

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

DECISIONS OF 119TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON
29-01-2026 (MANUAL APPLICATIONS PART-II)

119th 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 29th January, 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S. No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	Mr. Salik Zahid, Chief Drug Inspector, Balochistan, a nominee of Director General Health, Health Department, Government of Balochistan	Member (attended meeting through videolink)
3.	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)
4.	Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist, 98, Babar Block, New Garden Town, Lahore.	Member (attended meeting through videolink)
5.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
6.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
7.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
8.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
9.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
10.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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

EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR)

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

FRESH CASES-ELM:

S.No	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1	M/s Matrix Pharma (Pvt) Ltd, Office/godown: Plot 12/1, Sector 15, Korangi Industrial area, Karachi, Pakistan.	Asif Ali B-Pharm Experience: 3 Years	Imrana Faheem Qureshi B-Pharm 3 Years	<p>The board considered the inspection report and approved Establishment License to Manufacture Medical Devices for the following sections:</p> <p>1. Facility for Manufacturing and Filling of Semi-Liquid in Prefilled Syringes / Vials. (Intra – Articular Implants (Vials / Prefilled syringes), Solid filler/scaffold implants.)</p> <p>2. Facility for Manufacturing and Filling of Semi-Solid & Solid External Preparations (Wound healing, hydration, lubrication /gels / lotions/ creams, wound healing, haemostatic & barrier powders.)</p> <p>3. Facility for Coating on Wound Dressing (Tulle/Gauze) (Coated wound dressing, hydrocolloid wound dressings (Tulle/Gauze).)</p> <p>4. Facility for Liquid coating on Medical Devices (Test Strips/Urinary Foley Catheters) (Coating on IVD tests / Coating on urinary Foley catheters.)</p>

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

(FRESH CASES-ELI):

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Crown Pharmaceuticals Pvt Ltd Office/godown: Office # F-3/16 Swiss Cottage, Block 4, Clifton, Karachi Karachi	Naresh Kumar Pharm D	Approved
2.	M/s Focus I Tech, Office /godown: 7-Jahanzaib block , allam Iqbal town , Lahore.	Mehak Fatima Bs biomedical Engineering	Approved
3.	M/s Felix Abs, Office/godown: 909-A, Block Shershan colony, Lahore.	Iqra Siraj M.Phil Microbiology	Rejected. The board considered the inspection report and observed major violations/ non-compliance to medical devices rules 2017 and prevailing policies of medical devices board. Therefore, the board decided to reject application of the firm for grant of establishment license to import medical devices.
4.	M/s Crestex International, 134/E Model Town Lahore Lahore.	Sami Ullah Umar Pharm D	Rejected. The considered report of the inspector and statement of the applicant that they are no more interested, decided to reject application of the firm for grant of establishment license to import medical devices.

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

(FRESH RENEWAL CASES-ELI):

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Ferozsons Laboratories Limited, Office: 5 Km, Sunder	Sohail haider Pharmacist	Akhtar Khalid Waheed Usman Khalid Waheed Munize Azhar Peracha Amna Peracha Khan	Approved

	Raiwind road, riawind. Lahore. godown: P.O. Ferozsons, Nowshera, Pakistan. ELI-00120		Arshad Saeed Hussain Nihal F. Cassim Shahid Anwar	
2.	M/s Concept Pharma (Pvt) Ltd, Office/godown: Plot No. 421, block C, LDA , Avenue 1, Lahore. ELI-00112	Talha Mabood MSc Biotechnology	Naseem Ahmad Faizan Ahmad Usman Ahmad Shafiq ahmad	Approved
3.	M/s forcare, Office/godown: 788, Block J-2, M.A, Johar town , Lahore. ELI-00379	Muhammad Awais Pharm D	Sheikh Naeem Ahmad Shoukat ali Talat Mehmood Qureshi	Approved
4.	M/s Forcare, Office/godown: 788, block J-2, M.A Johar Town, Lahore. ELI-00379	Muhammad Awais Pharm D	Sheikh Naeem Ahmad Shoukat Ali Talat Mehmood Qureshi	Repetition of case No. 3 hence deleted.
5.	M/s S. Ejazuddin & Co Office/godown: 237/B, Block II, PECHS, Shahrah-e-quideen, Karachi. ELI-00078	M Hamdan Afridi Bs Biomedical Engineering	Taufiq feroz Mumtazudidn feroz Nazimuddin feroz Sultan ahmad feroz Rizwan Feroz	Approved
6.	M/s Zedco, Office: 602, 603, sky mark tower, plot no A- 13, BLOCK 7/8, KCHSU, shahrah e faisal Karachi. Godown 1: 2 nd floor ,, 203, 204 sky mark tower, plot no A-13, BLOCK 7/8, KCHSU, shahrah e faisal Karachi. ELI-00347	Asiya amjad Pharm D	Shujaat Hussain CEO	Approved

7.	M/s Remington pharmaceutical Industries (Pvt) Ltd, Office/godown: 18-Km Multan road, Lahore. ELI-00395	Muhammad Usman Bilal Pharm D	Shahab Qadeer Khokhar Shahina Qadeer Adbul Qadeer Khokhar Faisal Qadeer Khokhar	Approved
8.	M/s Mian Enterprises, Office: TF-66-67 Deans Trade Centre, Peshawar Cantt. Godown: TF-77-78 Deans Trade Centre, Peshawar Cantt.	Ameer Hamza Farooq Pharm D	Naeem Ullah CEO	Approved
9.	M/s Reaction Scientific pvt. Ltd, Office/godown: 337 Street No. 17, Sector B-17, Block B, Islamabad.	Syed Aoon Haider Biomedical Engineering	Muhammad Kashif Muahmmad Altaf Muhammad Imarn Muhammad Jamil Hussain Nawaz Lalee Ghulam Shabbir	Approved
10.	M/s Physiomed (Pvt), Office/godown: 268/3, Kamal road, saddar, Rawalpindi. ELI-0000199	Babar ali Khan Biomedical engineer	M ramzan Sher zaman Nusrat	Deferred for approval of technical staff and fee.
11.	M/s Biocare Enterprises, Office/godown: 64/2, st/2, St, FESCH NPF, 0-9 PWD road, Islamabad. ELI-00220	Noor qadir	Muhammad Asif CEO	Deferred for approval of technical staff and fee
12.	M/s Premium Pharmaceutical pvt ltd, Office/godown: Plot No. D-2/1, SITE, area, Kotri, Jamshoro , Sindh. ELI-00000	Mihbah Pharm D	Khan Muhammad Allah Dino	Deferred for fee and documents for approval of new godown.
13.	M/s Ahmad Care International ,	Syed amin abbas	Amir Ijaz butt CEO	Show cause notice. The board

	<p>Office/godown: 2nd Floor, 7 Shahrah e Taj bagh, phase 1, main market, opp unique solution girls high school, Tajbagh housing scheme, Lahore.</p> <p>ELI-00361</p>			<p>considered the inspection report and observed major violations/ non-compliance to medical devices rules 2017 and prevailing policies of medical devices board. Therefore, the board decided to issue show cause notice for contraventions to medical devices rules 2017 and to provide opportunity of personal hearing before final decision is made on renewal of establishment license to import medical devices.</p>
14.	<p>M/s Claris Medical,</p> <p>Office/godown: Flat No.1, Ground Floor, Rayyan Heights, gangal east, service road , Islamabad express way , Islamabad.</p> <p>ELI-00269</p>	<p>Ada Iqra nayab saleem</p> <p>Pharm D</p>	<p>Saqib Altaf Chaudhry</p> <p>CEO</p>	<p>Show cause notice. The board considered the inspection report and observed major violations/ non-compliance to medical devices rules 2017 and prevailing policies of medical devices board. Therefore, the board decided to issue show cause notice for contraventions to medical devices rules 2017 and to provide</p>

				opportunity of personal hearing before final decision is made on renewal of establishment license to import medical devices.
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Item No. I(D): APPLICATIONS FOR RENEWAL OF LICENSE TO IMPORT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

(DEFERRED CASES FOR RENEWAL OF -ELI):

1.	<p>M/s Life Care, M-20, Mezzanine Floor, Falak Naz Plaza Near Natha Khan Bridge, Shahrah-e-Faisal, Karachi</p> <p>Old Godown: CB-53, Al Falah Society near Sindh Bank Shah Faisal Colony No. 1, Karachi</p> <p>New Godown Address: House No. 104/A-102, Area Asifabad Shah Faisal Town, Karachi</p>	<p>Nasir Ali Qureshi MSC. Microbiology</p>	<p>Imtiaz Ur Rehman CEO</p>	<p>Decision: Approved</p>
2.	<p>M/s Nimrall Farma</p> <p>Office: 15E 2nd Floor Sheikh Building Bata Chowk, Aziz Bhatti Road Lalkurti Rawalpindi</p> <p>Godown: Nimrall Farma Flat No. E-15, Aziz Bhatti Road, 2nd Floor, LalKurti, District Rawalpindi</p> <p>ELI-00251</p>	<p>Ms Tanya Waseem Pharm D</p>	<p>Shahzad Saeed Muhammad Kashif Kalsoom Mubbshir</p>	<p>Approved. The firm shall submit differential fee before issuance of license.</p>

3.	<p>M/s Medi Bridge,</p> <p>Office: Plot No. 500, Block-D, 2nd Floor, M.A Jinnah Road, Lahore.</p> <p>Godown: Plot No. 500, Block-D, Ground Floor, M.A Jinnah Road, Lahore.</p> <p>ELI-00058</p>	<p>Haroon Ahmad</p> <p>Bio Medical Engineer</p>	<p>Iftikhar Ahmad</p> <p>CEO</p>	<p>Approved</p>
4.	<p>M/s Cabbot Surgicals,</p> <p>Office: Ho No CB 6060 Rose Lane 3-A New Lalazar Rawalpindi.</p> <p>Godown: 09 Rose Lane 01, Gulberg Avenue, New Lalazar Rawalpindi.</p> <p>ELI-00415</p>	<p>Firdous Rasheed</p> <p>Pharm D</p>	<p>Muhammad Attique Shahid</p> <p>CEO</p>	<p>Approved</p>
5.	<p>M/s MUSLIM SCIENTIFIC CORPORATION, 2nd Floor. 03 Syed Mouj Darya Road Lahore</p> <p>Godown: 57B PAF Colony Zarrar Shaheed Road Lahore Cantt</p> <p>ELI-00431</p>	<p>Muhammad Faisal Samee</p> <p>Pharm D</p>	<p>Sami Ullah Shaikh</p>	<p>Approved.</p> <p>The new address of godown shall be as under:</p> <p>36 PAF Colony Zarrar Shaheed road, Lahore Cant, Lahore.</p> <p>The firm shall submit an undertaking that the proposed facility shall not be used for residential purposes and could be inspected anytime without hindrance.</p>

6.	<p>M/s National Enterprises, Office No. 409, 4th Floor, Al-Sehat Center, Annexe Regent Plaza, Shahrah-e-Faisal, Karachi.</p>	<ul style="list-style-type: none"> Mr. Wajahat Ali, Member MDB, DRAP Islamabad. Add Director DRAP Karachi or his nominee. 	<p>Approved the renewal of ELM.</p> <p>The board considered the inspection report of the panel comprising Mr. Wajahat Ali Member MDB and Mr. Shoaib Ahmad, Add Director DRAP Karachi. The board was apprised on inspection findings and Mr. Wajahat Ali Member MDB also briefed upon the improvements made by the firm.</p>
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			Keeping in view the inspection report and improvements made by the applicant the board decided to renew establishment license to import medical devices under Medical Devices Rules 2017
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Item No. I(E): ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES - INVALID

Following Establishment License for Import has become invalid for not submitting renewal applications, the relevant clause Rule 7(5) of Medical Devices Rules 2017 is reproduced as under:

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

S.NO.	Name of Firm	Renewal Due Date	Date of Renewal Application	Decision
1.	M/s Hospicare System, Office/Godown: Mezzanine Floor, Rabbiya garden, Plot No. 3, MCHS Society, Shaheed e Millat road, Karachi. ELI No. 00274	19-10-2023	Not submitted. In response to our letter Ref No. 2-1/2024-MD dated 22 nd December, 2025, the firm failed to provide any evidence of submission of application for Renewal of Establishment License to import Medical Devices.	The board observed that the firm has not applied for renewal of license even after expiry of one-year grace period given in the medical devices rules 2017 (Rule 7(5) of Medical Devices Rules 2017). Therefore, it was decided to declare the license invalid . Accordingly, all the enlistment / registrations granted to the firm have also become invalid and fresh applications need to be submitted for both the purposes. The firm shall be served with show cause notice for cancellation of license and registrations simultaneously.

PERSONAL HEARING CASES

Item No. I(F): RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Name of Panel Inspector (s)	Cold Chain (Yes/No)	Recommendations by the panel.
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1.	M/s N-Ovative Health Technologies (NHT) Pvt. Ltd., Adjacent to SMME Building National University of Science & Technology (NUST), Sector H-12 Campus Islamabad (ELM-0018)		Cardio	Muhammad Asad, Deputy Director QA<, DRAP Islamabad		Not Recommended
<p>Reply of the Firm: It is submitted that the NUST being the cradle of learning is fully committed to the quality of education being imparted at all of institutes/schools and elevation of its Regional and International standing. In this backdrop, NUST is re-aligning its business process to give full impetus to its core business; thus, attaining the international position of top ranking 100 universities at THED and QS rankings.</p> <p>In this backdrop, NUST management has decided that renewal of Drug Manufacturing License (Establishment License ELM_0018) in respect of N-Ovative Health Technologies (NHTPL) will not be pursued further, any correspondence in this regard through NUST may be considered held in abeyance. Submitted for information necessary action, please.</p> <p>Personal hearing notice has also been issued to the firm.</p>						
<p>Decision: The board considered the response received from Capt (PN) Shahid Akbar Satti on behalf of NUST Islamabad wherein it was mentioned that NUST management has decided that renewal of Manufacturing License (Establishment License ELM_0018) in respect of N-Ovative Health Technologies (NHTPL) will not be pursued further, any correspondence in this regard through NUST may be considered held in abeyance. Furthermore, in response to show cause notice and personal hearing notice no person appeared before the board to explain their position.</p> <p>Therefore board considered the aforementioned response/ letter received from NUST Isb and decided to cancel establishment license to manufacture medical devices issued to M/s N-Ovative Health Technologies (NHT) Pvt. Ltd., Adjacent to SMME Building National University of Science & Technology (NUST), Sector H-12 Campus Islamabad (ELM-0018). All the registrations/ enlistments issued to the firm also stands cancelled with immediate effect.</p>						

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

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Name of Panel Inspector (s)	Cold Chain (Yes/No)
1.	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	Shoaib Ahmed Additional Director (QMS) DRAP Karachi	No
Recommendations of Panel: Reference is made to DRAP Islamabad letter No. F.2-1/2022-MD dated 29					

	<p>August. 2025 and the directions of the Additional Director, DRAP, Karachi on the subject mentioned above. It is submitted that the undersigned contacted Mr. Muhammad Shariq. Director of Ms. Transheal Pharma (Pvt.) Limited, 301-A, Jofa Tower, Plot No. SB-23-24, Main University Road, Gulshan-e-Iqbal, Karachi, on his mobile number (0300-8217201) for conducting their ELI renewal inspection. Mr. Muhammad Shariq informed that the firm has halted its business operations from last two years; therefore, their ELI may be considered for cancellation.</p>				
	<p>Decision: The board noticed that the applicant has not submitted any response to the show cause notice and no person appeared before the board to explain their position. Moreover, Add Director DRAP Karachi reported that at the site of godown, there is a clinic now. Therefore, board considered the report of the inspector that the firm is no more interested and company is not existing at proposed location decided to cancel establishment license to import medical devices issued in favour of 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. Accordingly, all the enlistments/ registrations granted to the firm shall also stand cancelled with immediate effect.</p>				
2.	<p>M/s IRTEQA BIOTEK, Office/Godown: H 159, St 8 Chaklala Scheme 3 ELI-00218</p>	<p>Mahwish Dar M.Phil biochemistry</p>	<p>Muhammad Azam Saeed Dar CEO</p>	<p>Malik Muhammad Asad Deputy Director QA&LT</p>	<p>No</p>
<p>Recommendations of Panel: Not Recommended. Reference your office letter No. F. 2-1/2024 MD dated 19/11/2025 regarding inspection of the M/s Irteq Biotech. The undersigned on 27th November 2025 inspected the warehouse and office of the afore mentioned firm which was located in a house situated at 159, 8, CHAKLALA SCHEME 3. RAWALPINDI and at the time of inspection found their warehouse (comprising of 1 store room at ground floor) located at a house at un-satisfactory level of Good Storage Practices for medical devices:-</p> <ul style="list-style-type: none"> i. There was no environmental monitoring (temperature and humidity control). ii. QMS documentation, SOPs, JDs/appointment letters were not presented during the inspection. iii. The technical person was not present during inspection. iv. Rapid diagnostic test kits requiring storage conditions 2 to 8 degree centigrade were stored in a deep freezer without any temperature monitoring V. Warranty system and Post Marketing Surveillance was not established as per MDR, 2017. <p>Therefore, M/s IRTEQA BIOTECH (SMC) PVT. LTD is not recommended for the grant of Establishment License to import and store medical devices. Furthermore, the premises are located in a residential area.</p>					
<p>Decision: The board provided opportunity of personal hearing to the firm under medical devices rules 2017. CEO of the firm along with qualified person Dr. Mehwish Dar appeared before the board. They denied the inspection findings and report of inspector and stated that they are complying with all the conditions of medical devices rules 2017 and their facility could be inspected any time to verify the objections raised during initial renewal inspection and other conditions of license as defined under the rules. The board deliberated on the matter and decided to re-inspect the facility with following panel before a final decision is made.</p> <ol style="list-style-type: none"> 1. Dr. Aleem Awan, Member MDB. 2. Mr. Asif Jalil, Deputy Director DRAP, Islamabad. 					

Case No.03: APPLICATIONS FOR REGISTRATION/ENLISTMENT TO IMPORT MEDICAL DEVICES.

With reference to the subject noted above, it is to state M/s Moon Enterprises, 324-Rawaz Garden, Lahore has applied for grant of enlistments/registrations of medical devices which were considered by the Medical Device Board in its 102nd meeting held on 3rd October, 2025 and operative part of decision is reproduced below :-

“Rejected due to the reason that applicant has not submitted Free sale certificate from concerned regulatory Authority of China and instead submitted edited free sale certificate which is not genuine. The Board further decided to issue show cause notice to applicant as to why the ELI may not be cancelled due to submission of forged documents.”

2. In the light of the above decision of MDB, under sub-rule (1) of Rule 10 of Medical Devices Rules, 2017 Show Cause/Personal Hearing Notice under the said Rules, that why your Establishment License should not be cancelled on account of submission of forged/edited documents for enlistment/registration of medical devices has been issued to firm to appear before MDB in its 119th meeting to be held on 29th January, 2026 at 11.30.a.m. in Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister’s National Health Complex, Park Road, Islamabad alongwith reply of show cause notice.

Decision:

The board provided opportunity of personal hearing to the applicant under medical devices rules 2017. Mr. Mursaleen Proprietor of the firm and Mr. Yasir Siddique Manager of the firm appeared before the board. The accused informed the board that some confusion/ mistake occurred at the time of uploading legal documents on DRAP’s portal which was totally unintentional therefore this show cause notice be withdrawn and they apologized before the board.

The board took serious notice of such a non-serious and casual attitude of the applicant towards submitting legal documents. However, board observed that all such registration applications of the applicant where these documents were used have already been rejected. Therefore, board took a lenient view and decided to issue strict warning to the applicant for committing this act and in case similar action happens in future, establishment license issued to the firm including all registrations/ enlistments shall be cancelled after fulfilling all legal obligations.

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

Evaluator: Saadat Ali Khan (Deputy Director)

IMPORTED PRODUCT AGENDA:

Imported products Agenda

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 3860561849	Itena Clinical Central Parc,97 Allee de la Louve 93420 Villepin France. LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: Valid for four years FSC Type: Scan copy of non-notarized copy Issued By: CCI Paris Issuance Date: 11-07-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 08-08-2025	Total C-Ram Resin cement Applied as Family: Class-B Shelf life: 2 Years Codes/Model/Sizes TTCRAM-TR TTCRAM-OD TTCRAM-BLC ECHTCRAM ECHTCR-BLC	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form7A duly signed. 5. Stability Study data or evidence of shelf life. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
2.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/-	Itena Clinical Central Parc,97 Allee de la Louve 93420 Villepin France. LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: Valid for four years FSC Type: Scan copy of non-	Dentocore Composite Resin Applied as Family: Class-B Shelf life: 2 Years Codes/Model/Sizes DCSAKI DCB-50 DCA3-50	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form7A duly signed. 5. Stability Study data or evidence of shelf life.

	Challan No. 7216216591	<p>notarized copy Issued By: CCI Paris Issuance Date: 11-07-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 08-08-2025</p>		Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
3.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 06-03-2023</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 2295611330</p>	<p>Itena Clinical Central Parc,97 Allee de la Louve 93420 Villepin France.</p> <p>LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: Valid for four years</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: CCI Paris Issuance Date: 11-07-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 08-08-2025</p>	<p>Dentotemp Dental Cement</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 2 Years</p> <p>Codes/Model/Sizes DT-2.10 DTCA2-20 DTCA1-5 DTCA4-VP ECHDTP</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form7A duly signed. 5. Stability Study data or evidence of shelf life. <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
4.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 06-03-2023</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 63738211774</p>	<p>Itena Clinical Central Parc,97 Allee de la Louve 93420 Villepin France.</p> <p>LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: Valid for four years</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: CCI Paris Issuance Date: 11-07-</p>	<p>Prevent Seal Dental sealant</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 2 Years</p> <p>Codes/Model/Sizes PVSEAL-1.2 PVSEAL ECHPVSEAL</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form7A duly signed. 5. Stability Study data or evidence of shelf life. <p>Furthermore, the MDB decided the application shall be processed after decision on</p>

		2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 08-08-2025		the Renewal case.
5.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 96211975513	Itena Clinical Central Parc,97 Allee de la Louve 93420 Villepin France. LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: Valid for four years FSC Type: Scan copy of non-notarized copy Issued By: CCI Paris Issuance Date: 11-07-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 08-08-2025	Provitemp Dental cement Applied as Family: Class-B Shelf life: 2 Years Codes/Model/Sizes PTEMP-10 ECHPVTEMP PTEMP2-VP	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form7A duly signed. 5. Stability Study data or evidence of shelf life. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
6.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 388989076668	Itena Clinical Central Parc,97 Allee de la Louve 93420 Villepin France. LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: Valid for four years FSC Type: Scan copy of non-notarized copy Issued By: CCI Paris Issuance Date: 11-07-2022 Validity: Not mentioned	Dentocrown HD Composite Resin Applied as Family: Class-B Shelf life: 2 Years Codes/Model/Sizes DWNHD50-A1 DWNHD50-A2 DWNHD50-A3	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Revised Form7A duly signed. 4. Stability Study data or evidence of shelf life. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.

		<p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 08-08-2025</p>		
7.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 078522787</p>	<p>President Dental GMBH Kesselbodenstraße 5, 85391, Allershausen Germany</p> <p>LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issuance Date: 22-12-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-04-2024</p>	<p>Endoplus Rasin based root canal sealer</p> <p>Applied as Set: Class-B</p> <p>Shelf life: 3 Years</p> <p>Codes/Model/Sizes DE/CA61/1P35/11</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Revised Form7A duly signed. 4. Stability Study data or evidence of shelf life. <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
8.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 749383182109</p>	<p>President Dental GMBH Kesselbodenstraße 5, 85391, Allershausen Germany</p> <p>LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issuance Date: 22-12-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-04-2024</p>	<p>Extracem Glass Ionomerluting Cement</p> <p>Applied as Set: Class-B</p> <p>Shelf life: 4 Years</p> <p>Codes/Model/Sizes DE/CA61/1P35/43</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Revised Form7A duly signed. 4. Stability Study data or evidence of shelf life. <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>

9.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 06-03-2023 Fee Details: Paid Fee: 25,000/- Challan No. 6391169387	President Dental GMBH Kesselbodenstraße 5, 85391, Allershausen Germany LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: 31-12-2025 FSC Type: Scan copy of non-notarized copy Issued By: Germany Issuance Date: 22-12-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-04-2024	Prebonde SE Self-Etching Universal Bond 7th Generation (Dental Bonding Agent) Applied as Set: Class-B Shelf life: 3 Years Codes/Model/Sizes DE/CA61/1P35/7 (5mL)	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Revised Form7A duly signed. 4. Stability Study data or evidence of shelf life. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
10.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi ELI-00327 Date of R&I 06-03-2023 Fee Details: Paid Fee: 5,000/- Challan No. 73906190376	President Dental GMBH Kesselbodenstraße 5, 85391, Allershausen Germany LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: 31-12-2025 FSC Type: Scan copy of non-notarized copy Issued By: Germany Issuance Date: 22-12-2022 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-04-2024	Presigum Putty Impression Additional Silicone Applied as Single: Class-A Shelf life: 2 Years Codes/Model/Sizes DE/CA61/1P35/38	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Revised Form6A duly signed. 4. Stability Study data or evidence of shelf life. Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.
11.	M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari	President Dental GMBH Kesselbodenstraße 5, 85391, Allershausen Germany	Zenchroma Dental Filling Material Applied as Set: Class-B	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin.

	<p>Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 06-03-2023</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 48157197841</p>	<p>LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issuance Date: 22-12-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-04-2024</p>	<p>Shelf life: 7 Years Codes/Model/Sizes DE/CA61/00176984</p>	<p>2. Valid Notarized LOA & ISO 13485 3. Revised Form 7A duly signed. 4. Stability Study data or evidence of shelf life.</p> <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
12.	<p>M/s. Bilal Enterprises Office no 8, Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Rawalpindi</p> <p>ELI-00327</p> <p>Date of R&I 06-03-2023</p> <p>Fee Details: Paid Fee: 5,000/- Challan No. 747190428</p>	<p>President Dental GMBH Kesselbodenstraße 5, 85391, Allershausen Germany</p> <p>LOA Type: Scan copy of non-notarized copy. Date of signature: Not mentioned. Validity date: 31-12-2025</p> <p>FSC Type: Scan copy of non-notarized copy Issued By: Germany Issuance Date: 22-12-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 04-04-2024</p>	<p>Presigum Light Body Impression Additional Silicone</p> <p>Applied as Single: Class-A</p> <p>Shelf life: 2 Years Codes/Model/Sizes DE/CA61/1P35/39</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form 6A duly signed. 5. Stability Study data or evidence of shelf life. <p>Furthermore, the MDB decided the application shall be processed after decision on the Renewal case.</p>
13.	<p>J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan</p> <p>ELI-00246</p> <p>Date of R&I 07-05-2020</p>	<p>Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China.</p> <p>LOA</p>	<p>Xiehe Ambulane Stretcher</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A Codes/Model/Sizes</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form 6A duly signed.

	<p>Fee Details: Paid Fee: 5,000/- Challan No. 2006251</p>	<p>Type: Scan copy of notarized copy. Validity date: 29-06-2024 New LOA attached in CMS: valid upto 10-05-2029.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity:15-05-2021</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020</p>	<p>YXH-3A YXH-3B YXH-3A2 YXH-3A3 YXH-3A5 YXH-3B2 YXH-3C YXH-3D YXH-3D2 YXH-3E YXH-3F YXH-3G YXH-2A YXH-2B YXH-3E2 YXH-3K</p>	<p>signed. 5. Verifiable fee slip</p>
14.	<p>J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246</p> <p>Date of R&I 07-05-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006252</p>	<p>Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024. New LOA attached in CMS: valid upto 10-05-2029.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity:15-05-2021</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020</p>	<p>Xiehe Basket Stretcher</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A Codes/Model/Sizes YXH-6A YXH-6B YXH-6E</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip
15.	<p>J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan</p>	<p>Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600</p>	<p>Xiehe Folding Stretcher</p> <p>Applied as family: Class-A</p> <p>Shelf life:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping

	<p>ELI-00246</p> <p>Date of R&I 07-05-2020</p> <p>Fee Details: Paid Fee: 5,000/- Challan No. 2006253</p>	<p>China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024 New LOA attached in CMS: valid upto 10-05-2029.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity: 15-05-2021</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020</p>	<p>N/A</p> <p>Codes/Model/Sizes YXH-1A1 YXH-1A2 YXH-1A3 YXH-1A5 YXH-1A6 YXH-1B1 YXH-1B2 YXH-1B3 YXH-1C YXH-1D YXH-1DL YXH-1E YXH-1EF YXH-1EL YXH-1F1 YXH-1F1B YXH-1F2 YXH-1F3 YXH-1F4 YXH-1F4A YXH-1G YXH-1GL YXH-1H YXH-1L YXH-1M YXH-1N(A) YXH-1N(B) YXH-1N(C) YXH-1K</p>	<p>multiple codes as family with catalog & family fee.</p> <p>4. Revised Form6A duly signed.</p> <p>5. Verifiable fee slip</p>
16.	<p>J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246</p> <p>Date of R&I 07-05-2020</p> <p>Fee Details: Paid Fee: 5,000/- Challan No. 2006254</p>	<p>Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024 New LOA attached in CMS: valid upto 10-05-2029.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity: 15-05-2021</p>	<p>Xiehe Head Immobilizer Applied as family: Class-A</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes XH-16A XH-16B</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin.</p> <p>2. Valid Notarized ISO 13485</p> <p>3. Justification of grouping multiple codes as family with catalog & family fee.</p> <p>4. Revised Form6A duly signed.</p> <p>5. Verifiable fee slip</p>

		<p>• ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020</p>		
17.	<p>J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246</p> <p>Date of R&I 07-05-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006255</p>	<p>Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024 New LOA attached in CMS: valid upto 10-05- 2029.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity:15-05-2021</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020</p>	<p>Xiehe Neil—Robertson Stretcher</p> <p>Applied as Single: Class-A</p> <p>Shelf life: N/A Codes/Model/Sizes YXH-7N</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip
18.	<p>J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246</p> <p>Date of R&I 07-05-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006256</p>	<p>Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024. New LOA attached in CMS: valid upto 10-05- 2029.</p> <p>FSC Type: Scan copy of notarized copy</p>	<p>Xiehe Scoop Stretcher</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A Codes/Model/Sizes YXH-4A YXH-4B YXH-4C YXH-4D</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip

		Issued By: China Validity: 15-05-2021 • ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020		
19.	J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246 Date of R&I 07-05-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006257	Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China. LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024. New LOA attached in CMS: valid upto 10-05-2029. FSC Type: Scan copy of notarized copy Issued By: China Validity: 15-05-2021 • ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020	Xiehe Spine Board Applied as family: Class-A Shelf life: N/A Codes/Model/Sizes YXH-1A6B YXH-1A6C YXH-1A6D YXH-1A6E YXH-1A6F YXH-1A6G YXH-1A6K	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip
20.	J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246 Date of R&I 07-05-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006258	Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. Address: No.7th, Middle Xinzha Road, Zhashang Industrial Zone ,215600 China. LOA Type: Scan copy of notarized copy. Validity date: 29-06-2024. New LOA attached in CMS: valid upto 10-05-2029.	Xiehe Stair Stretcher Applied as family: Class-A Shelf life: N/A Codes/Model/Sizes YXH-5A YXH-5B YXH-5C YXH-5D YXH-5E YXH-5G YXH-5H YXH-5L	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip

		FSC Type: Scan copy of notarized copy Issued By: China Validity: 15-05-2021 • ISO 13485: Type: Scan copy of notarized copy Validity: 28-05-2020		
21.	J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246 Date of R&I 10-03-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2105311	Shenzhen Hawk medical instrument. Co.Ltd 5F building no 2 lijincheng industrial park east gongye road, longhoua district, Shenzhen china. LOA Type: Scan copy of notarized copy. Validity date: 20-09-2025. FSC Type: Scan copy of notarized copy Issued By: China Validity: 07-12-2020 • ISO 13485: Type: Scan copy of notarized copy Validity: 07-12-2022 • CE (FQA): Type: Scan copy of notarized copy Validity: 26-05-2024	Hawk Med Infusion pump Applied as Single: Class-B Shelf life: 5 Years Codes/Model/Sizes HK-100II	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Notarized LOA & ISO 13485 4. Revised Form7A duly signed. 5. Verifiable fee slip
22.	J.F International 4TH Floor, 10 C, 6TH Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, Pakistan ELI-00246 Date of R&I 10-03-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2105312	Shenzhen Hawk medical instrument. Co.Ltd 5F building no 2 lijincheng industrial park east gongye road, longhoua district, Shenzhen china. LOA Type: Scan copy of notarized copy. Validity date: 20-09-2025. FSC Type: Scan copy of	Hawk Med Syringe pump Applied as Single: Class-B Shelf life: 5 Years Codes/Model/Sizes HK-400III	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Notarized LOA & ISO 13485 4. Revised Form7A duly signed. 5. Verifiable fee slip

		<p>notarized copy Issued By: China Validity:07-12-2020</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 07-12-2022</p>		
23.	<p>Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247</p> <p>Date of R&I 03-11-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2047387</p>	<p>Hengshui Zhukang Medical Instrument CO.,LTD</p> <p>Weitun Village, Weitun Town, Binhu, New Area, Henghui.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 03-10-2024.</p> <p>FSC not attached.</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 02-03-2023</p>	<p>Kangrgharay Bed Side Cabinet</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes D17 D28</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip
24.	<p>Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247</p> <p>Date of R&I 03-11-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2047391</p>	<p>Hengshui Zhukang Medical Instrument CO.,LTD</p> <p>Weitun Village, Weitun Town, Binhu, New Area, Henghui.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 03-10-2024.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity:24-01-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 02-03-2023</p>	<p>Kangrgharay Electric Hospital Bed</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes C10-5 C1-06 C1-08</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Notarized LOA & ISO 13485 3. Justification of grouping multiple codes as family with catalog & family fee. 4. Revised Form6A duly signed. 5. Verifiable fee slip
25.	<p>Tritech International Tri-Tech International 10-C, 6th Sunset</p>	<p>Hengshui Zhukang Medical Instrument CO.,LTD</p>	<p>Kangrgharay IV Standing and Dining Table</p> <p>Applied as family:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of

	<p>Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247</p> <p>Date of R&I 03-11-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2047392</p>	<p>Weitun Village, Weitun Town, Binhu, New Area, Henghui.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 03-10-2024.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity: 24-01-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 02-03-2023</p>	<p>Class-A</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes P10 P10-1</p>	<p>origin.</p> <ol style="list-style-type: none"> Valid Notarized LOA & ISO 13485 Justification of grouping multiple codes as family with catalog & family fee. Revised Form6A duly signed. Verifiable fee slip
26.	<p>Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247</p> <p>Date of R&I 03-11-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2047386</p>	<p>Hengshui Zhukang Medical Instrument CO.,LTD</p> <p>Weitun Village, Weitun Town, Binhu, New Area, Henghui.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 03-10-2024.</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity: 24-01-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 02-03-2023</p>	<p>Kangrgharay Manual Hospital Bed</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes C02-5 C02-7 C02-11 C12-1 ZK10 ZK32</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> Valid Legalized Free Sale Certificate of country of origin. Valid Notarized LOA & ISO 13485 Justification of grouping multiple codes as family with catalog & family fee. Revised Form6A duly signed. Verifiable fee slip
27.	<p>Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247</p> <p>Date of R&I 03-11-2020 Fee Details: Paid Fee: 5,000/-</p>	<p>Hengshui Zhukang Medical Instrument CO.,LTD</p> <p>Weitun Village, Weitun Town, Binhu, New Area, Henghui.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 03-10-2024.</p> <p>FSC</p>	<p>Kangrgharay Medical Trolley</p> <p>Applied as family: Class-A</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes MT750 J103</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> Valid Legalized Free Sale Certificate of country of origin. Valid Notarized LOA & ISO 13485 Justification of grouping multiple codes as family with catalog & family fee. Revised Form6A duly signed. Verifiable fee slip

	Challan No. 2047388	Type: Scan copy of notarized copy Issued By: China Validity: 24-01-2024 • ISO 13485: Type: Scan copy of notarized copy Validity: 02-03-2023		
28.	Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247 Date of R&I 10-07-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006271	BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 6-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA LOA Type: Scan copy of notarized copy. Validity date: 30-06-2026. FSC Type: Scan copy of notarized copy Issued By: Korea Issuance Date: 21-01-2020 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 09-09-2027 • EC (FQA): Type: Scan copy of notarized copy Validity: 27-05-2024	Bistos Fetal Doppler System Applied as Single: Class-B Shelf life: One year Codes/Model/Sizes BT-200	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Revised Form7A duly signed. 4. Verifiable fee slip
29.	Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247 Date of R&I 10-07-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006281	BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 6-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA LOA Type: Scan copy of notarized copy. Validity date: 30-06-2026. FSC Type: Scan copy of notarized copy Issued By: Korea	Bistos Fetal Doppler System Applied as Single: Class-B Shelf life: 6 year Codes/Model/Sizes BT-350	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Revised Form7A duly signed. 4. Verifiable fee slip

		Issuance Date: 21-01-2020 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 09-09-2027 • EC (FQA): Type: Scan copy of notarized copy Validity: 27-05-2024		
30.	Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247 Date of R&I 10-07-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006276	BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 6-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA LOA Type: Scan copy of notarized copy. Validity date: 30-06-2026. FSC Type: Scan copy of notarized copy Issued By: Korea Issuance Date: 30-01-2020 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 09-09-2027 • EC (FQA): Type: Scan copy of notarized copy Validity: 27-05-2024	Bistos Breast Pump Electrically powered Applied as Single: Class-B Shelf life: One year Codes/Model/Sizes Hi Bebe plus BT-100	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Revised Form7A duly signed. 4. Verifiable fee slip
31.	Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247 Date of R&I 10-07-2020 Fee Details: Paid Fee: 25,000/-	BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 6-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA LOA Type: Scan copy of notarized copy. Validity date: 30-06-2026. FSC	Bistos Fetal Monitor Applied as Single: Class-B Shelf life: 2 year Codes/Model/Sizes BT-300	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Revised Form7A duly signed. 4. Verifiable fee slip

	Challan No. 2006275	Type: Scan copy of notarized copy Issued By: Korea Issuance Date: 21-01-2020 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 09-09-2027 • EC (FQA): Type: Scan copy of notarized copy Validity: 27-05-2024		
32.	Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247 Date of R&I 10-07-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2006274	BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 6-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA LOA Type: Scan copy of notarized copy. Validity date: 30-06-2026. FSC Type: Scan copy of notarized copy Issued By: Korea Issuance Date: 21-01-2020 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 09-09-2027 • EC (FQA): Type: Scan copy of notarized copy Validity: 27-05-2024	Bistos Neonatal Phototherapy Unit Applied as Single: Class-B Shelf life: 2 year Codes/Model/Sizes BT-400	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Revised Form7A duly signed. 4. Verifiable fee slip
33.	Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247	BISTOS CO., Ltd 7th Fl., A Bldg., Woolim Lions Valley 6-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-d0, KOREA LOA	Bistos Hear-Worn Light Applied as Single: Class-A Shelf life: 1 year	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin. 2. Revised Form6A duly signed. 3. Verifiable fee slip

	<p>Date of R&I 10-07-2020 Fee Details: Paid Fee: 5,000/- Challan No. 2006268</p>	<p>Type: Scan copy of notarized copy. Validity date: 30-06-2026.</p> <p>FSC Type: Scan copy of notarized copy Issued By: Korea Issuance Date: 21-01-2020 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 09-09-2027</p>	<p>Codes/Model/Sizes BT-410</p>	
34.	<p>Tritech International Tri-Tech International 10-C, 6th Sunset Commercial Lane, Phase 2 EXT, DHA, Karachi, ELI-00247</p> <p>Date of R&I 20-10-2024 Fee Details: Paid Fee: 31,000/- Challan No. 83510740941</p>	<p>Shenzhen Le Medical Technology CO.,LTD 5/F, Block A, Xinyongfeng Industrial Park, No2 Tianbao Road, Yinresnshi Community, Shiayan, Subdistrict Baoan Distyric Shenzhen Guanggong China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 13-09-2028.</p> <p>FSC not attached</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 17-02-2025</p> <p>• EC (FQA): Type: Scan copy of notarized copy Validity: 27-05-2024</p>	<p>LE MEDICAL Electro Cardio Graph Applied as Single: Class-B</p> <p>Shelf life: 2 year</p> <p>Codes/Model/Sizes ECG 301</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin. 2. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 3. Revised Form7A duly signed. 4. Verifiable fee slip 5. Valid notarized ISO 13485
35.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 28-04-2022</p>	<p>IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 D-63303 Dreieich, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Issuing date: 14-01-2019. Validity date: Not mentioned</p>	<p>Immucor NEO Iris Blood Bank Automation System with Accessories and its Reagents</p> <p>Applied as System: Class-B</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or Valid Legalized Free Sale Certificate of any RRA 2. Valid notarized LOA & ISO 13485 3. Revised Form7A duly signed with all the data & relevant annexures including

	<p>Fee Details: Paid Fee: 25,000/- Challan No. 92894846995</p>	<p>FSC (Multiple FSC provided) Type: Scan copy of notarized copy Issued By: Germany Issuance Date: 16-01-2018, 22-02-2019, 08-03-2019 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (5 ISO Certificates) 22-07-2021 22-07-2021 22-07-2021 28-02-2021 31-12-2020.</p>	<p>Shelf life:</p> <p>Codes/Model/Sizes</p>	<p>the applied codes, description & shelf life.</p> <p>4. Justification of grouping with catalog & system fee.</p> <p>5. Justification of class is required.</p> <p>The system will be considered in the current application while for the reagents the firm shall apply separately through online MDMC portal.</p>
36.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 27-04-2022</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 24166914</p>	<p>IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 D-63303 Dreieich, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Issuing date: 14-01-2019. Validity date: Not mentioned</p> <p>FSC (Multiple FSC provided) Type: Scan copy of notarized copy Issued by: Germany Issuance Date: 16-01-2018, 22-02-2019, 08-03-2019 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (5 ISO Certificates) 22-07-2021 22-07-2021 22-07-2021 28-02-2021</p>	<p>Immucor ECHO Blood Bank Automation System with Accessories and its Reagents.</p> <p>Applied as System: Class-B</p> <p>Shelf life:</p> <p>Codes/Model/Sizes</p>	<p>Deferred for submission of the followings”</p> <p>1. Valid Legalized Free Sale Certificate of country of origin or Valid Legalized Free Sale Certificate of any RRA</p> <p>2. Valid notarized LOA & ISO 13485</p> <p>3. Revised Form7A duly signed with all the data & relevant annexures including the applied codes, description & shelf life.</p> <p>4. Justification of grouping with catalog & system fee.</p> <p>5. Justification of class is required.</p> <p>The system will be considered in the current application while for the reagents the firm shall apply separately through online MDMC portal.</p>

		31-12-2020.		
37.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 27-04-2022 Fee Details: Paid Fee: 25,000/- Challan No. 47835500732</p>	<p>IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 D-63303 Dreieich, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Issuing date: 14-01-2019. Validity date: Not mentioned</p> <p>FSC (Multiple FSC provided) Type: Scan copy of notarized copy Issued by: Germany Issuance Date: 16-01-2018, 22-02-2019, 08-03-2019 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (5 ISO Certificates) 22-07-2021 22-07-2021 22-07-2021 28-02-2021 31-12-2020.</p>	<p>Immucor ECHO Lumena Blood Bank Automation System with Accessories and its Reagents.</p> <p>Applied as System: Class-B</p> <p>Shelf life:</p> <p>Codes/Model/Sizes</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or Valid Legalized Free Sale Certificate of any RRA 2. Valid notarized LOA & ISO 13485 3. Revised Form7A duly signed with all the data & relevant annexures including the applied codes, description & shelf life. 4. Justification of grouping with catalog & system fee. 5. Justification of class is required. <p>The system will be considered in the current application while for the reagents the firm shall apply separately through online MDMC portal.</p>
38.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 27-04-2022 Fee Details: Paid Fee: 25,000/- Challan No. 23413058722</p>	<p>IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 D-63303 Dreieich, Germany.</p> <p>LOA Type: Scan copy of notarized copy. Issuing date: 14-01-2019. Validity date: Not mentioned</p> <p>FSC (Multiple FSC provided) Type: Scan copy of notarized copy Issued by: Germany Issuance Date: 16-01-</p>	<p>Immucor Capture Workstation Blood Bank Manual System with Accessories and its Reagents.</p> <p>Applied as System: Class-B</p> <p>Shelf life:</p> <p>Codes/Model/Sizes</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin or Valid Legalized Free Sale Certificate of any RRA 2. Valid notarized LOA & ISO 13485 3. Revised Form7A duly signed with all the data & relevant annexures including the applied codes, description & shelf life. 4. Justification of grouping with catalog & system fee. 5. Justification of class is required.

		2018, 22-02-2019, 08-03-2019 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: (5 ISO Certificates) 22-07-2021 22-07-2021 22-07-2021 28-02-2021 31-12-2020.		The system will be considered in the current application while for the reagents the firm shall apply separately through online MDMC portal.
39.	M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005 Date of R&I 28-04-2022 Fee Details: Paid Fee: 25,000/- Challan No. 1780409960	IMMUCOR Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 D-63303 Dreieich, Germany. LOA Type: Scan copy of notarized copy. Issuing date: 14-01-2019. Validity date: Not mentioned FSC (Multiple FSC provided) Type: Scan copy of notarized copy Issued by: Germany Issuance Date: 16-01-2018, 22-02-2019, 08-03-2019 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: (5 ISO Certificates) 22-07-2021 22-07-2021 22-07-2021 28-02-2021 31-12-2020.	Immucor NEO Blood Bank Automation System with Accessories and its Reagents. Applied as System: Class-B Shelf life: Codes/Model/Sizes	Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of country of origin or Valid Legalized Free Sale Certificate of any RRA 2. Valid notarized LOA & ISO 13485 3. Revised Form7A duly signed with all the data & relevant annexures including the applied codes, description & shelf life. 4. Justification of grouping with catalog & system fee. 5. Justification of class is required. The system will be considered in the current application while for the reagents the firm shall apply separately through online MDMC portal.
40.	M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 &	Legal manufacturer Haemonetics Corporation: Address as per Form-7A: 400 Wood Road, Braintree, MA	Haemonetics Blood transfusion filter Applied as family: Class-B	Deferred for submission of the followings” 1. Valid notarized ISO 13485 2. Justification of grouping multiple codes applied with catalog & family fee.

	<p>8, Karachi. ELI-00005</p> <p>Date of R&I 07-04-2022</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 67310940874</p>	<p>02184, USA Address as per FSC: 125 Summer Street, 02110 Boston, MA, US.</p> <p>Manufacturing Site.</p> <p>Haemonetics Manufacturing Inc 1630 Industrial Park Street, Covina CA 91722, USA</p> <p>Haemonetics México Manufacturing S. de R.L. de C.V. Calle Colinas No. 11731 Secc. Colinas Parque Industrial el Florido Tijuana, B.C. México C.P. 22244.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028</p> <p>FSC Type: Scan copy of notarized copy Issued by: Swiss medic Validity:23-10-2026</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (2 ISO Certificates) 31-10-2020 28-03-2022</p>	<p>Shelf life: 5Yr</p> <p>Codes/Model/Sizes RC1VAE, RC2VAE</p>	<p>3. Clarification regarding the difference in the name of the applied product as mentioned Form-7A from LOA/FSC.</p>
41.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi.</p>	<p>Legal manufacturer Haemonetics Corporation: Address as per Form-7A: 400 Wood Road, Braintree, MA 02184, USA</p>	<p>Haemonetics Platelet transfusion filter</p> <p>Applied as family: Class-B</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid notarized ISO 13485 2. Justification of grouping multiple codes applied with catalog & family fee. 3. Clarification regarding the

	<p>ELI-00005</p> <p>Date of R&I 07-04-2022 Fee Details: Paid Fee: 25,000/- Challan No. 0423556206</p>	<p>Manufacturing Site.</p> <p>Haemonetics Manufacturing Inc 1630 Industrial Park Street, Covina CA 91722, USA</p> <p>Haemonetics México Manufacturing S. de R.L. de C.V. Calle Colinas No. 11731 Secc. Colinas Parque Industrial el Florida Tijuana, B.C. México C.P. 22244.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028</p> <p>FSC Type: Scan copy of notarized copy Issued by: USFDA Validity:23-07-2021</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (2 ISO Certificates) 31-10-2020 28-03-2022</p>	<p>Shelf life: 5Yr</p> <p>Codes/Model/Sizes PL2VAE, PL3VAE</p>	<p>difference in the name of the applied product as mentioned Form-7A from LOA/FSC.</p>
42.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 07-04-2022 Fee Details: Paid Fee: 25,000/- Challan No.</p>	<p>Legal manufacturer Haemonetics Corporation: Address as per Form-7A: 400 Wood Road, Braintree, MA 02184, USA</p> <p>Manufacturing Site.</p> <p>Haemonetics Manufacturing Inc 1630 Industrial Park Street, Covina CA 91722, USA</p>	<p>Haemonetics Blood transfusion filter</p> <p>Applied as Single:</p> <p>Class-B</p> <p>Shelf life: 3-Yr</p> <p>Codes/Model/Sizes BPFAPLUS</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid notarized ISO 13485 2. Justification of grouping multiple codes applied with catalog & family fee. 3. Clarification regarding the difference in the name of the applied product as mentioned Form-7A from LOA/FSC.

	829220388	<p>Haemonetics México Manufacturing S. de R.L. de C.V. Calle Colinas No. 11731 Secc. Colinas Parque Industrial el Florido Tijuana, B.C. México C.P. 22244.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028</p> <p>FSC Type: Scan copy of notarized copy Issued by: USFDA Validity: 25-07-2021</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (2 ISO Certificates) 31-10-2020 28-03-2022</p>		
43.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 07-04-2022 Fee Details: Paid Fee: 25,000/- Challan No. 094301357 for registration of ACP215 Automated Cell processor with Accessories and its Disposables.</p>	<p>Legal manufacturer Haemonetics Corporation: 400 Wood Road, Braintree, MA 02184, USA</p> <p>Manufacturing Site. Haemonetics México Manufacturing S. de R.L. de C.V. Calle Colinas No. 11731 Secc. Colinas Parque Industrial el Florido Tijuana, B.C. México C.P. 22244. Sanmina-SCI Systems (Malaysia) Sdn. Bhd 202 Lorong Perusahaan</p>	<p>Haemonetics Blood cell freeze /thaw system Applied as System: Class: 02215-220-E (Class. B) 00225-00 (Class.B) 00235-00 (Class.C) 00236-00 (Class.C)</p> <p>Shelf life: 02215-220-E (Shelf Life: N/A) 00225-00 (Shelf Life: 5 Yr) 00235-00 (Shelf Life: N/A) 00236-00 (Shelf Life: N/A) Codes/Model/Sizes ACP 215: 02215-220-E,</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of country of origin (USFDA) 2. Valid notarized ISO 13485 3. Justification of grouping multiple codes applied with catalog & system fee. Also justify class of the product. 4. Clarification regarding the difference in the name of the applied product as mentioned Form-7A from LOA/FSC. 5.

		<p>Maju 9, Bukit Tengah Industrial Park, 13600 Perai Penang, Malaysia.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-02-2028</p> <p>FSC Type: Scan copy of notarized copy Issued by: USFDA Validity:25-07-2021</p> <p>FSC Type: Scan copy of notarized copy Issued by: Malaysia Validity:03-07-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: (2 ISO Certificates) 27-08-2020 28-03-2022</p>	<p>RBC Glycerolization Set: 00225-00, RBC De-Glycerol Cell Wash Set: 00235-00 RBC De-Glycerol Set 325mL BMB: 00236-00</p>	
44.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 14-05-2022 Fee Details: Paid Fee: 5,000/- Challan No. 7478584897</p>	<p>Legal manufacturer Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy.</p> <p>Manufacturing Site. Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy.</p> <p>Haemotronic S.p.a Via Ugo Roncada, 83/E, Localita Carbonara di Po, 46021 Borgocarbonara (MN), ITALY.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: Dec.,2026</p>	<p>Haemotronic H3051(3-Way Manifold/Adapter) Applied as Single; Class: A Shelf life: N/A Codes/Model/Sizes H3051</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of country of origin (Italy) 2. Valid notarized ISO 13485 3. Justification of class of the product.

		FSC Type: Scan copy of notarized copy Issued by: Italy Issuance date: 16-09-2019 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 15-12-2024		
45.	M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005 Date of R&I 14-05-2022 Fee Details: Paid Fee: 5,000/- Challan No. 3131348659	Legal manufacturer Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy. Manufacturing Site. Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy. Haemotronic S.p.a Via Ugo Roncada, 83/E, Localita Carbonara di Po, 46021 Borgocarbonara (MN), ITALY. LOA Type: Scan copy of notarized copy. Validity date: Dec.,2026 FSC Type: Scan copy of notarized copy Issued by: Italy Issuance date: 16-09-2019 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 15-12-2024	Haemotronic Waste Bag Applied as Single: Class: A Shelf life: N/A Codes/Model/Sizes B3052	Deferred for submission of the followings” 1. Valid legalized FSC of country of origin (Italy) 2. Valid notarized ISO 13485 3. Justification of class of the product.
46.	M/S Hospital Supply Corporation Address: 42 Darul Aman Housing	Legal manufacturer Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy.	Haemotronic Aquaset Applied as family:	Deferred for submission of the followings” 1. Valid legalized FSC of country of origin (Italy) 2. Valid notarized ISO 13485

	<p>Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 11-05-2022</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 091069907130</p>	<p>Legal manufacturer of the filters: Nikkiso Belgium bv Industriepark 6, 3300 Tienen Belgium</p> <p>Manufacturing Site. Manufacturer Responsible for the assembly of the set: Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy.</p> <p>Physical Manufacturer of the lines: Haemotronic S.p.a Via carreri 16 41037 Mirandola (Mo) Italy.</p> <p>Haemotronic S.p.a Via Ugo Roncada, 83/E, Localita Carbonara di Po, 46021 Borgocarbonara (MN), ITALY.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: Dec.,2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: Italy Issuance date: 16-09-2019 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 15-12-2024</p>	<p>Class: B</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes 03LV, 12, 19</p>	<p>3. Justification of grouping with catalog & family fee.</p>
47.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing</p>	<p>Dornier MedTech GmbH Argelsrieder Feld 7, 82234 Wessling Germany.</p>	<p>Dornier Thulio (Holmium Laser)</p> <p>Applied as System:</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid notarized LOA 2. Valid notarized ISO 13485 3. Justification of grouping

	<p>Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 02-09-2022 Fee Details: Paid Fee: 50,000/- Challan No. 4456322586</p>	<p>LOA Type: Scan copy of notarized copy. Validity: 31-03-2025.</p> <p>FSC for Thulio (Holmium Laser) Type: Scan copy of notarized copy Issued by: Germany Issuance Date: 24-06-2024 Validity: Not mentioned</p> <p>FSC for other product. Type: Scan copy of notarized copy Issued by: USFDA Validity: 06-04-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 27-02-2024</p>	<p>Class-C</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes Product: K2016000</p> <p>Other products /accessories: Dornier SmartFlex Reusable Laser Fibers 270 micron Reusable Laser Fiber K2013151 400 micron Reusable Laser Fiber K2013152 600 micron Reusable Laser Fiber K2013153 1000 micron Reusable Laser Fiber K2013154 270 micron Reusable Laser Fiber Slim K2013162 Dornier SingleFlex Single Use Laser Fibers 270 micron Single Use Laser Fiber K2013062 400 micron Single Use Laser Fiber K2013063 600 micron Single Use Laser Fiber K2013064 1000 micron Single Use Laser Fiber K2013065 270 micron Single Use Laser Fiber Slim K2013161 400 micron Single Use Laser Fiber 4.5 meter K2013156 Dornier GentleFlex Single Use Ball Tip Laser Fibers 270 micron Single Use Ball Tip Laser Fiber K2014290</p>	<p>with submission of catalog & system fee.</p> <p>One system along with required accessories (after justification & availability in the FSC) shall be considered in the current application, while the other systems & optional accessories shall be applied separately through online MDMC portal.</p>
48.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 &</p>	<p>Meditop Co., Ltd. 334 Soi Lat Phrao 71 (Sangkomsongkrawnu 1), Lat Phrao Road Khlong Chaokhun Sing, Wang Thonglang, Bangkok</p>	<p>KIDNY KLEEN Dialyzer Reprocessor Model Compact Single Chamber Applied as Single:</p>	<p>Deferred for submission of the followings” 1. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate</p>

	<p>8, Karachi. ELI-00005</p> <p>Date of R&I 11-05-2022</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 92449085 for product KIDNEY KLEEN Dialyzer Reprocessor Model Compact with Accessories.</p>	<p>10310, Thailand.</p> <p>LOA Type: Scan copy of notarized copy. Validity: Dec. 2025.</p> <p>FSC Type: Scan copy of notarized copy Issued by: Thailand Validity: 06-01-2027</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 01-01-2028</p> <p>CE (FQA). Not attached.</p>	<p>Class-B</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes Model Compact-Single Chamber</p>	<p>2. Notarized LOA 3. Justification of Class & revised fee if in higher class.</p>
49.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 11-05-2022</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 036203717265 for product KIDNEY KLEEN Dialyzer Reprocessor Model Compact with Accessories.</p>	<p>Meditop Co., Ltd. 334 Soi Lat Phrao 71(Sangkomsongkrawnu 1), Lat Phrao Road Khlong Chaokhun Sing, Wang Thonglang, Bangkok 10310, Thailand.</p> <p>LOA Type: Scan copy of notarized copy. Validity: Dec. 2025.</p> <p>FSC Type: Scan copy of notarized copy Issued by: Thailand Validity: 06-01-2027</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 01-01-2028</p> <p>CE (FQA). Not attached.</p>	<p>KIDNEY KLEEN Dialyzer Reprocessor Model Compact-II Single Chamber</p> <p>Applied as Single:</p> <p>Class-B</p> <p>Shelf life: N/A</p> <p>Codes/Model/Sizes Model Compact-II Single Chamber</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 2. Notarized LOA 3. Justification of Class & revised fee if in higher class.
50.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi.</p>	<p>Legal manufacturer as per Form-7A: Meditop Co., Ltd. 334 Soi Lat Phrao 71(Sangkomsongkrawnu 1), Lat Phrao Road Khlong Chaokhun Sing, Wang</p>	<p>MDT Plus 4 Cold Sterilant</p> <p>Applied as Single:</p> <p>Class-A</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 2. Notarized LOA

	<p>ELI-00005</p> <p>Date of R&I 14-05-2022</p> <p>Fee Details: Paid Fee: 5,000/- Challan No. 06621365775for product MDT Plus 4 Cold Sterilant.</p>	<p>Thonglang, Bangkok 10310, Thailand.</p> <p>Contract Manufacturer: Thai Peroxide Company Limited 70 Moo 4, Sudbantad Road, Tambol Tandiew, Amphur Kaengkhoi, Saraburi 18110 Thailand.</p> <p>LOA Type: Scan copy of notarized copy. Validity: Dec. 2025.</p> <p>FSC Type: Scan copy of notarized copy Issued by: Thailand Validity:08-12-2022</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 01-01-2028</p> <p>CE (FQA). Not attached.</p>	<p>Shelf life: 18 months</p> <p>Codes/Model/Sizes</p>	<p>3. Justification of Class & revised fee & form-7A if in higher class.</p> <p>4. Revised FSC of country of origin wherein the legal manufacturer & manufacturing site shall be mentioned.</p>
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51.	<p>M/S Hospital Supply Corporation Address: 42 Darul Aman Housing Society, Block 7 & 8, Karachi. ELI-00005</p> <p>Date of R&I 14-05-2022 Fee Details: Paid Fee: 5,000/- Challan No. 0415690767 for TOPPURE Portable Reverse Osmosis System, Model SMART 60 AC with spare parts and Accessories.</p>	<p>Legal manufacturer as per Form-7A: Meditop Co., Ltd. 334 Soi Lat Phrao 71(Sangkomsongkrawnua 1), Lat Phrao Road Khlong Chaokhun Sing, Wang Thonglang, Bangkok 10310, Thailand.</p> <p>Contract Manufacturer: Thai Peroxide Company Limited 70 Moo 4, Sudbantad Road, Tambol Tandiew, Amphur Kaengkhoi, Saraburi 18110 Thailand.</p> <p>LOA Type: Scan copy of notarized copy. Validity: Dec. 2025.</p> <p>FSC Type: Scan copy of notarized copy Issued by: Thailand Validity:06-10-2022</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 01-01-2028</p> <p>CE (FQA). Not attached.</p>	<p>TOPPURE Portable Reverse Osmosis System, Model SMART 60 AC with spare parts and Accessories</p> <p>Applied as Single: Class-A</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes Model SMART 60</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of any RRA or valid notarized CE Certificate 2. Notarized LOA 3. Justification of Class & revised fee & form-7A if in higher class. 4. Revised FSC of country of origin wherein the legal manufacturer & manufacturing site shall be mentioned.
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52.	<p>Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi.</p> <p>ELI -00020</p> <p>Date of R&I 05-05-2023 Fee Details: Paid Fee: 25,000/- Challan No. 3632867705</p>	<p>M/s. Intersurgical Limited. Address: , Crane House ,Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>LOA Type: Scan copy of notarized copy. Validity: 01-03-2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: MHRA UK Validity:30-06-2029</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 26-11-2026</p> <p>• EC: Type: Scan copy of notarized copy Validity: 26-11-2023</p>	<p>Pediatric bagging system with 0.5L closed tail bag , 1.8m Anesthetic breathing system</p> <p>Applied as Set:</p> <p>Class: B</p> <p>Shelf life: 5 Yrs</p> <p>Codes/Model/Sizes 2124000</p>	Approved
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53.	<p>Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi.</p> <p>ELI -00020</p> <p>Date of R&I 15-08-2022</p> <p>Fee Details: Paid Fee: 25,000/- Challan No. 006076498</p>	<p>Legal Manufacturer & manufacturer (as per FSC UK): M/s. Intersurgical Limited. Crane House , Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>Manufacturing Site (as per Form-7A while legal as previous): No.1011 Liaohe Road ,Xinbei District, Changzhou, Jiangsu, China</p> <p>LOA Type: Scan copy of notarized copy. Validity: 01-03-2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: MHRA UK Validity:30-06-2029</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 26-11-2026</p> <p>• EC: Type: Scan copy of notarized copy Validity: 26-11-2023</p>	<p>Oxygen tube ,1.8m Oxygen Administration Tubing Applied as Single:</p> <p>Class: B</p> <p>Shelf life: 5 Yrs</p> <p>Codes/Model/Sizes 1174000</p>	<p>Approved with the following manufacturing site as per FSC: M/s. Intersurgical Limited. Crane House , Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p>
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54.	<p>Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi.</p> <p>ELI -00020</p> <p>Date of R&I 14-06-2024 Fee Details: Paid Fee: 25,000/- Challan No. 1053055052</p>	<p>M/s. Intersurgical Limited. Address: , Crane House ,Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>LOA Type: Scan copy of notarized copy. Validity: 01-03-2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: MHRA UK Validity:30-06-2029</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 26-11-2026</p> <p>• EC: Type: Scan copy of notarized copy Validity: 26-11-2023</p>	<p>i-view video laryngoscope Generic name Video laryngoscope</p> <p>Applied as Single:</p> <p>Class: B</p> <p>Shelf life: 5 Yrs</p> <p>Codes/Model/Sizes 8008000</p>	Approved
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55.	<p>Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi.</p> <p>ELI -00020</p> <p>Date of R&I 10-10-2023 Fee Details: Paid Fee: 25,000/- Challan No. 122253488896</p>	<p>Legal Manufacturer & manufacturer (as per FSC UK): M/s. Intersurgical Limited. Crane House , Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>Manufacturing Site (as per Form-7A while legal as previous): M/s. UAB Intersurgical Arnioniu 60, Pabrade, Lithuania, LT-18170.</p> <p>LOA Type: Scan copy of notarized copy. Validity: 01-03-2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: MHRA UK Validity:23-10-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 26-11-2026</p> <p>• EC: Type: Scan copy of notarized copy Validity: 26-11-2023</p>	<p>USB Universal Stylet Bougie 15FR OD 5.0mm Universal Stylet Bougie</p> <p>Applied as Single:</p> <p>Class: B</p> <p>Shelf life: 3 Yrs</p> <p>Codes/Model/Sizes 8090015</p>	<p>Approved with the following manufacturing site as per FSC: M/s. Intersurgical Limited. Crane House, Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>The firm shall submit valid FSC (UK).</p>
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56.	<p>Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi.</p> <p>ELI -00020</p> <p>Date of R&I 25-10-2023 Fee Details: Paid Fee: 25,000/- Challan No. 430124015973</p>	<p>Legal Manufacturer & manufacturer (as per FSC UK): M/s. Intersurgical Limited. Crane House , Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>Manufacturing Site (as per Form-7A while legal as previous): M/s. UAB Intersurgical Arnioniu 60, Pabrade, Lithuania, LT-18170.</p> <p>LOA Type: Scan copy of notarized copy. Validity: 01-03-2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: MHRA UK Validity:23-10-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 26-11-2026</p> <p>• EC: Type: Scan copy of notarized copy Validity: 26-11-2023</p>	<p>LiteScope Laryngoscope One-piece single use laryngoscope</p> <p>Applied as Single:</p> <p>Class: B</p> <p>Shelf life: 3 Yrs</p> <p>Codes/Model/Sizes 7124000</p>	<p>Approved with the following manufacturing site as per FSC: M/s. Intersurgical Limited. Crane House, Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>The firm shall submit valid FSC (UK).</p>
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57.	<p>Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town, Phase 7, Rawalpindi.</p> <p>ELI -00020</p> <p>Date of R&I 10-10-2023 Fee Details: Paid Fee: 25,000/- Challan No. 1150097465 for nFlow infant nasal CPAP breathing system with its accessories</p>	<p>Legal Manufacturer & manufacturer (as per FSC UK): M/s. Intersurgical Limited. Crane House, Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>Manufacturing Site (as per Form-7A while legal as previous): M/s. UAB Intersurgical Arnioniu 60, Pabrade, Lithuania, LT-18170.</p> <p>LOA Type: Scan copy of notarized copy. Validity: 01-03-2026</p> <p>FSC Type: Scan copy of notarized copy Issued by: MHRA UK Validity: 23-10-2024</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 26-11-2026</p> <p>• EC: Type: Scan copy of notarized copy Validity: 26-11-2023</p>	<p>nFlow infant nasal CPAP breathing system</p> <p>Specified names for accessories</p> <p>nFlow silencer kit with Clear-Guard midi nFlow infant bonnets nFlow nasal prongs nFlow nasal masks</p> <p>Applied as Family: Class: B</p> <p>Shelf life: nFlow infant nasal CPAP breathing system : 3Yrs</p> <p>Specified names for accessories</p> <p>nFlow silencer kit with Clear-Guard midi: 5 Yrs nFlow infant bonnets: 5 yrs nFlow nasal prongs nFlow nasal masks: 5 Yrs</p> <p>Codes/Model/Sizes Product code: 4700000 nFlow infant nasal CPAP heated wire breathing system 1.6m 4700001 nFlow infant nasal CPAP heated wire breathing system. ≥ 1.8m 4760000 nFlow infant nasal CPAP adaptor kit with detachable monitoring line for Fabian ventilators. ≥ 1.6m 4761000 nFlow infant nasal CPAP</p>	<p>Approved nFlow infant nasal CPAP breathing system only</p> <p>with the following manufacturing site as per FSC: M/s. Intersurgical Limited. Crane House, Molly Millars Lane, Wokingha, Berkshire, United Kingdom.</p> <p>The firm shall submit valid FSC (UK).</p> <p>The firm shall apply separately through online MDMC portal for the rest of the products.</p>
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			<p>heated wire breathing system with detachable monitoring line. $\geq 1.8\text{m}$</p> <p>4800000 nFlow CosyFit infant CPAP</p> <p>heated wire breathing system. $\geq 1.6\text{m}$</p> <p>4800001 nFlow CosyFit infant CPAP</p> <p>heated wire breathing system. $\geq 1.8\text{m}$</p> <p>4800016 nFlow CosyFit infant CPAP</p> <p>heated wire breathing system with detachable monitoring line. $\geq 1.8\text{m}$</p> <p>4861000 nFlow CosyFit infant CPAP</p> <p>heated wire breathing system for Fabian ventilators with detachable monitoring line.</p> <p>$\geq 1.8\text{m}$</p> <p>4700011 nFlow replacement straps</p> <p>4708000 Clear-Guard™ Midi breathing filter with luer port and nFlow silencer kit</p> <p>With Accessories</p> <p>nFlow nasal prongs</p> <p>4703000 nFlow nasal prong large</p> <p>4702000 nFlow nasal prong medium</p> <p>4701000 nFlow nasal prong small</p> <p>4711000 nFlow nasal prong extra small</p> <p>nFlow nasal Masks</p> <p>4716000 nFlow nasal mask</p> <p>4706000 nFlow nasal mask</p> <p>4705000 nFlow nasal mask</p> <p>4704000 nFlow nasal mask</p> <p>nFlow Bonnets</p> <p>4907009 nFlow</p>	
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			<p>CosyFit, infant bonnet, navy, size 9 (40 - 42 cm) 4907008 nFlow</p> <p>CosyFit, infant bonnet, turquoise, size 8 (38 - 40 cm) 4907007 nFlow</p> <p>CosyFit, infant bonnet, orange size 7 (36 - 38 cm) 4907006 nFlow</p> <p>CosyFit, infant bonnet, red, size 6 (34 - 36 cm) 4907005 nFlow</p> <p>CosyFit, infant bonnet, green, size 5 (32 - 34 cm) 4907004 nFlow</p> <p>CosyFit, infant bonnet, light orange, size 4 (30 - 32 cm) 4907003 nFlow</p> <p>CosyFit, infant bonnet, blue, size 3 (28 - 30 cm)</p>	
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58.	<p>M/s Medtex Address: 2/236A Ground Floor, P.E.C.H.S., Main Shahrah-e- Quaideen Karachi - 75400, Pakistan. ELI-00892</p> <p>Date of R&I 13-06-2024 Fee Details: Paid Fee: 25,000/- Challan No. 9986915784</p>	<p>Tianchang City Anrui Medical Equipments Co., Ltd Renhe Industiral District, Tianchang City, Anhui Province, China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 05-12-2028</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity: 15-01-2026</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 19-07-2024</p> <p>• CE (Production QA): Type: Scan copy of notarized copy Validity: 26-05-2024</p>	<p>Puffin Sterile Latex Surgical gloves</p> <p>Applied as family: Class-B</p> <p>Shelf life: 3 Yrs Codes/Model/Sizes 6, 6.5, 7, 7.5, 8, 8.5 and 9</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of RRA or valid notarized CE Certificate. 2. Family fee along with verifiable fee slip.
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59.	<p>M/s Medtex Address: 2/236A Ground Floor, P.E.C.H.S., Main Shahrah-e- Quaideen Karachi - 75400, Pakistan. ELI-00892</p> <p>Date of R&I 17-05-2024 Fee Details: Paid Fee: 25,000/- Challan No. 6792340632</p>	<p>Legal Manufacturer) as per Form-7A): Shanghai Kinmed Import & Export Co. Ltd., Suit L, 12th Floor, No. 588, Yingkou Road, Shanghai, china.</p> <p>Manufacturing Site: Shandong Wuzhou Medical Equipment Co., Ltd., Dingtoa County (Yantai) Industrial Zone, Heze City, 274100, Shandong, china.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 19-07-2028</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity: 07-01-2026</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 04-09-2025</p> <p>• CE (Production QA): Type: Scan copy of notarized copy Validity: 26-05-2024</p>	<p>Puffin Disposable sterile Blood Transfusion Set</p> <p>Applied as family: Class-B</p> <p>Shelf life: 5 Yrs Codes/Model/Sizes With needle, without needle</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin, avlid ISO 13485 wherein the legal manufacturer & manufacturing site shall be mentioned. 2. Valid Legalized Free Sale Certificate of RRA or valid notarized CE Certificate wherein the legal manufacturer & manufacturing site shall be mentioned. 3. Family fee along with verifiable fee slip.
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60.	<p>M/s Medtex Address: 2/236A Ground Floor, P.E.C.H.S., Main Shahrah-e- Quaideen Karachi - 75400, Pakistan. ELI-00892</p> <p>Date of R&I 28-06-2024 Fee Details: Paid Fee: 25,000/- Challan No. 01419195</p>	<p>Legal Manufacturer) as per Form-7A): Shanghai Kinmed Import & Export Co. Ltd., Suit L, 12th Floor, No. 588, Yingkou Road, Shanghai, china. Manufacturing Site: Bonree Medical Co., Ltd. 1st Floor of Building No.2, Building No.4, Longzhu Village Economic Estate , Longzhu Avenue, Nanlang, 528451, Zhongshan, Ghangdong, China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 19-07-2028</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity:24-10-2025</p> <p>• ISO 13485: Not provided</p> <p>• CE (Production QA): Type: Scan copy of notarized copy Validity: 26-05-2024</p>	<p>Puffin Tracheostomy Tube</p> <p>Applied as family: Class-B</p> <p>Shelf life: 5 Yrs Codes/Model/Sizes 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10mm</p>	<p>Deferred for submission of the followings”</p> <ol style="list-style-type: none"> 1. Valid Legalized Free Sale Certificate of country of origin, avlid ISO 13485 wherein the legal manufacturer & manufacturing site shall be mentioned. 2. Valid Legalized Free Sale Certificate of RRA or valid notarized CE Certificate wherein the legal manufacturer & manufacturing site shall be mentioned. 3. Family fee along with verifiable fee slip. 4. Shelf life evidence or study
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61.	<p>M/s Medtex Address: 2/236A Ground Floor, P.E.C.H.S., Main Shahrah-e- Quaideen Karachi - 75400, Pakistan. ELI-00892</p> <p>Date of R&I 08-11-2023 Fee Details: Paid Fee: 25,000/- Challan No. 423032860</p>	<p>Guangzhou AXD Electronic Co., Ltd. Address: Factory 3, No.9 Changxin Road, Changshapu, Zhongluotan Town, 510550, Baiyun District, Guangzhou City, Guangdong Province, P.R. China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 11-03-2028</p> <p>FSC Type: Scan copy of notarized copy Issued By: China Validity:04-01-2025</p> <p>FSC Type: Scan copy of notarized copy Issued By: Germany Issuance date: 21-09-2022 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 25-03-2025</p>	<p>Puffin Medical Compressor Nebulizer</p> <p>Applied as Set: Class-B</p> <p>Shelf life: 5 Yrs Codes/Model/Sizes AXD-301</p>	Approved.
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