • FSC: Type: Original Issued By: Legalization: Apostille Validity: 20-07-2025 ISO – Certificate: Type: Original Notarization: Apostille Validity: 04-11-2027 Original of Apostille EU QMS certificate also submitted</p>	<p>Brand Name: Innovex Ureteral Access Sheaths Generic Name: Ureteral Access Sheaths Applied as: Single Class: B Shelf Life: 3 years</p>	<p>Approved subject to <i>Differential fee for Family</i></p>

50.	<p>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. 075994978304</p>	<p>Name of Manufacturer: GuangDong Baihe Medical Technology Company China Address: No. 89 Taiyuan East Road Nanhi Foshan 528225 Guangdong Province China LOA Type: Original Notarization: Notarized Validity: 5 years • FSC: Type: Original Issued By: Provincial Supervision Body Legalization: Apostille Validity: 22-07-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 06-08-2027 Notarized copy of EC certificate valid till 26-05-2024 has been submitted.</p>	<p>Brand Name: ABLE Disposable Urology Guide Wire Generic Name: Disposable Urological Guidewire Applied as: Single Class: B Shelf Life: 3 years</p>	<p>Deferred for following observations: <i>Differential fee shall be submitted for applied product as Family since various models have been applied.</i> <i>Valid notarized CE certificate shall be submitted.</i></p>
51.	<p>M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip # 68191003</p>	<p>Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning 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:</p>	<p>Brand Name: Lansionbio Generic Name: LH Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months</p>	<p>Deferred for following observations: <i>Original Legalized valid FSC shall be submitted.</i> <i>Original Notarized LOA & ISO certificate shall be submitted.</i> <i>The intended model of the products shall be submitted</i> <i>Evidence for submission of application for renewal of Import Establishment License is required</i> <i>Notarized CE certificate or legalized free sale form any RRA shall be submitted</i></p>

		Type: Copy Notarization: Yes Validity: 02-04-2027		
52.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip 525339444829	Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning 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	Brand Name: Lansionbio Generic Name: CRP 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: <i>Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.</i> <i>The intended model of the products shall be submitted</i> <i>Evidence for submission of application for renewal of Import Establishment License is required</i> <i>Notarized CE certificate or legalized free sale form any RRA shall be submitted</i>
53.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip 598436840	Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning 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	Brand Name: Lansionbio Generic Name: TT3 Test Kit (Dry Fluorescence Immunoassay) FT3 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: <i>Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.</i> <i>The intended model of the products shall be submitted</i> <i>Evidence for submission of application for renewal of Import Establishment License is required</i> <i>Notarized CE certificate or legalized free sale form any RRA shall be submitted</i>

		Validity: 02-04-2027		
54.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip 665759020126	Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning 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	Brand Name: Lansionbio Generic Name: HbA1c 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. The intended model of the products shall be submitted Evidence for submission of application for renewal of Import Establishment License is required Notarized CE certificate or legalized free sale form any RRA shall be submitted
55.	M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad. ELI-00459 R&I Date: 10-07-2025 Fee: 31000/- Slip 68191003	Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning 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	Brand Name: Lansionbio Generic Name: 25-OH-VD 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: <i>Original Legalized valid FSC shall be submitted.</i> <i>Original Notarized LOA & ISO certificate shall be submitted.</i> <i>The intended model of the products shall be submitted</i> <i>Evidence for submission of application for renewal of Import Establishment License is required</i> <i>Notarized CE certificate or legalized free sale form any RRA shall be submitted</i>

56.	<p>M/s. Shams Scientific Traders, 22-Y-J Madina Town Faisalabad.</p> <p>ELI-00459</p> <p>R&I Date: 10-07-2025 Fee: 31000/- Slip 10110911330</p>	<p>Name of Manufacturer: Lansion Biotechnology Co., Ltd., Address: No. 6 Qiande Road, Science Park, Jiangning District, Nanjing Jiangsu, P.R. China LOA Type: Copy Notarization: Yes Validity: 07-04-2028</p> <ul style="list-style-type: none"> • 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 	<p>Brand Name: Lansionbio Generic Name: PRL Test Kit (Dry Fluorescence Immunoassay) Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: 18 months</p>	<p>Deferred for following observations: <i>Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.</i></p> <p><i>The intended model of the products shall be submitted</i></p> <p><i>Evidence for submission of application for renewal of Import Establishment License is required</i></p> <p><i>Notarized CE certificate or legalized free sale form any RRA shall be submitted</i></p>
57.	<p>M/s. Norvax Pharma, 44/G PECHS Block 6 Razi Road, Karachi ELI-00459</p> <p>R&I Date: 14-07-2025 Fee: 31000/- Slip 9199049738</p>	<p>Name of Manufacturer: Hangzhou Rollmed Co. Ltd, Address: Room 913, Yuanmao Mansion No. 5, Wen Er West, Xihu District, Hangzhou, Zhejiang, 310012, China LOA Type: Copy Notarization: No Validity: 24-04-2028</p> <ul style="list-style-type: none"> • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 08-04-2027 • ISO – Certificate: Type: Copy Notarization: No Validity: 27-1-2026 	<p>Brand Name: Generic Name: Infusion set Applied as: Kit Class: B Models/Code/sizes (as per FSC & application) Model: -- Shelf Life: --</p>	<p>Deferred for following observations: The submitted application has not been filled for the details of the manufacturer, brand name, specification, description and shelf life.</p> <p>Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.</p> <p>The intended model/codes of the products to be marketed shall be submitted</p> <p>Norized CE certificate or legalized free sale form any RRA shall be submitted.</p>

<p>58.</p>	<p>M/s. Norvax Pharma, 44/G PECHS Block 6 Razi Road, Karachi ELI-00459</p> <p>R&I Date: 14-07-2025 Fee: 6000/- Slip 54401645731</p>	<p>Name of Manufacturer: Hangzhou Rollmed Co. Ltd, Address: Room 913, Yuanmao Mansion No. 5, Wen Er West, Xihu District, Hangzhou, Zhejiang, 310012, China</p> <p>LOA Type: Copy Notarization: No Validity: 24-04-2028</p> <p>• FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 08-04-2027</p> <p>• ISO – Certificate: Type: Copy Notarization: No Validity: 27-1-2026</p>	<p>Brand Name: Generic Name: Nasal Canulla Applied as: Kit Class: A Models/Code/sizes (as per FSC & application</p> <p>Model: -- Shelf Life: --</p>	<p>Deferred for following observations: The submitted application has not been filled for the details of the manufacturer, brand name, specification, description and shelf life.</p> <p>Original Legalized valid FSC shall be submitted. Original Notarized LOA & ISO certificate shall be submitted.</p> <p>The intended model/codes of the products to be marketed shall be submitted</p> <p>Norized CE certificate or legalized free sale form any RRA shall be submitted.</p>
<p>59.</p>	<p>S.J Trades, Office No. 14, 3rd Floor Majeed Plaza Bank Road, Saddar, Rawalpindi (ELI-00531)</p> <p>R&I No. & Date: 20482; 10-Jul-2025 Fee: 31,000/- Slip # 87857980586</p>	<p>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</p> <p>LOA: Type: Original Legalization: Notarized Validity: 28-04-2028</p> <p>FSC: Type: Original Issued By: Provincial Supervision Body Legalization: Apostille Validity: 01-12-2026</p> <p>ISO – Certificate: original Legalization: Notarized Validity: 16-11-2026</p>	<p>Brand Name: Daseon Generic Name: Introducer Set (Femoral/Radial) Applied as: Set</p> <p>Class: B Models/Code/sizes (as per FSC & application</p> <p>Model: IS-0407, IS-0409, IS- 0411, IS-0507, IS-0511, IS-0523, IS-0607, IS- 0611,1 IS-0623, IS- 0707,IS-0711,IS-0723, IS-0811, S-0823,IS- 0911, IS-0923,IS-1011</p> <p>Shelf Life: 3 years</p>	<p>Approved. <i>Differential fee shall be submitted for applied product as Family since various models have been applied</i></p>

		Notarized copy of EC certificate also submitted		
60.	M/s Mana & Co., Office No. 401, 4th Floor, Masood Chamber, Shahrah-e-Liaquat, Karachi (ELI-00098) R&I Date: 03-06-2025 Fee: 31,000/- Slip # 276267987208.	Name of Manufacturer: Shandong Ruyue Medical Technology Co., Ltd., Address: North of Xinwu Road, West of Gaojiu Road, High-Tech Industrial Development Zone, Binzhou City, 256600 Shandong, P.R. China LOA: Type: Original Notarization: Notarized Validity: 01-03-2029 FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 25-03-2026 Copy of Free Sale certificate issued by German Authority has also been submitted issued dated 15-06-2023 ISO – Certificate: Type: Original Notarization: Notarized Validity: 29-12-2026 Notarized copy of EC certificate dated 16-05-2024 also submitted	Brand Name: Medicare Generic Name: Disposables Infusion Set Applied as: Set Class: B Models/Code/sizes (as per FSC & application) Model: RYSY-A, RYSY-B, RYSYS-C, RYSSY-D, RYSSY-E, RYSY-F, RYSYS-G, RYSY-H Shelf life: 3 years (Room temperature)	Deferred for following observations: Original Legalized valid FSC, issued by the relevant regulatory authority of country of origin shall be submitted for applied product. Justification for applying various models
61.	M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I. Chandrigar Road, Karachi (ELI-00282)	Name of Manufacturer: Tianchang HengSheng Medical Devices Co.,Ltd Address: Qinlan Industrial Park Tianchang City, Anhui Province, China.	Brand Name: LifeCare Generic Name: Disposable Latex Surgical Gloves, powder free, sterile Applied as: Single Class: B	Deferred for following observations: Original Legalized valid FSC, issued by the relevant regulatory authority of country of

	<p>R&I Date: 30-06-2025 Fee: 31,000/- Slip # 747783338602.</p>	<p>LOA: Type: Copy Notarization: Notarized Validity: 29-04-2030</p> <p>FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 04-05-2027</p> <p>Copy of Free Sale certificate issued by German Authority has also been submitted issued dated 15-06-2023</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-04-2026</p> <p>Notarized copy of EC certificate also submitted</p>	<p>Models/Code/sizes (as per FSC & application)</p> <p>Model: Size: 6.0#, 6.5#, 7.0#, 7.5#,8.0#,8.5#,9.0#</p> <p>Shelf life: 5 years</p>	<p>origin shall be submitted for applied product.</p> <p>Differential fee for family.</p>
62.	<p>M/s Maqsood Brothers, Office No. 503-B, 5th Floor, Saima Trader Tower, I.I. Chandrigar Road, Karachi</p> <p>(ELI-00282)</p> <p>R&I Date: 30-06-2025 Fee: 31,000/- Slip # 86512482957.</p>	<p>Name of Manufacturer: Tianchang HengSheng Medical Devices Co.,Ltd Address: Qinlan Industrial Park Tianchang City, Anhui Province, China.</p> <p>LOA: Type: Original Notarization: Notarized Validity: 29-04-2030</p> <p>FSC: Type: Original Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille</p>	<p>Brand Name: LifeCare Generic Name: Disposable Latex Surgical Gloves, Powdered, Sterile Applied as: Single Class: B Models/Code/sizes (as per FSC & application)</p> <p>Model: Size: 6.0#, 6.5#, 7.0#, 7.5#,8.0#,8.5#,9.0#</p> <p>Shelf life: 5 years</p>	<p>Deferred for following observations: Original Legalized valid FSC, issued by the relevant regulatory authority of country of origin shall be submitted for applied product.</p> <p>Differential fee for family.</p>

		<p>Validity: 04-05-2027</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 11-04-2026</p> <p>Notarized copy of EC certificate also submitted</p>		
63.	<p>M/s Echelon Diagnostic, B-12, 3rd Floor, Jumani, Arcade, University Road, Old Sabzi Mandi, Gulshan-e-Iqbal, Block-14, Karachi</p> <p>(ELI-00604)</p> <p>R&I Date: 24-06-2025 Fee: 31,000/- Slip # 432196030768.</p>	<p>Name of Manufacturer: Shenzhen Xilaiheng Medical Electronics Co.,Ltd. Address: 10/F, YiFang Building, No. 315 ShuangMing Road, DongZhou Community, GuangMing District, Shenzhen, China</p> <p>LOA: Type: Original Notarization: Notarized Validity: 29-04-2030</p> <p>FSC: Type: Original Issued By: AEMPS of Spain Legalization: Apostille Date of Issue: 22-06-2023</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 04-12-2026</p> <p>Notarized copy of Full Quality Management System also submitted</p>	<p>Brand Name: Horrion Generic Name: Reagent for Electrolyte Analyzer Applied as: Class: B Models/Code/sizes (as per FSC & application) Model: H900 Shelf life: 5 years</p>	<p>Deferred for clarification of brand name, generic name and product description.</p>
64.	<p>M/s Endoaid Biomedica, 85-D, DHA EME Sector, Phase XII, Multan Road, Lahore.</p> <p>(ELI-00169)</p> <p>R&I Date: 25-06-2025 Fee: 31,000/-</p>	<p>Name of Manufacturer: Qingdao Weheal Technology Co., Ltd. Address: , 2F, Plant 5, NO. 60 Minjiang Road, Jiaozhou Economic and Development Zone Qingdao, Shangdong Province, China</p>	<p>Brand Name: Heartpal 12-Lead Wireless ECG Recorder Generic Name: ECG Recorder Applied as: Single Class: B Models/Code/sizes</p>	<p>Deferred for provision of model/codes to be marketed.</p>

	Slip # 86512482957.	<p>LOA: Type: Original Notarization: Apostille Validity: 30-04-2030</p> <p>FSC: Type: Original Issued By: Provincial Supervision Body Legalization: Apostille Validity: 11-05-2027</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 14-01-2028</p> <p>Apostille copy of EC certificate also submitted</p>	<p>Model: Shelf life: 5 years</p>	
65.	<p>M/s Endoaid Biomedica, 85-D, DHA EME Sector, Phase XII, Multan Road, Lahore.</p> <p>(ELI-00169)</p> <p>R&I Date: 25-06-2025 Fee: 6,000/- Slip # 56029273.</p>	<p>Name of Manufacturer: Hangzhou Yoniner Pharmaceutical Co. Ltd., Address:No. 42, Yangcheng Road, Nanyang Street, Xiaoshan, Hangzhou, Zhejiang, China LOA: Type: Copy Notarization: No Validity: 08-06-2045</p> <p>FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines & Health Products. Legalization: Apostille Validity: 30-10-2025</p> <p>ISO – Certificate: Not submitted</p>	<p>Brand Name: RSKINS Generic Name: Surgical Paper tape Applied as: Class: A Models/Code/sizes (as per FSC & application Size): 1.25cm/2.5cm /5cm/7.5cm/10cm x 3Yards/3m/4yards/4m/5 yards/5m/9m/10Yards/10m Shelf life: 5 years</p>	<p>Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted</i></p> <p><i>Differential Fee as Family shall be submitted since several sizes have been applied.</i></p>
66.	<p>MR Medical Pakistan Pvt Ltd, Office No. 1101, 11th Floor, ISE Tower, Jinnah Avenue, Blue Area Islamabad.</p> <p>(ELI-01008)</p>	<p>Name of Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd Address: , 666th Middle Zhengfang Road,</p>	<p>Brand Name: Mindray Generic Name: Operating Table Applied as: Single Class: A</p>	<p>Approved</p>

	<p>R&I Date: 24-06-2025 Fee: 6,000/- Slip # 462472949.</p>	<p>Jiangning, 211111 Nanjing, Jiangsu, P.R. China. LOA: Type: Original Notarization: Apostille Validity: 15-05-2026 FSC: Type: Original Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 11-05-2027 ISO – Certificate: Type: Original Notarization: Notarized Validity: 26-01-2027</p>	<p>Models/Code/sizes (as per FSC & application)</p> <p>Model: Hybase 3000 Shelf life: 10 years</p>	
67.	<p>Sure Bio-Diagnostics & Pharmaceuticals EE-IO, Defence View Phase 11, Near Iqra University, Shaheed-e- Millat Express Way, Karachi (ELI-00084)</p> <p>R&I Date: 03-06-2025 Fee: 25,000/- Slip # 68766464852.</p>	<p>Name of Manufacturer: Nanjing Dianuo Biotechnology Co. Ltd., Address: , Room 301, Building C3, No. 9, Kechuang Avenue, Zhongshan Science and Technology Park, Jiangbei New District, Nanjing City, Jiangsu Province, P.R. China LOA: Type: Original Notarization: Apostille Validity: 27-02-2026</p> <p>FSC: Type: Original Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity: 12-10-2026</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-12-2025</p>	<p>Brand Name: Dianuo Ediagnosis Electrolyte Analyzer Model: DN- X3 Generic Name: i. Electrolyte Analyzer Model: DN-X3 ii. Matching Reagent for electrolyte analyzer (Ion Selective electrode method)</p> <p>1. Cal-1 Solution 650ml/bag 2. Cal-2 Solution 250ml/bag 3. Cal-1 Solution 450ml/bag 4. Cal-2 Solution 450ml/bag 5. QC solution 1 10ml/bottle 6. QC solution 2 10ml/bottle 7. QC solution 3 10ml/bottle</p> <p>Applied as: System Class: A Models/Code/sizes (as per FSC & application)</p> <p>Model:</p>	<p>Deferred for justification regarding application of Electrolyte analyzer and matching electrolytes have been applied in the same application.</p>

			<p>i. Electrolyte Analyzer Model: DN-X3</p> <p>ii. Matching Reagent for electrolyte analyzer (Ion Selective electrode method)</p> <p>1. Cal-1 Solution 650ml/bag</p> <p>2. Cal-2 Solution 250ml/bag</p> <p>3. Cal-1 Solution 450ml/bag</p> <p>4. Cal-2 Solution 450ml/bag</p> <p>5. QC solution 1 10ml/bottle</p> <p>6. QC solution 2 10ml/bottle</p> <p>7. QC solution 3 10ml/bottle</p> <p>Shelf life: 5 years</p>	
68.	<p>Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-1, Mezzanine Floor , Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi (ELI-00232)</p> <p>R&I Date: 20-06-2025 Fee: 6,000/- Slip # 55670591.</p>	<p>Name of Manufacturer: Promised Hangzhou Meditech Co., Ltd., Address: No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhoucity, 311121 Zhejiang P.R. China</p> <p>LOA: Type: Original Notarization: Notarized Validity: 22-04-2030</p> <p>FSC: Type: Copy Issued By: Zheijiang Medical Product Administration Legalization: No Validity: 25-04-2026</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 22-10-2027</p>	<p>Brand Name: Verifine Lancing Device Generic Name: Lancing Device Applied as: Single Class: A Models/Code/sizes (as per FSC & application</p> <p>Model: LD-2.5 Shelf life: 5 years</p>	<p>Deferred for following observations: Original Legalized valid FSC shall be submitted</p>
69.	<p>IJS Healthcare, Office No. 79/1, Block A-2 P&D Society, Canal Bank Road, Lahore (ELI-01448)</p>	<p>Name of Manufacturer: Zhejiang CuraWay Medical Technology Co., Ltd</p>	<p>Brand Name: Breast Lesion Localization Wire</p>	<p>Approved with model/codes as per FSC and differential fee accordingly.</p>

	<p>R&I Date: 03-07-2025 Fee: 31,000/- Slip # 59969166968.</p>	<p>Address: Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub District, Qiantang, New District, 310018 Hangzhou City, Zhejiang Province, People's Republic of China LOA: Type: Copy Notarization: Notarized Validity: 31-12-2027 FSC: Type: Copy Issued By: Zheijiang Medical Product Administration Legalization: Apostille Validity: 21-07-2026 ISO – Certificate: Type: Original Notarization: Notarized Validity: 22-10-2027 Copy of Notarized EU Quality Management Certificate submitted.</p>	<p>Generic Name: Breast Lesion Localization Wire Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: Shelf life: 3 years</p>	
70.	<p>IJS Healthcare, Office No. 79/1, Block A-2 P&D Society, Canal Bank Road, Lahore (ELI-01448)</p> <p>R&I Date: 03-07-2025 Fee: 31,000/- Slip # 9803555090.</p>	<p>Name of Manufacturer: Zhejiang CuraWay Medical Technology Co., Ltd Address: Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub District, Qiantang, New District, 310018 Hangzhou City, Zhejiang Province, People's Republic of China LOA: Type: Original Notarization: Notarized Validity: 31-12-2027 FSC: Type: Original Issued By: Zheijiang Medical Product Administration Legalization: Apostille Validity: 21-07-2026 ISO – Certificate:</p>	<p>Brand Name: Disposable Biopsy Needle Generic Name: Disposable Biopsy Needle Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: BN-MAR-1, BN-MAR-2, BN-MAR-3, BN-MAR-4, BN-MAR-8 Shelf life: 3 years</p>	<p>Approved. <i>Differential fee shall be submitted for the enlistment of applied product as Family, since several model /sizes have been applied.</i></p>

		Type: Original Notarization: Notarized Validity: 22-10-2027 Notarized copy of EU Quality Management Certificate submitted.		
71.	Sonoscape Medical Corporation Pakistan, Office No. FF-21, Ist Floor Hayat Arsallah Heights, Commercial Block, CBR Town Phase 1, Islamabad (ELI-01301) R&I Date: 30-06-2025 Fee: 31,000/- Slip # 4879255436.	Name of Manufacturer: Sonoscape Medical Corporation, Address: Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Sub district, Nanshan District, Shenzhen, 518057, Guangdong P.R. China LOA: Type: Copy Notarization: No Validity: 31-12-2027 FSC: Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 16-03-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 22-04-2028 Copy of EU Quality Management Certificate submitted.	Brand Name: Digital Color Doppler Ultrasound Diagnostic Machine Generic Name: Model: P10 Applied as: System Class: B Models/Code/sizes (as per FSC & application) P10 Shelf life: --	Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted.</i> <i>Differential fee for system</i>
72.	Biocept Intl Co. 28-29 A/E1 Old FCC Gulberg 3, Lahore (ELI-01225) R&I Date: 23-06-2025 Fee: 31,000/- Slip # 4879255436.	Name of Manufacturer: Zheijang Xinke Technology Co., Ltd. Address: No. 133, Lengshui Road, Jinpan Development Zone, Jinhua City, Zhejiang Province, China LOA: Type: Copy Notarization: No Validity: 20-11-2026 FSC: Not submitted ISO – Certificate: Not submitted	Brand Name: Zheijang XinkeTechnology Co., Ltd Generic Name: The Mindray LH Lyse BC5000/BC5120/BC5130/BC5140/BC5150 Applied as: System Class: B Models/Code/sizes (as per FSC & application) Shelf life: --	Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted along with product description.</i> Justificaion for applying multiple models in single application. Which model to be considered for instant application. Differential fee for system

73.	<p>Arham Enterprises, Plot No. 95, Mezzanine Floor, Kashmir Arcade, Blue Area, Islamabad (ELI-00509)</p> <p>R&I Date: 17-07-2025 Fee: 31,000/- Slip # 4879255436.</p>	<p>Name of Manufacturer: Vapo Healthcare Co., Ltd. Address: Southern Unit of Third Floor Building B No.99 Yudai West Rd High Tech District Kunshan, Suzhou 215301 Jiangsu China LOA: Not submitted FSC: Type: Copy Issued By: Jiangsu Medical Product Administration Legalization: No Validity: 08-03-2026 ISO – Certificate: Not submitted</p>	<p>Brand Name: Liaca Generic Name: Nebulizer NE1011 Applied as: System Class: B Models/Code/sizes (as per FSC & application) 20212080098 Shelf life: --</p>	<p>Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted.</i> <i>Shelf life/service life Differential fee for system</i></p>
74.	<p>Arham Enterprises, Plot No. 95, Mezzanine Floor, Kashmir Arcade, Blue Area, Islamabad (ELI-00509)</p> <p>R&I Date: 17-07-2025 Fee: 31,000/- Slip # 4879255436.</p>	<p>Name of Manufacturer: Vapo Healthcare Co., Ltd. Address: Southern Unit of Third Floor Building B No.99 Yudai West Rd High Tech District Kunshan, Suzhou 215301 Jiangsu China LOA: Not submitted FSC: Type: Copy Issued By: Jiangsu Medical Product Administration Legalization: No Validity: 26-11-2025 ISO – Certificate: Not submitted</p>	<p>Brand Name: Liaca Generic Name: Nebulizer Applied as: System Class: B Models/Code/sizes (as per FSC & application) Shelf life: --</p>	<p>Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted.</i> <i>Details for the description of the product, Shelf life, model</i></p>
75.	<p>Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road Rawalpindi (ELI-01172)</p> <p>R&I Date: 15-07-2025 Fee: 31,000/- Slip # 7383749529.</p>	<p>Name of Manufacturer: Xi'an Friendship Ivmedical Electronics Co., Ltd., Address: No. 9 Gao Xin 1st Road, High-Tech Developer Tlent Zone, IXI an, 710075 Shaanxi, P.R. China LOA: Type: Copy Notarization: No Validity: 01-01-2028 FSC:</p>	<p>Brand Name: Disposable EMG Concentric Needle Electrodes Generic Name: EMG Needle Electrode Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Model: Shelf life: 3 years</p>	<p>Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted along with the intended model/codes of applied product</i></p>

		Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 04-06-2027 ISO – Certificate: Type: Copy Notarization: No Validity: 17-11-2025		
76.	Health Ways International, 3rd Floor, Taj Plaza, Gordon College Road Rawalpindi (ELI-01172) R&I Date: 15-07-2025 Fee: 31,000/- Slip # 13974578304.	Name of Manufacturer: Xi'an Friendship Ivmedical Electronics Co., Ltd., Address: No. 9 Gao Xin 1st Road, High-Tech Developer Tlent Zone, IXI an, 710075 Shaanxi, P.R. China LOA: Type: Copy Notarization: No Validity: 16-04-2027 FSC: Type: Copy Issued By: Ministry of Health Turkey Legalization: No Validity: 29-04-2028 ISO – Certificate: Type: Copy Notarization: No Validity: 14-11-2025	Brand Name: Medbar MVA Kit Generic Name: EMG Karman Cannula and Manual (Single and Double Valve) Vacuum Aspirator Applied as: Kit Class: B Models/Code/sizes (as per FSC & application Model): 208 04 208 05 208 06 208 07 208 08 208 09 208 10 208 12 209 01 209 02 209 04 209 05 Shelf life: 5 years	Deferred for following observations: <i>Original documents of Legalized FSC & notarized LOA, ISO and CE certificate shall be submitted</i> <i>Justification for applying multiple models in single application.</i>
77.	BNS Trading Est. Office No. 339, 3rd Floor, Landmark Plaza, Jail Road, Lahore (ELI-00583) R&I Date: 08-07-2025 Fee: 31,000/- Slip # 90655129.	Name of Manufacturer: Jiangsu Kangjin Medical Instruments Co., Ltd., Address: No. 56, Changzheng Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China LOA: Type: Copy Notarization: Yes Validity: 13-05-2028 FSC: Type: Copy Issued By: Provincial Supervision Body	Brand Name: 3S Safe Transfusion Set Generic Name: Transfusion Set Applied as: Kit Class: B Models/Code/sizes (as per FSC & application Model): TS-T1 TS-T2 TS-T3 TS-T4 Shelf life: 5 years	Deferred for following observations: <i>justifications shall be submitted for applying different models as Kit which type to be considered for instant application.</i>

		Legalization: Apostille Validity: 17-08-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 01-02-2025 Copy of EC certificate also submitted		
78.	BNS Trading Est. Office No. 339, 3rd Floor, Landmark Plaza, Jail Road, Lahore (ELI-00583) R&I Date: 08-07-2025 Fee: 31,000/- Slip # 6580023410.	Name of Manufacturer: Jiangsu Kangjin Medical Instruments Co., Ltd., Address: No. 56, Changzheng Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China LOA: Type: Original Notarization: Yes Validity: 13-05-2028 FSC: Type: Original Issued By: Jiangsu Provincial Drug Administration Legalization: Apostille Validity: 17-08-2025 ISO – Certificate: Type: Original Notarization: Notarized Validity: 31-01-2028 Notarized Copy of EC certificate also submitted	Brand Name: 3S Safe Infusion Set Generic Name: Infusion Set Applied as: Kit Class: B Models/Code/sizes (as per FSC & application Model: IS-M-A1 IS-M-A2 IS-M-A2-3 IS-M-A3-3 IS-M-A21 IS-M-A22 Shelf life: 5 years	Deferred for following observations: <i>justifications shall be submitted for applying different models as Kit which type to be considered for instant application.</i>
79.	Hospital Solutions, H. No. 174/E, P.E.C.H.S., Block -2 Karachi (ELI-00250) R&I Date: 20-06-2025 Fee: 31,000/- Slip # 8297307014.	Name of Manufacturer: Surgaid Medical (Xiamen) Co., Ltd., Address: Building 5, No. 18, Shanbianhong East Road, Haicang District, 361026, Xiamen, Fujian, P.R. China LOA: Type: Copy Notarization: Yes Validity: 19-02-2027 FSC: Type: Copy Issued By: Provincial Supervision Body	Brand Name: Single Use Veress Needle Generic Name: -- Applied as: -- Class: -- Models/Code/sizes (as per FSC & application Model: -- Shelf life: --	Deferred for following observations: <i>Application on the prescribed form has not been submitted.</i> <i>Original documents of Legalized valid FSC & notarized LOA, ISO and CE certificate shall be submitted Model/code Shelf life Class of applied product</i>

		Legalization: Apostille Validity: 22-01-2027 ISO – Certificate: Type: Copy Notarization: No Validity: 17-08-2025		
80.	Nextawits Private Limited, Office No. 8, First Floor, Shaheen View, Block-6, P.E.C.H.S, Main Shahrah-e-Faisal, Karachi (ELI-01171) R&I Date: 27-06-2025 Fee: 6,000/- Slip # 48992258675.	Name of Manufacturer: Jiangsu Changzhou Lvying Medical Treatment Apparatus Co., Ltd Address: Wugang Industrial Zone, Sanhekou, Wujin, Changzhou, Jiangsu, P.R. China LOA: Type: Original Notarization: Yes Validity: 13-02-2030 FSC: Type: Copy Issued By: Jiangsu Provincial Food and Drug Administration Legalization: Apostille Validity: 20-09-2025 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 06-06-2028 Copy Notarized EC certificate also submitted	Brand Name: Curaflo Sterile Urine Bag Generic Name: Urine Bag Applied as: Kit Class: A Models/Code/sizes (as per FSC & application Model): TS-T1 TS-T2 TS-T3 TS-T4 Shelf life: 5 years	Deferred for following observations: <i>Original valid FSC shall be submitted</i> <i>Justification for applying various models in single application</i>
81.	Surgical World, Office No. 105, 1st Floor, Rehmani Chambers, Altaf Hussain Road, New Chali, Karachi (ELI-00462) R&I Date: 13-06-2025 Fee: 6,000/- Slip # 67555858481.	Name of Manufacturer: Besmed Health Business Corp. Address: No. 5 Lane, 116 Wu-Kong 2nd Road, Wu-Ku district New Taipei City, Taiwan LOA: Type: Original Notarization: Yes Validity: 16-11-2025 FSC: Type: Original Issued By: FDA Taiwan Legalization: Legalized Validity 31-10-2025 ISO – Certificate:	Brand Name: Besmed Generic Name: Heating Pad Applied as: Single Class: A Models/Code/sizes (as per FSC & application Size): HT-00220 (BE-220), HT-00240 (BE-240) Shelf life: 5 years	Approved subject to Differential fee for the application of product as family shall be submitted.

		Type: Copy Notarization: No Validity: 16-11-2027		
82.	Surgical World, Office No. 105, 1st Floor, Rehmani Chambers, Altaf Hussain Road, New Chali, Karachi (ELI-00462) R&I Date: 13-06-2025 Fee: 31,000/- Slip # 18548754.	Name of Manufacturer: Besmed Health Business Corp. Address: No. 5 Lane, 116 Wu-Kong 2nd Road, Wu-Ku district New Taipei City, Taiwan LOA: Type: Original Notarization: Yes Validity: 16-11-2025 FSC: Type: Original Issued By: FDA Taiwan Legalization: Legalized Validity: 27-05-2030 ISO – Certificate: Type: Copy Notarization: No Validity: 16-11-2027 Original Legalized Free Sale Certificate issued by CIBG of Netherland has been issued valid till 25- 03-2030	Brand Name: Besmed Generic Name: Digital Tens Applied as: Single Class: B Models/Code/sizes (as per FSC & application Size: BE-550 BE-660 Shelf life: 5 years	Approved BE-550.
83.	Mian Enterprises, Office No. UG-400 Deans Trade Center, Peshawar (ELI-00507) R&I Date: 03-07-2025 Fee: 6,000/- Slip # 73353108.	Name of Manufacturer: ChongQing Sunkingdom Medical Instruments Co., Ltd., Address: 35-2 Yingtan Guangdian Gonggu, Cai.JiaGang Industrial Zone BeiBei, ChongQing, China LOA: Type: Copy Notarization: No Validity: 25-12-2026 FSC: Type: Copy Issued By: Provincial Supervision Body Legalization: No Validity: 09-04-2026 ISO – Certificate: Type: Copy	Brand Name: Ocular Surface Analyzer Generic Name: Dry Eye Detector Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model: DA-01 DA-02 DA-03 Shelf life: 5 years	Deferred for following observations: <i>Clarification regarding class of product and differential fee accordngl. Original Legalized valid FSC shall be submitted.</i> <i>Original Documents of the Notarized LOA, ISO and CE certificate shall be submitted</i>

		Notarization: legalized Issue date: 18-05-2021		
84.	Bio-Tech Services, 746-Shadman-1, Lahore, Pakistan. (ELI-00715) R&I Date: 04-07-2025 Fee: 31,000/- Slip # 13952150530.	Name of Manufacturer: Da Wei Medical (Jiangsu) Co., Ltd., Address: 28 Jinqiao Road, Economic and Technological Development Zone, Xuzhou, Jiangsu, China LOA: Type: Original Notarization: Apostille Validity: Not mentioned FSC: Type: Original Issued By: Jiangsu Medical Product Administration Legalization: Apostille Validity 20-10-2025 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 03-02-2027 Notarized copy of EC certificate is also submitted	Brand Name: DA Wei Generic Name: Diagnostics Ultrasound Device Applied as: Single Class: B Models/Code/sizes (as per FSC & application Size: DW-580 Shelf life: 5 years	Approved.
85.	Capri Medical, 51/C-1, Park Avenue, University Town, Peshawar (ELI-00667) R&I Date: 04-07-2025 Fee: 6,000/- Slip # 619385640051.	Name of Manufacturer: Changsha Yingtai Instrument Co., Ltd. Address: , A3 Building, Liando U Valley, Maqiaohe Road, Wangchen, Changsha China LOA: Type: Copy Notarization: No Validity: 19-01-2028 FSC: Type: Original Issued By: Hunan Medical Product Administration Legalization: Apostille Validity 10-05-2025 ISO – Certificate: Not submitted	Brand Name: Laboratory Centrifuge Machine Generic Name: Laboratory Centrifuge Machine Applied as: Single Class: B Models/Code/sizes (as per FSC & application Size: Shelf life:	Deferred for following observations: <i>The submitted FSC was valid till 10-05-02025.</i> <i>The Submitted FSC mentions the name of the device is Medical Centrifuge, while application form mentions the name as Laboratory Centrifuge machine.</i> <i>Original Legalized valid FSC shall be submitted.</i> <i>Original Documents of the Notarized LOA, ISO and CE certificate shall be submitted Shelf life</i>

				Model/codes
86.	<p>Bay-G Pharma, House No. 103-A A Block Satellite Town Rawalpindi</p> <p>ELI-00016 R&I Date: 09-07-2025 Fee: Rs. 31,000 vide deposit slip no. 36753680</p>	<p>Name of Manufacturer: Jianguo 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: Original Issued By: Jiangsu Medical Product Administration Legalization: Notarized Validity: 13-07-2025</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-01-2027</p> <p>EU Quality management certificate submitted.</p>	<p>Brand Name: Believia Portable Phlegm Suction Unit SU-10 Generic Name: Believia Portable Phlegm Suction Unit SU-10 Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Shelf Life: 5 years</p>	<p>Deferred for following observations: <i>Evidence for submission of application for renewal of Import Establishment License is required</i> <i>The submitted FSC is notarized and not legalized/Apostille.</i> Model/code</p>
87.	<p>Bay-G Pharma, House No. 103-A A Block Satellite Town Rawalpindi</p> <p>ELI-00016 R&I Date: 09-07-2025 Fee: Rs. 62,000 vide deposit slip no. 310027118</p>	<p>Name of Manufacturer: Jianguo 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 Validity date: 03-06-2030 • FSC: Type: Original Issued By: Jiangsu Medical Product Administration Legalization: Notarized</p>	<p>Brand Name: Believia Oxygen Concentrator OXC-10 Generic Name: Believia Oxygen Concentrator Applied as: Single Class: B Models/Code/sizes (as per FSC & application) Shelf Life: --</p>	<p>Deferred for following observations: Evidence for submission of application for renewal of Import Establishment License is required The submitted FSC is notarized and not legalized/Apostille. Shelf life model</p>

		<p>Validity: 13-07-2025</p> <p>ISO – Certificate: Type: Original Notarization: Notarized Validity: 04-01-2027</p> <p>EU Quality management certificate submitted.</p>		
88.	<p>Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi, Pakistan. ELI-00109 R&I Date: -16-07-2025 Fee: Rs. 6,000 vide deposit slip no. 8237227858</p>	<p>Name of Manufacturer: Biomerieux, Inc Address: 100 Radolphe Street, Durham, North Carolina 27712 USA LOA Type: Copy Notarization: Apostille Validity date: 31-03-2026 • FSC: Type: Copy Issued By: CCI of France Legalization: Legalized Date of issue: 02-07-2024</p> <p>ISO – Certificate: Type: Copy Notarization: No Validity: 17-12-2027</p>	<p>Brand Name: BacT/Alert 3D System Generic Name: Blood Culture Analyzer Applied as: System Class: A Models/Code/sizes (as per FSC & application)</p> <p>Shelf Life: --</p>	<p>Deferred for following observations: Original Legalized valid FSC shall be submitted.</p> <p>Notarized LOA and ISO Shelf life Model/code</p>
89.	<p>Intek Corporation Pvt. Ltd., Office No. 501, Kohistan Towers, Opp. AFIC The Mall Rawalpindi ELI-00794 R&I Date: 03-07-2025 Fee: Rs. 6,000 vide deposit slip no. 64079743</p>	<p>Name of Manufacturer: Lepu Medical Technology (Beijing) Co, Address: No. 37 Chaoqian Road, Changping District Beijing 102200, China LOA Type: Copy Notarization: Notarized Validity date: 17-03-2027 • FSC: Not submitted</p> <p>ISO – Certificate: Type: Copy Notarization: Notarized Validity: 10-09-2026</p>	<p>Brand Name: Rayband Radial Artery Compression Tourniquets Generic Name: Radial Artery Compression Device Applied as: Set Class: A Models/Code/sizes (as per FSC & application)</p> <p>Shelf Life: 3 years</p>	<p>Deferred for following observations: Original Legalized valid FSC shall be submitted.</p> <p>Original Documents of the Notarized LOA, ISO and DOC certificate shall be submitted Class of product Codes/sizes</p>

90.	<p>Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, K.C.H.S.U, Karachi ELI-00090 R&I Date: 18-07-2025 Fee: Rs. 6,000 vide deposit slip no. 675179060</p>	<p>Name of Manufacturer: Wenzhou Longwan Medical Device Factory Address: Unit 4 Building 27, No. 706 Yanyun Road, Oujiangkou Industrial Cluster District, 325026 Wenzhou, Zhejiang, China LOA Type: Copy Notarization: Notarized Validity date: 24-11-2029 • FSC: Type: Copy Issued by : Zheijiang Medical product Administration Notarization: Notarized Validity: 12-01-2027 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 24-11-2027</p>	<p>Brand Name: Precision+ Generic Name: Stethoscope (TY-S05) Applied as: -- Class: A Models/Code/sizes (as per FSC & application Model: TY-S05 Shelf Life: 5 years</p>	<p>Deferred for following observations: Original Legalized valid FSC shall be submitted. Original Documents of the Notarized LOA, ISO and DOC certificate shall be submitted</p>
91.	<p>Labserv, House No. B-165/2, Block 3A Gulistan e Jauhar, Scheme 36, Karachi ELI-00105 R&I Date: 21-07-2025 Fee: Rs. 31,000 vide deposit slip no. 742406563537</p>	<p>Name of Manufacturer: Vidia Spol. S.r.o. Address: Nad Safinou II 365, 252 50 Vestec, Czech Republic LOA Type: Original Notarization: Notarized Validity date: 30-07-2027 • FSC: Type: original Issued by : State Institute Drug Control Unit of Czech Republic Notarization: Legalized Validity: 31-03-2026 ISO – Certificate: Type: original Notarization: Notarized Validity: 10-07-2027</p>	<p>Brand Name: Elisa-Viditest anti-complement factor H Generic Name: Immuno-Chemistry Test Kit Applied as: Single Class: B Models/Code/sizes (as per FSC & application Shelf Life: 2 years</p>	<p>Deferred for product code/model Legalized FSC of any RRA or Notrized CE.</p>
92.	<p>Medco, 19-Khyber Bazar Peshawar</p>	<p>Name of Manufacturer: Ecotron Co., Ltd.,</p>	<p>Brand Name:</p>	<p>Deferred for following observations:</p>

<p>ELI-00105 R&I Date: 21-07-2025 Fee: Rs. 50,000 vide deposit slip no. 649929409800</p>	<p>Address: 505Ho, Hanshin IT Tower II, 47, Digital-ro 9-gil Geumcheon-Gu, Seoul, 08511, Korea LOA Type: Copy Notarization: Notarized Validity date: 14-05-2029 • FSC: Type: Copy Issued by : National Institute of Medical Device Safety Information Notarization: Apostille Issue date: 22-05-2025 ISO – Certificate: Type: Copy Notarization: Notarized Validity: 18-02-2028 Notarized copy of EU QMS certificate submitted.</p>	<p>Ecotron Stationary/Conventional X-Ray System ESX Series EXS-32-R, EXS-40R, EXS-52R, EXS-68R Generic Name: Conventional X-Ray system Applied as: Family Class: B Models/Code/sizes (as per FSC & application) EXS-32R, EXS-40R, EXS-52R, EXS-68R Shelf Life: 2 years</p>	<p><i>Original Legalized valid FSC shall be submitted.</i> <i>Original Documents of the Notarized LOA, ISO and DOC certificate shall be submitted</i> <i>Justification for applying multiple models</i></p>
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DEFERRED CASES

(Evaluator: Mr.Rana Ahsan-ul-Haq Athar, Deputy Director-VIII)

DEFERRED CASES LOCAL MANUFACTURING

S#	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	<p>Faisal Pharmaceutical Industries, 602-B, Punjab Small Industrial Estate Sargodha Road Faisalabad (ELM-0019 valid till 06-04-2025) [960-6L] D. No. 15090 dated 27-05-2025 Approved Sections/Medical devices: 1.Gauze Section (Sterile/Non-Sterile) 2.Eye Pad Section (Sterile) 3.Tulle Section (Sterile) 4.Surgical Bandage Section 5.Sponge Section (Sterile) 6.Crepe Bandage Section</p>	<p>Sterimax-Ortho Orthopedic Padding Class: A Sizes: 7.5 cm × 2.7m 10cm × 2.7 m 15cm × 2.7 m Shelf Life: 5 Years Fee: 6000 Fee Slip No. 95798656</p>	<p>MDB hold the case in the light of DRAP Lahore office letter till completion of Investigation and final report thereof by additional Director DRAP Lahore regarding the case mentioned in remarks.</p>

2.	<p>Faisal Pharmaceutical Industries, 602-B, Punjab Small Industrial Estate Sargodha Road Faisalabad (ELM-0019 valid till 06-04-2025) [623-7L] R & I: 21265 dated 11-12-2024 Approved Sections/Medical devices: 1.Gauze Section (Sterile/Non-Sterile) 2.Eye Pad Section (Sterile) 3.Tulle Section (Sterile) 4. Surgical Bandage Section 5. Sponge Section (Sterile) 6. Crepe Bandage Section</p>	<p>Silon (Silver Coated Dressing) Strength: Silver.....1.0g/m² Class: C Sizes: 4 inch × 4 inch 4 inch × 8 inch 8 inch × 16 inch 16 inch × 16 inch 4 inch × 48-inch Roll 2 inch × 2 inch 5 inch × 5 inch Shelf Life: 3 Years Fee: 25,000/- Fee Slip No. 3915283854</p>	<p>MDB hold the case in the light of DRAP Lahore office letter till completion of Investigation and final report thereof by additional Director DRAP Lahore regarding the case mentioned in remarks.</p>
3.	<p>Faisal Pharmaceutical Industries, 602-B, Punjab Small Industrial Estate Sargodha Road, Faisalabad. (ELM-0019 valid till 06-04-2025) [961-6L] D. No. 15089 dated 27-05-2025 Approved Sections/Medical devices: 1.Gauze Section (Sterile/Non-Sterile) 2.Eye Pad Section (Sterile) 3.Tulle Section (Sterile) 4.Surgical Bandage Section 5.Sponge Section (Sterile) 6.Crepe Bandage Section</p>	<p>Sterimax-Absorbent Cotton Wool BPC Class: A Shelf Life: 5 Years Fee: 6000 Fee Slip No. 265186865359</p>	<p>MDB hold the case in the light of DRAP Lahore office letter till completion of Investigation and final report thereof by additional Director DRAP Lahore regarding the case mentioned in remarks.</p>
4.	<p>M/s Faisal Pharmaceutical Industries,602 -B ,SIE,Sargodha Road, Faisalabad [ELM No -0019]</p>	<p>Actisil+ Nano silver film dressing Class: D Shelf-life: 3 Years Sizes: <ul style="list-style-type: none"> • 10cm x 10cm film dressing with 20ml loading • 10cm x 20cm film dressing with 40ml loading • 15cm x 30cm film dressing with 60ml loading • 15cm x 1m film dressing with 100ml loading • 15cm x 1.5m film dressing with 120ml loading </p>	<p>MDB hold the case in the light of DRAP Lahore office letter till completion of Investigation and final report thereof by additional Director DRAP Lahore regarding the case mentioned in remarks.</p>

		<ul style="list-style-type: none"> 15cm x 2m film dressing with 150ml loading <p>Fee Challan No. Paid Challan receipt not found in record.</p>	
5.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim X-Ray Fixer Powder (Fixer, Alkali, Retainer, Preservative) Pack Sizes: To make 10L Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 2627741713	Deferred for confirmation of facility for manufacturing of applied product i.e. X-Ray Fixer Powder (Fixer, Alkali, Retainer, Preservative).
6.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim X-Ray Film Developer Powder (Fixer, Alkali, Retainer, Preservative) Pack Size: 2 gallons (9 liters), 3 gallons (13.5 liter) Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 25509411781	Deferred for confirmation of facility for manufacturing of applied product i.e. X-Ray Film Developer Powder (Fixer, Alkali, Retainer, Preservative).
7.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Towels Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 195988186 Sizes: Pack of 6 Towels 12" x 17"	Deferred for confirmation of facility for manufacturing of applied product i.e. Glim Disposable Towels. Furthermore, firm has not submitted fee for the family. The firm is advised to get approval first of the section/manufacturing facility for the applied product.
8.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Sterile Surgical Drape-All Purpose Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 68684024735	Deferred for confirmation of facility for manufacturing of applied product i.e. Glim Sterile Surgical Drape-All Purpose. Furthermore, firm has not submitted fee for the family. The firm is advised to get approval first of the section/manufacturing facility for the applied product.

9.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Side Adhesive Drape STD/Laminated Sheet Pack Size: 70*90cm, 75*90cm, 100*100cm, 100*130cm, 100*150cm Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 58225351205	Deferred for confirmation of facility for manufacturing of applied product i.e. Glim Disposable Side Adhesive Drape STD/Laminated Sheet. Furthermore, firm has not submitted fee for the family. The firm is advised to get approval first of the section/manufacturing facility for the applied product.
10.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Standard/ Reinforced Gown Sterile/ Unsterile Pack Size: L, XL, XXL, XXXL Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 4014501622	Deferred for confirmation of facility for manufacturing of applied product i.e. Glim Disposable Standard/ Reinforced Gown Sterile/ Unsterile. Furthermore, firm has not submitted fee for the family. The firm is advised to get approval first of the section/manufacturing facility for the applied product.
11.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Dignity Sheets Pack Size 10/15/20/30 pieces (60x90 cm) Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 471360306	Deferred for confirmation of facility for manufacturing of applied product i.e. Glim Dignity Sheets. Further, firm has not submitted fee for the family. The firm is advised to get approval first of the section/manufacturing facility for the applied product.
12.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Disposable Drape Pack Sterilized Shelf Life: 04 Years Class: A Fee: 6,000 Fee Slip No: 7842732216	Deferred for confirmation of facility for manufacturing of applied product i.e. Glim Disposable Drape Pack Sterilized. Furthermore, firm has not submitted fee for the family. The firm is advised to get approval first of the section/manufacturing facility for the applied product.
13.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan	EquaSafe Powder Pack Sizes: 100/125/162/300/500 gm	Deferred for confirmation of facility for manufacturing of applied product i.e. Hemodialysis Concentrates and

	(ELM-0096)	Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 5598622537	cannot be utilized for manufacturing EquaSafe Powder. The firm is advised to get approval first of the section/manufacturing facility for the applied product.
14.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Eroxlit Gel Ethanol, Propylene Glycol, Glycerin, Carbomer, Potassium Hydroxide, Aqua Pack Size / Tube: 10g , 15g, 30g Shelf Life: 03 Years Class: A Fee: 6,000 Fee Slip No: 9598582203	Deferred for confirmation of facility for manufacturing of applied product i.e. Eroxlit Gel. Further no rationale for the formulation was found and firm has advised to establish/justify that given formulation falls under definition of medical device.
15.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim ECG Gel Pack Size: Variable Pack Size Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 493914129360	Deferred for submission of formulation and justification that how the ECG Gel can be manufactured in Ostomy Gel Section.
16.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Liquid Paraffin Pack Size: 400ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 00389225	Deferred for: 1. Clarification with documentary evidences that Liquid Paraffin is a medical device under MDR 2017. 2. Justification for manufacturing Liquid Paraffin in Liquid Section approved for Diluents and cleaning solutions for analyzers. 3. Liquid paraffin is already registered as Drug by DRAP by way of repacking.
17.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Glycerin Pack Size: 30ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 85011132	Deferred for: 1. Clarification with documentary evidences that Glycerin is a medical device under MDR 2017. 2. Justification for manufacturing Glycerin in Liquid Section approved for

			Diluents and cleaning solutions for analyzers. 3. Glycerin is registered as Drug by DRAP by way of repacking.
18.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Glim Methylated spirit Pack Size: 300ml Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 736957207258	Deferred for: 1. Clarification with documentary evidences that Methylated Spirit used for cleaning hard surfaces, stains and sticker removal, falls under definition of medical device under MDR 2017. 2. Justification for manufacturing Methylated Spirit in Liquid Section approved for Diluents and cleaning solutions for analyzers.
19.	Glitz Pharmaceutical Plot No. 34-C to 41-C, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir, Pakistan (ELM-0096)	Zetol Pack Size: 50/100 /125/200/250 /500/1000/4000/ 5000/30000ml Conetnts: Chloroxylenol Compe Pine oil Isopropanol Castor oil Soap RO water Shelf Life: 02 Years Class: A Fee: 6,000 Fee Slip No: 39400137	Deferred for: 1. Clarification with documentary evidences that Zetol used as antiseptic, falls under definition of medical device under MDR 2017 as it acts chemically on microbes — pharmacological/biocidal action, not a physical action. 2. Justification for manufacturing Zetol in Liquid Section approved for Diluents and cleaning solutions for analyzers.
20.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [746-7L]	ACCUJECT Disposable Syringe Class: B Shelf Life: 5 Years Sizes: ACCUJECT Disposable Syringe 1ml (With 27G Needle), ACCUJECT Disposable Syringe 1ml (With 21G Needle), ACCUJECT	The MDB approved 10ml Disposable Syringe with different needle size subject to submission of fee for family.

	<p>Disposable Syringe 1ml (With 22G Needle), ACCUJECT Disposable Syringe 1ml (With 23G Needle), ACCUJECT Disposable Syringe 1ml (With 24G Needle), ACCUJECT Disposable Syringe 1ml (With 25G Needle), ACCUJECT Disposable Syringe 1ml (With 26G Needle), ACCUJECT Disposable Syringe U-100 (U-100 With 30G Needle), ACCUJECT Disposable Syringe U-100 (U-100 With 31G Needle), ACCUJECT Disposable Syringe 10ml (With 21G Needle), ACCUJECT Disposable Syringe 10ml (With 22G Needle), ACCUJECT Disposable Syringe 10ml (With 23G Needle), ACCUJECT Disposable Syringe 10ml (With 24G Needle), ACCUJECT Disposable Syringe 10ml (With 25G Needle), ACCUJECT Disposable Syringe 10ml (With 26G Needle), ACCUJECT Disposable Syringe 20ml (With 21G Needle), ACCUJECT Disposable Syringe 30ml (With 21G Needle), ACCUJECT Disposable Syringe 50ml (Catheter tip), ACCUJECT Disposable Syringe 50ml (21G Needle), ACCUJECT Disposable Syringe 60ml (Catheter tip), ACCUJECT Disposable Syringe 60ml (With 21G Needle)</p> <p>Fee: 50,000 Class: B Shelf Life: 5 Years</p>	
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21.	Faiz Surgical and Medical industries pvt Ltd. Plot No. 540-B Sundar Industrial Estate, Lahore (ELM-0093) [747-7L]	ACCUJECT Hypodermic Syringe ACCUFLOW IV Cannula ACCUJECT Butterfly Class: B Shelf Life: 5 Years Fee: 50000 Fee Slip No. 834392091518 Sizes:), ACCUJECT Butterfly (14G), ACCUJECT Butterfly (15G), ACCUJECT Butterfly (16G), ACCUJECT Butterfly (17G), ACCUJECT Butterfly (18G), ACCUJECT Butterfly (19G), ACCUJECT Butterfly (20G), ACCUJECT Butterfly (21G), ACCUJECT Butterfly (22G), ACCUJECT Butterfly (23G), ACCUJECT Butterfly (24G)	MDB approved ACCUFLOW IV Cannula only subject to submission of fee for family.
22.	Bioron Medics (Pvt) Ltd. 6-Km, Off Manga Raiwind Road, Glamour Stop, Sunder Industrial Estate, Lahore. (ELM-0084 valid till 27-10-2029) [885-7L] Dy. No. 11860 dated 06-05-2025 Approved Sections: 1. Syringes (Auto-disable) Section. 2. Syringes (Disposable) Section. 3. Tubes Section (Endocrine, Stomach, Feeding, Nelaton, Nasogastric, Foley catheter tube). 4. IV Burette Set, Blood Transfusion Set (IV Set, IV Y-port set, Scalp Vein Set). 5. IV Dialysis Set Section. 6. Foley Catheter Section. 7. Needle assembly section (Dental, spine, hypodermic, fistula, scalp vein, biopsy, tonsil needle). 8. Assembling and Repacking Section (Threeway stopper, umbilical card clump,	Venus Guide Wire (Guide Wire) Class: B Shelf Life: 5 Years Fee: 25000 Fee Slip No. 86180666035	Deferred for: 1. submission of length and diameter of each guide wire. 2. Fee for the family. 3. clarification of manufacturing process along with section where process will be carried out and submission of testing method.

<p>heparin cap, Endocrine Tube, IV cannula, IV Burette Set, Blood transfusion, IV set, Y-port set, Scalp vein set, Dialysis set, Endotracheal tubes, stomach tubes, feeding tubes, Nelaton tubes, Nasogastric tube, Foley catheter).</p> <p>9. Gauze swabs and sponges sterile and non-sterile Section.</p> <p>10. Gauze Roll Section (Non sterile).</p> <p>11. Medicated dressing Section (Tulle Gras Dressing and Paraffin Gauze Dressing, Non-Woven dressing,).</p> <p>12. Bandage Section (Cotton Bandages, Crepe Bandage, Eye pad, Non-Woven surgical tape).</p> <p>13. Lap sponges with X-Ray Threads Section</p> <p>D. No. 11860 dated 06-05-2025</p>		
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DEFERRED CASES IMPORT

	Name of Importer	Manufacturer	Product details	Decision
23.	<p>Mediland Pakistan (Pvt) Ltd, Office No. B-09 2nd Floor, masood Arcade IJP Road near Saidpur Road Rawalpindi.</p> <p>ELI-00202 5930-P 62,000/-</p>	<p>Legal Manufacturer: Wuxi Hisky Medical Technologies Co., Ltd Room B401, 530 Plaza, University Science Park, Taihu International Science & Technology Park, 214135 Wuxi, Jiangsu Province, People's Republic of China.</p> <p>FSC: China. Validity: 28-02-2026. LOA validity 24-11-2026 ISO 13485 validity 22-03- 2026 CE certificate validity 26- 05-2024 with extension letter.</p>	<p>iLivTouch FT9000 Shear Wave Quantificational Ultrasound Diagnostic System</p> <p>Class-C</p> <p>Shelf Life: N/A</p> <p>Model: FT9000</p>	<p>Deferred for:</p> <ol style="list-style-type: none"> 1. that applied brand name is not mentioned in LOA and FSC. 2. Clarification that product was applied in class C while as per DOC, the Class of device is IIa (B). 3. The name of device as per label is shear wave quantification ultrasound diagnostic system and as per catalog of iLiVETOUCH. 4. Justification that why brand name and were not correct in initial application. 5. Advised to submit a complete application rectifying all above discrepancies.
24.	<p>Mediland Pakistan (Pvt) Ltd, Office No. B-09 2nd Floor, masood Arcade IJP Road</p>	<p>Legal Manufacturer: Wuxi Hisky Medical Technologies Co., Ltd</p>	<p>iLivTouch FT100 Shear Wave Quantificational</p>	<p>Deferred for:</p>

	near Saidpur Road Rawalpindi. ELI-00202 5931-P 62,000/-	Room B401, 530 Plaza, University Science Park, Taihu International Science & Technology Park, 214135 Wuxi, Jiangsu Province, People's Republic of China. FSC: China. Validity: 28-02-2026. LOA validity 24-11-2026 ISO 13485 validity 22-03-2026 CE certificate validity 26-05-2024 with extension letter.	Ultrasound Diagnostic System Class-C Shelf Life: N/A Model: FT100	1. that applied brand name is not mentioned in LOA and FSC. 2. Clarification that product was applied in class C while as per DOC, the Class of device is IIa (B). 3. The name of device as per label is shear wave quantification ultrasound diagnostic system and as per catalog of iLiVETOUCH. 4. Justification that why brand name and were not correct in initial application. 5. Advised to submit a complete application rectifying all above discrepancies.
25.	Melamine Emporium 814,Star City Mall , Saddar Karachi (ELI-00414)	SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany	Angio Band Air TR Closure Band Codes and sizes as per FSC Class: A Shelf Life: not Mentioned Fee: 5000	Deferred for submission of legalized FSC having all pages.
26.	Melamine Emporium 814,Star City Mall , Saddar Karachi (ELI-00414)	SWL Medizin GmbH Havelstr.16 64295 Darmstadt Germany	VAS Power Balloon Inflation Devices Kit Codes and Sizes as per FSC Class: A Shelf Life: not Mentioned Fee: 5000	Deferred for submission of legalized FSC having all pages.
27.	Melamine Emporium 814,Star City Mall , Saddar Karachi (ELI-00414)	SWL Medizin GmbH, Havelstr. 16 64295 Darmstadt, Germany	Guard Hemostasis Valve Set Codes and Sizes as per FSC	Deferred for submission of legalized FSC having all pages.

			Class: B Shelf Life: 3 Years Fee: 25000	
28.	<p>Applicant Name: Audio Medics, 13-F, Fatima Centre, 14-A Queens Road, Lahore</p> <p>ELI-01011</p> <p>Date of R&I 02-06-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 31528363257</p>	<p>Name of Manufacturer: Cochlear Limited, 1 University Avenue, Macquarie University, NSW 2109, Australia</p> <p>LOA Validity: 31-03-2027 (Copy)</p> <p>FSC: Australia TGA Issue Date: 08-05-2025 (Copy of embassy attested)</p> <p>ISO Validity: 14-07-2026 (Copy)</p> <p>EU QMS / EC Certificate Validity: 05-08-2026 notarized copy</p>	<p>Brand name: Cochlear</p> <p>Generic Name: Hearing Prosthesis System</p> <p>Class-D</p> <p>Shelf life: 2 years</p> <p>Models/ Specification: CI422</p>	<p>Approved subject to submission of legalized FSC.</p>
29.	<p>M/s Global Health Care, Midway Commercial Plaza No. 20, Back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi</p> <p>(ELI-00086)</p> <p>Date of R& I 19-05-2025</p> <p>Fee: PKR 31,000/- Slip # 2565067656</p>	<p>M/s Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chungcheon-si, Gang-won-do 24398, Korea</p> <p>LOA Validity: 31-12-2025</p> <p>FSC: Korea Issue date: 14-04-2025</p> <p>ISO Validity: 31-10-2025</p> <p>EU QA /CE Certificate Validity: 09-11-2028</p>	<p>Brand name: Hemochroma Plus</p> <p>Generic Name: Hemochroma Plus</p> <p>Class-B</p> <p>Shelf life: N/a</p> <p>Models/ Specification: FPRR016</p>	<p>Approved Hemochroma Plus (Hemoglobin Analyzer) with service life of 10 years.</p>
30.	<p>M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi</p>	<p>Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial</p>	<p>POT PTCA Balloon Dilatation Catheter</p>	<p>Approved in class D subject to submission of FSC of RRA or DE Certificate and sizes as per FSC.</p>

	00074 Date of R& I 10.10.2023 Fee Rs.50,000/ through slip no.54557371 , dated 10.10.2023	Development Zone, Dongguan, 523808, Guangdong, China		
31.	M/s Advance Cardiology System, 316-317, 3rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi 00074 Date of R& I 10.10.2023 Fee Rs.50,000/ through slip no.088853923 , dated 10.10.2023	Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China	Alveo HP Balloon Dilatation Cather	Approved in calss D subject to submission of FSC of RRA of DE Certificate and sizes as per FSC.
32.	M/s Advance Cardiology System, 316-317, 3 rd Floor, Building 2, Panorama Center, Raja Ghazanfar Ali Khan Road, Near Awari Hotel, Karachi 00074 Date of R& I 10.10.2023 Fee Rs.50,000/ through slip no.33794457580 , dated 10.10.2023	Legal Manufacturer BrosMed Medical Co., Ltd. 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan, 523808, Guangdong, China	Pronavi Microcatheter	Approved in calss D with sizes as per FSC.
33.	IRTEQA BIOTEK (ELI-00218)	Legal Manufacturer: M/S PRECISION BIOSENSOR INC. South Korea Manufacturing Site: 306, Techno 2-ro, Yuseong- gu, Daejeon, South Korea Date of R&I 30th Nov 2022	Exdia Trop I Exdia NT proBNP Exdia D Dimer Exdia Hs CRP Exdia 3 in 1 Test (Trop I + Myoglobin + CKMB) Exdia SOB Test	Approved separately 1. Exdia NT proBNP (Class C) 2. Exdia SOB Test (Shortness of Breath) (TROP 1 + NT PROBNP + D DIMER) (class C).

		<p>FSC: Country of Origin: South Korea Valid &</p> <p>FSC: FSC of Reference Country: Germany Valid LOA Validity: 15-02-2025 Attached EC Certificate Valid ISO 13485 Validity: 04-04-2025</p>	<p>(Trop I + NT proBNP + D Dimer) Exdia TRF Plus Analyzer</p> <p>Class-B</p> <p>Shelf life: 1 year</p>	<p>3. Exdia TRF Plus Analyzer. (Class A).</p>
34.	<p>Name M/S GHAZALI BROTHERS</p> <p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Fees: Challan # 80150949204 Rs 31,000 Date: 27/04/2025</p> <p>Date of R& I 14th April 2025</p>	<p>Legal Manufacturer: M/S JIANGSU WEBEST MEDICAL PRODUCT CO., LTD</p> <p>Manufacturing Site: NO. 5 YINGCHUN ROAD INDUSTRIAL PARK, XUYI, JIANGSU, CHINA. Tel: +86-517-88296001 WWW.CNWEBEST.COM</p> <p>LOA: Sole Agency Agreement Valid till: 31-12-2029</p> <p>FSC: CHINA FSC Validity: 30-06-2025</p> <p>ISO: Production Quality Management System Certificate (ISO 13485:2016) Valid till: 2026-05-31</p>	<p>EASYFLOW I.V. DIAFLOW REGULATOR</p> <p>Class B</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes:</p> <p>Flow range from 5 to 250ml/hour</p>	<p>Deferred due to following reasons.</p> <p>1. the FSC of China was not valid at the time of submission of reply and the name of applied product not mentioned in the submitted FSC.</p> <p>2. Firm has not submitted FSC of any RRA.</p> <p>3. Firm has not submitted original LoA, nortized CE Certificate.</p>
35.	<p>Name M/S GHAZALI BROTHERS</p> <p>Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p>	<p>Legal Manufacturer: NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD</p> <p>Manufacturing Site: YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS</p>	<p>Brand Name: YINGMED ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE Class D</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes:</p>	<p>Deferred due to reasons that firm has not submitted following:</p> <p>1. fee for the family.</p> <p>2. original documents or any evidence for the submission of original documents.</p> <p>3. design Examination certificate.</p> <p>4. catalog that has products codes.</p>

<p>ELI-00240</p> <p>Fees: Rs 62,030 Paid on 19/05/2025 Challan # 07706326549</p> <p>Date of R& I 14th April 2025</p>	<p>ZONE, 315199, NINGBO, CHINA</p> <p>Copy of FQA valid till 23.11.2028</p> <p>Copy of DEC valid till 23.11.2028</p> <p><u>Copy of LOA:</u> Sole Agency Agreement (Notarized by CCPIT, Valid till Jan. 2029</p> <p><u>Copy of FSC:</u> Copy of CHINA FSC (issued by china chamber of commerce for import and export of medicines and health) REGISTRATION NUMBER: 2023YB2690 DATE OF REGISTRATION STATUS: 2024 Valid Upto: Dec, 2025</p> <p><u>Copy of ISO:</u> ISO 13485:2016 (Notarized by CCPIT, submitted along with the file) Valid Upto: 23.11.2026</p>	<p>S. No DESCRIPTI ON GB CODE</p> <p>1. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied(PGA101)</p> <p>2. Thread 75cm, 90cm, 0, Needle 35mm, ½ Circle Round Bodied (PGA102)</p> <p>3. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Round Bodied (PGA103)</p> <p>4. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGA104)</p> <p>5. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Round Bodied (PGA105)</p> <p>6. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Round Bodied (PGA106)</p> <p>7. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGA107)</p> <p>8. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGA108)</p> <p>9. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Round Bodied (PGA109)</p>	
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			<p>Cutting (PGA205)</p> <p>20. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGA206)</p> <p>21. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGA207)</p> <p>22. Thread 75cm, 90cm, 2/0, Needle 16mm, ½ Circle Curved Cutting (PGA208)</p> <p>23. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Curved Cutting (PGA209)</p> <p>24. Thread 75cm, 90cm, 2/0, Needle 60mm, Straight Cutting (PGA210)</p> <p>25. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGA211)</p> <p>26. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGA212)</p> <p>27. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Curved Cutting (PGA213)</p> <p>28. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Round Bodied (PGA214)</p>	
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			<p>29 Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGA215)</p> <p>30. Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Round Bodied (PGA216)</p> <p>31. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGA217)</p> <p>32. Thread 75cm, 90cm, 4/0, Needle 25mm, ½ Circle Curved Cutting (PGA218)</p> <p>33. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Curved Cutting (PGA219)</p> <p>34. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Curved Cutting (PGA220)</p> <p>35 Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Curved Cutting (PGA221)</p> <p>36 Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Curved Cutting (PGA222)</p> <p>37 Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGA223)</p>	
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36.	<p>Name M/S GHAZALI BROTHERS Address of Importer 1ST FLOOR AZZAINAB COURT CAMPBELL STREET, KARACHI, PAKISTAN</p> <p>ELI-00240</p> <p>Fees: Rs 62,030 Paid on 19/05/2025 Challan # 89006840</p> <p>Date of R& I 14th April 2025</p>	<p><u>Legal Manufacturer:</u> NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD</p> <p><u>Address in FSC</u> Room 1201-9, No.456 Tai'an Middle RD, Yinzhou District, Ningbo, Zhejiang, CHINA.</p> <p><u>Address in credential:</u> YINGSHENG BUILDING, NO. 456 TAI'AN ROAD, SOUTHERN BUSINESS ZONE, 315199, NINGBO, CHINA</p> <p>Copy of FQA valid till 23.11.2028</p> <p><u>Copy of LOA:</u> Sole Agency Agreement (Notarized by CCPIT, submitted with file): Valid till Jan. 2029</p> <p><u>FSC:</u> Copy of CHINA FSC (issued by china chamber of commerce for import and export of medicines and health) Valid Upto: Dec, 2025</p> <p>Copy of FQA valid till 23.11.2028</p> <p>Copy of DEC valid till 23.11.2028</p> <p><u>Copy ISO:</u></p>	<p>Brand Name: YINGMED ABSORBABLE POLYGLACTIN SURGICAL SUTURE Class D</p> <p>Shelf Life: 5 Years</p> <p>Codes/Sizes:</p> <p>S. No DESCRIPTI ON</p> <p>1. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied (PGLA101)</p> <p>2. Thread 75cm, 90cm, 0, Needle 35mm, ½ Circle Round Bodied (PGLA102)</p> <p>3. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Round Bodied (PGLA103)</p> <p>4. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGLA104)</p> <p>5. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Round Bodied (PGLA105)</p> <p>6. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Round Bodied (PGLA106)</p> <p>7. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGLA107)</p>	<p>Deferred due to following reasons that firm has not submitted:</p> <ol style="list-style-type: none"> 1. fee for the family. 2. original documents or any evidence for the submission of original documents. 3. design Examination certificate. 4. catalog that has products codes.
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		<p>ISO 13485:2016 (Notarized by CCPIT, submitted along with the file) Valid Upto: 23.11.2026</p>	<p>8. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGLA108)</p> <p>9. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Round Bodied (PGLA109)</p> <p>10. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGLA110)</p> <p>11. Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGLA111)</p> <p>12. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Round Bodied (PGLA112)</p> <p>13. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGLA113)</p> <p>14. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGLA114)</p> <p>15. Thread 75cm, 90cm, 0, Needle 30mm, ½ Circle Round Bodied (PGLA201)</p> <p>16. Thread 75cm, 90cm, 0, Needle 60mm, Straight Cutting (PGLA202)</p> <p>17. Thread 75cm, 90cm, 1, Needle 30mm, ½ Circle Round Bodied (PGLA203)</p>	
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			<p>18. Thread 75cm, 90cm, 1, Needle 35mm, ½ Circle Round Bodied (PGLA204)</p> <p>19. Thread 75cm, 90cm, 1, Needle 40mm, ½ Circle Curved Cutting (PGLA205)</p> <p>20. Thread 75cm, 90cm, 2/0, Needle 25mm, ½ Circle Round Bodied (PGLA206)</p> <p>21. Thread 75cm, 90cm, 2/0, Needle 30mm, ½ Circle Round Bodied (PGLA207)</p> <p>22. Thread 75cm, 90cm, 2/0, Needle 16mm, ½ Circle Curved Cutting (PGLA208)</p> <p>23. Thread 75cm, 90cm, 2/0, Needle 35mm, ½ Circle Curved Cutting (PGLA209)</p> <p>24. Thread 75cm, 90cm, 2/0, Needle 60mm, Straight Cutting (PGLA210)</p> <p>25. Thread 75cm, 90cm, 2/0, Needle 40mm, ½ Circle Round Bodied (PGLA211)</p> <p>26. Thread 75cm, 90cm, 3/0, Needle 30mm, ½ Circle Round Bodied (PGLA212)</p> <p>27. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Curved Cutting (PGLA213)</p>	
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			<p>28. Thread 75cm, 90cm, 3/0, Needle 25mm, ½ Circle Round Bodied (PGLA214)</p> <p>29 Thread 75cm, 90cm, 3/0, Needle 20mm, ½ Circle Round Bodied (PGLA215)</p> <p>30. Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Round Bodied (PGLA216)</p> <p>31. Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGLA217)</p> <p>32. Thread 75cm, 90cm, 4/0, Needle 25mm, ½ Circle Curved Cutting (PGLA218)</p> <p>33. Thread 75cm, 90cm, 2, Needle 40mm, ½ Circle Curved Cutting (PGLA219)</p> <p>34. Thread 75cm, 90cm, 0, Needle 40mm, ½ Circle Curved Cutting (PGLA220)</p> <p>35 Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Curved Cutting (PGLA221)</p> <p>36 Thread 75cm, 90cm, 4/0, Needle 20mm, ½ Circle Curved Cutting (PGLA222)</p> <p>37 Thread 75cm, 90cm, 4/0, Needle 16mm, ½ Circle Round Bodied (PGLA223)</p>	
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MINUTES OF ADDITIONAL AGENDA

Mr. Ammar Ashraf Awan (Deputy Director-X)

Sr. No.	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025</p> <p>Fee: PKR 31,030.00</p> <p>Slip # 2544576690</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: Airvo 2 Humidifier (PT101EW)</p> <p>Generic Name: High Flow respiratory unit</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC & application) PT101EW</p> <p>Shelf Life: N/A</p>	Approved
2.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025</p> <p>Fee: PKR 31,030</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA 	<p>Brand Name: Airvo Spiral tube and chamber kit</p> <p>Generic Name: Breathing Circuit</p> <p>Applied as: Family</p> <p>Class: B</p>	Approved 900PT561.

	<p>Slip # 29625370</p>	<p>Type: Copy Notarization: Notarized Validity: 03-31-2026</p> <ul style="list-style-type: none"> • FSC <p>Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <p>Type: Copy Issued By: NZ FSC Legalization: Apostille Issued date: 08-12-2021 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: <p>Type: Copy Notarization: Notarized Validity: 11-13-2027</p> <ul style="list-style-type: none"> • CE Certificate <p>Type: Copy Notarization: Notarized Validity: 12-05-2026</p>	<p>Models/Code/sizes (as per FSC & application) 900PT561, 900PT562 Shelf Life: 3 years</p>	
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3.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025 Fee: 25000/- Slip # 583402087</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC 1. Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 17-04-2025 Validity: NA • 2. Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • 3. Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 08-12-2021 Validity: NA • 4. Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: Airvo Accessories</p> <p>Generic Name: Accessories</p> <p>Applied as: Set</p> <p>Class: A</p> <p>Models/Code/sizes (as per FSC & application) 900PT400, 900PT405, 900PT411, 900PT421, 900PT427, 900PT600, 900PT445, 900PT428, 900PT427L, 900PT475, 900PT474, 900PT473</p> <p>900PT400- Stand Compact (Airvo) 900PT405- Tray Pole Mount Airvo, 900PT411- Ups Mounting Kit , 900PT421- Mobile Pole Stand , 900PT427- Oxygen Bottle Holder, 900PT600- Disinfection kit Airvo 900PT445- Mobile pole stand handle , 900PT428- Mobile pole stand clamp , 900PT427L- Oxygen-bottle holder (Large) , 900PT475- Airvo 3 service app , 900PT474- Airvo 3 USB service cable , 900PT473- Airvo 3 data port adapter</p> <p>Shelf Life: N/A</p>	<p>Deferred as multiple products applied in single application. Which product to be considered for instant application. Shelf life</p>
4.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 07-07-2025</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited</p> <p>Address:</p>	<p>Brand Name: F&P 820 Chamber Manual Fill 500mL</p> <p>Generic Name: Humidification System Accessories</p>	<p>Approved.</p>

	<p>Fee: 31000/- Slip # 8792479946</p>	<p>15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued Date: 17-11-2023 Validity: NA Type: Original Issued By: NZ Medsafe Legalization: Apostille Issued by: Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Applied as: Single Class: B Models/Code/sizes (as per FSC & application) MR325 Shelf Life: 5 years</p>	
5.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025 Fee: 31000/- Slip # 874574964173</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited</p> <p>Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA <p>Type: original Issued By: Medsafe of Newzeland</p>	<p>Brand Name: F&P 820 Circuit Heated Single Limb 22mm (820A10)</p> <p>Generic Name: Ventilator Breathing Circuit</p> <p>Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 820A10 Shelf Life: 3 years</p>	Approved.

		<p>Legalization: Apostille Issued date: 13-10-2023 Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
6.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 62000/- Slip # 170290304</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: original Issued By: TGA Australia Issued date: 17-11-2023 Legalization: Apostille Validity: NA <p>Type: original Issued By: NZ Medsafe Legalization: Apostille Issued date: 13-11-2023 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: original Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: original Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P 820 Respiratory Humdifier Generic Name: Respiratory Humdifier Applied as: Single Class: C Models/Code/sizes (as per FSC & application): 820ANZ and 820AEU Shelf Life: N/A</p>	<p>Deferred for selection of one model against the submitted application and brief description of applied product</p>
7.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address:</p>	<p>Brand Name: F&P Breathing circuit Generic Name: Breathing circuit</p>	<p>Deferred for following: Justification for applying</p>

	<p>Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025 Fee: 50000/- Slip # 68474964</p>	<p>15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Original Issued By: NZ Medsfae Legalization: Apostille Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Applied as: Family Class: B Models/Code/sizes (as per FSC & application) 950A40, 950A60, 950A61, 950A80, 950A81, 950A82, 950P40, 950P81, 950N40, 950N60, 950N61, 950N62, 950N80, 950N81, 950N82 Shelf Life: 3 years</p>	<p>multiple models in single application. Which model to be considered for instant application.</p>
8.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 07-07-2025 Fee: 31000/- Slip # 373335688029</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: copy Issued By: TGA Australia Legalization: Apostille Validity: NA <p>Type: Copy</p>	<p>Brand Name: F&P ergonomic T Piece circuit Generic Name: ventilator breathing circuit</p> <p>Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RD1300-10, RD1340-10, RD1350-10, RD1360-10 Shelf Life: 3 years</p>	<p>Deferred for following: Justification for applying multiple models in single application. Which model to be considered for instant application. Confirmation of class</p>

		<p>Issued By: NZ FSC Legalization: Apostille Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
9.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 07-07-2025 Fee: 31000/- Slip # 2127481945</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P Heater wire adaptor (900MR805, 900MR806) Generic Name: Connection cables reusable (electrical accessories) Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 900MR805, 900MR806 Shelf Life: 3 years</p>	<p>Approved Subject to submission of differential fee for family.</p>
10.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-</p>	<p>Name of Manufacturer:</p>	<p>Brand Name:</p>	<p>Approved Subject to</p>

	<p>B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 901906811</p>	<p>Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 17-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>F&P Hpo Dual Input Manifold Generic Name: Manifold Applied as: Single Class: B Models/Code/sizes (as per FSC & application 900PT460D, 900PT460N, 900PT460S, 900PT462DN Shelf Life: N/A</p>	<p>submission of differential fee for family nad shelf life/service life.</p>
11.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8- B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 07-07-2025 Fee: 31000/- Slip # 50987983</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille 	<p>Brand Name: f&p classic T Piece circuit with mask Generic Name: Ventilator breathing circuit Applied as: Single Class: B Models/Code/sizes (as per FSC & application 900RD010, 900RD014-10, 900RD015-10, 900RD016-10, 900RD110 Shelf Life: 3 years</p>	<p>Deferred for following: Justification for applying multiple models in single application. Which model to be considered for instant application. Confirmation of class</p>

		<p>Issued date: 17-04-2025 Validity: NA</p> <p>Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
12.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025 Fee: 6000/- Slip # 420835533511</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 17-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P Anesthesia Accessories (Humidifier Pole) Generic Name: Service rail clamp Applied as: Family Class: A Models/Code/sizes (as per FSC & application) AA501, AA502, AA503 Shelf Life: N/A</p>	<p>Approved Subject to submission of differential fee for family</p>

13.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 90000/- Slip # 8154235143</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Original Issued By: Medsafe of Newzeland Legalization: Apostille Issued date: 20-12-2021 Validity: Not mentioned • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 05-12-2026 	<p>Brand Name: F&P Circuit kit Generic Name: Ventilator Breathing Circuit Applied as: family Class: B Models/Code/sizes (as per FSC & application) RT330, RT380, RT385, RT481, RT200, RT201, RT202, RT204, RT205, RT206, RT212, RT219, RT301, RT308, RT319, RT408, RT100, RT105, RT265, RT266, RT267, RT268, RT224, RT225, RT226, RT227, RT228, RT324, RT329 Shelf Life: 5 years</p>	<p>Deferred for following: Justification for applying multiple models in single application. Which model to be considered for instant application.</p>
14.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 07-07-2025 Fee: 31000/- Slip # 5260038999</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA 	<p>Brand Name: F&P Humidification chamber Generic Name: Inspiratory line humidification chamber single use Applied as: Single Class: B Models/Code/sizes (as per FSC & application) MR250, MR225, MR225X Shelf Life: N/A</p>	<p>Deferred for following: Justification for applying multiple models in single application. Which model to be considered for instant application.</p>

		<p>Type: Copy Issued By: Medsafe of Newzeland Legalization: Apostille Issued date: 20-12-2021 Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
15.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 2799767254</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Original Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P MR810 Respiratory humidifier Generic Name: Respiratory humidifier Applied as: Single Class: B Models/Code/sizes (as per FSC & application) MR810AEU Shelf Life: N/A</p>	Approved.

16.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025 Fee: 31000/- Slip # 31605547</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 17-04-2025 Validity: NA Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 30-05-2023 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P low flow oxygen tubing Generic Name: Oxygen low pressure Tube Applied as: Single Class: B Models/Code/sizes (as per FSC & application) AA020 Shelf Life: 5 years</p>	Approved.
17.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 18-07-2025 Fee: 25000/- Slip # 791861740597</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA 	<p>Brand Name: F&P Humidifier accessories Generic Name: Accessories Applied as: Set Class: A Models/Code/sizes (as per FSC & application) (900MR817, 900MR858, 900MR860, 900MR861, 900MR868, 900MR869, 900MR030, 900MR170) 900MR817- CONNECTION KIT S/U DUAL HTD 900MR858- HEATER WIRE ADAPTOR-850 INS RE</p>	Deferred for following: Justification for applying multiple models in single application. Which model to be considered for instant application. Confirmation of class

		<p>Type: Original Issued By: NZ FSC Legalization: Apostille Issued date: 25-05-2022 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>900MR860- PROBE TEMP/FLOW RT ANG 1640mm</p> <p>900MR861- PROBE TEMP/FLOW RT ANG 2200mm</p> <p>900MR868- PROBE TEMP/FLOW RT ANG 1450mm</p> <p>900MR869- PROBE TEMP/FLOW RT ANG 1850mm</p> <p>900MR030-MOUNTING BRACKET POLE 15-50mm</p> <p>900MR170-MOUNTING BRACKET - C-CLAMP</p> <p>Shelf Life: N/A</p>	
18.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 977900311</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA <p>Type: Original Issued By: NZ MEsafe Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized 	<p>Brand Name: F&P Nasal vented mask Generic Name: CPAP/BPAP Nasal Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT042, RT042L Shelf Life: 5 years</p>	<p>Deferred for following: Justification for applying multiple models in single application. Which model to be considered for instant application.</p>

		Validity: 11-13-2027 <ul style="list-style-type: none"> • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026		
19.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 04-07-2025 Fee: 31000/- Slip # 1251150030	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 <ul style="list-style-type: none"> • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Original Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2024 Validity: NA <ul style="list-style-type: none"> • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	Brand Name: F&P Nivairo RT045 Mask Generic Name: Nivairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT045L, RT045M, RT045S, RT045XS Shelf Life: 3 years	Approved subject to submission of <i>Differential fee for the Family</i>
20.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 07-07-2025 Fee: 31000/- Slip # 85076650388	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 <ul style="list-style-type: none"> • FSC Type: Copy	Brand Name: F&P Neopuff Side Mounting Block Generic Name: Portable active medical device mount Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 900RD301 Shelf Life: N/A	Approved.

		<p>Issued By: TGA Australia Legalization: Apostille Validity: NA</p> <p>Type: Copy Issued By: NZ FSC Legalization: Apostille Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
21.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 822492161426</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA <p>Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2024 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy 	<p>Brand Name: F&P Nivairo RT047 Mask Generic Name: Nivairo Mask Applied as: Family Class: B Models/Code/sizes (as per FSC & application) RT047L, RT047M, RT047S, RT047XS Shelf Life: 3 years</p>	<p>Approved subject to submission of <i>Differential fee for the Family</i></p>

		Notarization: Notarized Validity: 12-05-2026		
22.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 04-07-2025 Fee: 31000/- Slip 53368037874	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2024 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	Brand Name: F&P Nivairo RT055 Mask Generic Name: Nivairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT055L, RT055M, RT055S, RT055XS Shelf Life: 3 years	Approved subject to submission of Differential fee for the Family
23.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 04-07-2025 Fee: 31000/- Slip # 86271775	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: copy Issued By: TGA Australia	Brand Name: F&P Nivairo RT056 Mask Generic Name: Nivairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT056L, RT056M, RT056S, RT056XS Shelf Life: 3 years	Approved subject to submission of Differential fee for the Family

		<p>Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <p>Type: Copy Issued By: NZ Medsafe Legalization: Apostille Issued date: 15-04-2024 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
24.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 791899630600</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA <p>Type: Copy Issued By: NZ Medsafe Legalization: Apostille Validity: NA</p> <p>Type: Copy Issued By: NZ Medsafe Legalization: Apostille Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 	<p>Brand Name: F&P Nivairo RT046 Mask Generic Name: Nivairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT046L, RT046M, RT046S, RT046XS Shelf Life: 3 years</p>	<p>Approved subject to submission of <i>Differential fee for the Family</i></p>

		<ul style="list-style-type: none"> • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
25.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 296316738</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P Nivairo RT057 Mask Generic Name: Nivairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT057L, RT057M, RT057S, RT057XS Shelf Life: 3 years</p>	Approved subject to submission of Differential fee for the Family
26.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 08-07-2025 Fee: 31000/- Slip # 1167262470</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 	<p>Brand Name: F&P Optiflow+ Breathing circuit connector Generic Name: Breathing circuit connector Applied as: Single Class: B Models/Code/sizes (as per FSC & application) OPT970, OPT980 Shelf Life: 5 years</p>	Approved subject to submission of Differential fee for the Family

		<ul style="list-style-type: none"> • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
27.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 08-07-2025 Fee: 31000/- Slip # 69625211702	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: 	Brand Name: F&P freemotion NON Vented mask Generic Name: NON Vented mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT041L, RT041M, RT041S Shelf Life: 5 years	Approved subject to submission of Differential fee for the Family

		<p>Type: Copy Notarization: Notarized Validity: 11-13-2027</p> <ul style="list-style-type: none"> • CE Certificate <p>Type: Copy Notarization: Notarized Validity: 12-05-2026</p>		
28.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 67984583156</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA <p>Type: Copy Notarization: Notarized Validity: 03-31-2026</p> <ul style="list-style-type: none"> • FSC <p>Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <p>Type: Copy Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: <p>Type: Copy Notarization: Notarized Validity: 11-13-2027</p> <ul style="list-style-type: none"> • CE Certificate <p>Type: Copy Notarization: Notarized Validity: 12-05-2026</p>	<p>Brand Name: F&P OPTIFLOW+ Nasal Cannula Generic Name: nasal oxygen cannula</p> <p>Applied as: Single Class: B Models/Code/sizes (as per FSC & application) OPT942, OPT944, OPT946 Shelf Life: 5 years</p>	<p>Deferred for Justification for applying multiple models in single application. Which model to be considered for instant application.</p>
29.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 07-07-2025 Fee: 31000/- Slip # 337321222979</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA 	<p>Brand Name: F&P Resuscitation mask Generic Name: Resuscitation mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application)</p>	<p>Deferred for Justification for applying multiple models in single application. Which model to be considered</p>

		<p>Type: Copy Notarization: Notarized Validity: 03-31-2026</p> <ul style="list-style-type: none"> • FSC <p>Type: Copy Issued By: TGA Australia Legalization: Apostille Issued by: 17-04-2025 Validity: NA</p> <p>Type: Copy Issued By: NZ Medsafe Legalization: Apostille Issued by: 15-04-2025 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: <p>Type: Copy Notarization: Notarized Validity: 11-13-2027</p> <ul style="list-style-type: none"> • CE Certificate <p>Type: Copy Notarization: Notarized Validity: 12-05-2026</p>	RD800-EN, RD803-10, RD804-10, RD805-10, RD806-10, RD807-10 Shelf Life: 3 years	for instant application.
30.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 08-07-2025 Fee: 31000/- Slip # 03211283810	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand <ul style="list-style-type: none"> • LOA <p>Type: Copy Notarization: Notarized Validity: 03-31-2026</p> <ul style="list-style-type: none"> • FSC <p>Type: Copy Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <p>Type: Copy Issued By: NZ FSC Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p>	Brand Name: F&P Vented mask with antiasphyxiation valve Generic Name: CPAP/BPAP face mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 900MR805, 900MR806 RT040, RT040L, RT040M, RT040S Shelf Life: 5 years	Deferred for Justification for applying multiple models in single application. Which model to be considered for instant application.

		<ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
31.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 50000/- Slip # 58112133136</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA <p>Type: Original Issued By: NZ Medsfae Legalization: Apostille Issued date: 15-04-2025 Validity: NA</p> <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Brand Name: F&P Optiflow junior 2 cannula Generic Name: cannula Applied as: family Class: B Models/Code/sizes (as per FSC & application) OJR410, OJR410VT, OJR412, OJR412VT, OJR414, OJR414VT, OJR416, OJR416VT, OJR418, OJR418VT Shelf Life: 5 years</p>	<p>Deferred for Justification for applying multiple models in single application. Which model to be considered for instant application.</p>
32.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 676897783009</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p>	<p>Brand Name: F&P Visairo RT076 Mask Generic Name: Visairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT076A, RT076B, RT076C</p>	<p>Deferred for Justification for applying multiple models in single application. Which model to be considered</p>

		<ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	Shelf Life: 3 years	for instant application.
33.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 936927924</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Not submitted • FSC Not submitted • ISO – Certificate: Not submitted • CE Certificate Not submitted 	<p>Brand Name: F&P Visairo RT077 Mask Generic Name: Visairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT077A, RT077B, RT077C Shelf Life: 3 years</p>	<p>Deferred for following observations: <i>Original Legalized valid FSC shall be submitted.</i> <i>Original Notarized Documents for the LOA, ISO & CE certificate shall be submitted.</i> <i>Justification for applying multiple models in single application.</i> <i>Which model to be considered for instant application.</i></p>
34.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p>	<p>Brand Name: F&P WATERBAG AIRVO 2 PACK Generic Name: Inspiratory line humidification chamber reusable</p>	Approved.

	<p>Fee: 31000/- Slip # 86007182</p>	<ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Copy Issued By: NZ FSC Legalization: Apostille Issue date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 	<p>Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 900PT401 Shelf Life: N/A</p>	
35.	<p>M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274)</p> <p>R&I Date: 04-07-2025 Fee: 31000/- Slip # 3249714726</p>	<p>Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand</p> <ul style="list-style-type: none"> • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Original Issued By: TGA Australia Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate 	<p>Brand Name: F&P Visairo RT075 Mask Generic Name: Visairo Mask Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT075A, RT075B, RT075C Shelf Life: 3 years</p>	<p>Deferred for Justification for applying multiple models in single application. Which model to be considered for instant application.</p>

		Type: Copy Notarization: Notarized Validity: 12-05-2026		
36.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 07-07-2025 Fee: 31000/- Slip # 9966345102	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: NZ Medsafe Legalization: Apostille Issued date: 15-04-2025 Validity: NA • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026	Brand Name: F&P Inspiratory/Expiratory filter Generic Name: Microbial medical gas filter - Single Use (Breathing Tube Filter) Applied as: Single Class: B Models/Code/sizes (as per FSC & application) RT016, RT019 Shelf Life: 5 years	Approved subject to submission of Differential fee for the Family
37.	M/s. Hospicare Systems, 9th Floor, Emarah Suites, Plot 8-B Block A, SMCHS Shahrah-e-Faisal, Karachi, 75350 (ELI-00274) R&I Date: 08-07-2025 Fee: 31000/- Slip # 4711922188	Name of Manufacturer: Fisher & Paykel Healthcare Limited Address: 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand • LOA Type: Copy Notarization: Notarized Validity: 03-31-2026 • FSC Type: Copy Issued By: TGA Australia Legalization: Apostille Validity: NA Type: Original	Brand Name: Optiflow oxygen kit Generic Name: Humidified Oxygen Administration Set Applied as: Single Class: B Models/Code/sizes (as per FSC & application) AA454, AA452 Shelf Life: 5 years	Deferred for Justification for applying multiple models in single application. Which model to be considered for instant application.

		Issued By: NZ medsafe Legalization: Apostille Issued by: 22-03-2022 Validity: NA <ul style="list-style-type: none"> • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 11-13-2027 • CE Certificate Type: Copy Notarization: Notarized Validity: 12-05-2026 		
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