

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

DECISIONS OF 126th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 1st APRIL 2026 (MANUAL APPLICATIONS PART-II)

126th 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 1st April 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S#	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	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.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
6.	Abdul Aleem Awan, Asstt. Prof. Pharmacy Department, Abbottabad University of Science & Technology Havelian.	Member
7.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
8.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
10.	Mr. 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 of MDB
1	M/s Qadrimedtex, Office/godown: 69D, Abu-Bakar Saddique Industrial Estate, Band road Lahore.	Raja Muhammad Sajid Bsc Biomedical Engineer 10 Years experience	Muhammad Imran Munir Experience: ½ years	The board considered inspection findings in detail and observed that apparently the facility is in an industrial zone as per details provided by inspection team. Although the area has now turned into residential however the company intends to come under ambit of DRAP Act 2012 and rules framed thereunder. The board therefore decided to provide opportunity of personal hearing to the applicant to confirm status of the area as industrial with valid proof of allotment letter issued by a govt department or relevant authority and deliberate further on GMP status of the company. Nonetheless the board desired that such companies must shift premises to a suitable area preferably an industrial zone as per decision of Authority. The board after going through all details shall make a final decision on application.

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	Name of Panel Inspector (s)	Cold Chain (Yes/No)	Decision
1.	M/s MHS Enterprises, Office/godown: B-Block, Suite 54, Street No. 4, Eden Value homes Multan road, Lahore.	Shahid Waris B-Pharmacy	Shoaib Ahmed Additional Director (QMS) DRAP Karachi	No	Approved. The firm shall submit an undertaking that the facility shall not be used for residential purposes and could be inspected anytime without hindrance.
2.	M/s IIR CHEMSOL INTERNATIONAL (PRIVATE) LIMITED, Office/godown: 18,19,20,21- G, Mamoon Centre, Mediline Market Syed Mouj Darya Road, Lahore, Data Gunj Bukhsh Town, Pakistan Lahore	Nabeela Jabeen Pharm D	Shoaib Ahmed Additional Director (QMS) DRAP Karachi	No	Approved

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	Cold Chain (Yes/No)	Decision
1.	M/s Arham Enterprises, Office / godown: Flat No. 2 , Second floor, Khyber plaza, Fazal-ul- Haq road, Blue area, Islamabad. ELI-00509	Usman Ashfaq Mughal Pharm D	Ahsan Zafar Bakhtawari CEO	No	Approved

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.	M/s Biocare Enterprises, Office/godown: 64/2, st/2, St, FESCH NPF, 0-9 PWD road, Islamabad. ELI-00220	Noor Qadir Pharm D	Muhammad Asif CEO	Decision Approved
2.	M/s Care and cure international, Office/Godown: Toyota royal motors opposite road , 1-KM same Nala, Rahim yar khan ELI-00192	Arbab ali shah Pharm D	Raja abdal ur Rahman Rameesha Anwar Absam Ur rehman Saira Anwar	Approved
3.	M/s Yousaf & Co., Office / godown: 79-M, Gulberg- III, Lahore. ELI-00302	Wajiha Ghalib Pharm D	Mohammad Yousaf CEO	Approved

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	Remarks
1.	M/s Sultan Health Care, Office/Godown: Saadat Plaza, Mian Shahpur road, Adyala road, Rawalpindi ELI No. 00489	03-02-2025	Fresh application submitted on New portal vide application No. MDMC-20260324-30223 dated 24-03-2026	Fresh application submitted on new portal vide application No. MDMC-20260324-30223. Inspection for grant of license has also been conducted and included in portal agenda.
2.	M/s Uniferoz (Pvt) Limited: Office/godown: 32/8 & 33/2, Sector-15, Korangi Industrial Area, Karachi. ELM No. 00284	22-06-2023	04-11-2024	The firm has submitted differential fee for grant of license in the light of opinion of Legal affair division and Medical Devices Rules 2017. Furthermore, inspection of the firm has already been conducted, and renewal was recommended by the panel for the following sections. 1. First Aid Adhesive Bandages (Class-A) 2. Wound Dressing adhesive (sterile) (Class-B) 3. Surgical Tapes (Class-A) 4. Saniswab Alcohol Pad IPA 70% (Class-A)
3.	M/s Hafiz Pharma Office/godown: 44-KM (Ghaniya) Kamoke, District Gujranwala. ELM No. 0012	07-07-2021	31-10-2024	Differential fee for grant of license has not been received.

Opinion of legal affair Division was also obtained in the case of M/s Uniferoz Karachi and M/s Hafiz Pghma Gujranwala as per below details. Opinion of Legal Affair division and case history is also below.

- M/s Hafiz Pharma Kamoke was issued renewal of ELM on 02-12-2019 with renewal date of 08-07-2016. The firm applied for next renewal on 31-10-2024 in line with the issuance date of 02-12-2019. However, record since issuance of initial license shows that the renewal period was from 08-07-2016 to 07-07-2021.
- M/s Uniferoz Karachi was issued renewal license on 28-11-2019 with renewal date of 23-06-2018. The firm applied for next renewal on 04-11-2024 in line with the issuance date of 28-11-2019. However as per record and renewal date the renewal application should have been made before 23-06-2023.

Both of the firms are of the opinion that they have applied for next renewal keeping in view the issuance date and the same has been written on Form 3.

In view of above opinion of Legal Affairs Division was obtained on validity of license of both the firms in the light of MDR 2017 in general and wording of Form 3 in particular.

Legal Opinion

a. The licenses of both firms have lapsed and are not valid today. They expired on the dates implied by the “Renewal Date” field printed on Form-3 (i.e., 07-07-2021 for M/s Hafiz Pharma and 22-06-2023 for M/s Uniferoz). The applications submitted in October/December 2024 cannot revive them automatically; they must be treated as fresh applications under Rule 7(5) of the Medical Devices Rules, 2017. This opinion is based on the following facts stated below:

Form-3, which is prescribed under Rule 5(2) and used for both grant and renewal per Rule 7(9), contains two distinct fields:

“Date of issue” (header): This is the date the physical licence document is signed/issued by the MDB (02-12-2019 for M/s Hafiz; 28-11-2019 for M/s Uniferoz).

“Renewal Date” (footer): This is the commencement date of the 5-year validity period for the licence being issued/renewed.

b. Moreover, the standard condition (a) in Form-3 states: “The licence shall be in force for a period of five years from the date of issue...”. This wording is generic and appears in the template for initial grants under Rule 5. It does not override the specific statutory provision for renewals under Rule 7.

c. The “Renewal Date” field is deliberately inserted in the approved Form-3 template (and referenced in application forms as “Last renewal date and its validity”). It reflects the MDB’s internal record of when the 5-year cycle actually began. In these cases:

d. M/s Hafiz Pharma renewal date is 08-07-2016, therefore, validity ran from 08-07-2016 to 07-07-2021.

M/s Uniferoz renewal date is 23-06-2018, therefore, validity ran from 23-06-2018 to 22-06-2023.

The 2019 documents were renewal licenses issued during the running term of the previous cycle. The “Date of issue” (2019) is merely administrative; the legal validity period is anchored to the “Renewal Date”.

e. The relevant provisions of Medical Devices Rules, 2017 (especially Rule 5 and licence validity provisions) to this particular case of Hafiz Pharma and Uniferoz s given here below:

Rule 5(3) (Grant of licence): “A licence issued under these rules shall ... be valid for a period of five years from the date of its issuance.” This applies to initial licences.

Rule 7(4) prescribed renewal, the governing provision here: “If satisfied ... the MDB may approve renewal of establishment licence for a period of five years from the date of expiry of previous licence ...” (Emphasis added). The renewal is not measured from the new “Date of issue” on the document.

Rule 7(9) confirms that renewal is granted on the same Form-3, but the validity period is explicitly reset from the previous expiry date (not from the 2019 issuance date).

Furthermore, under Rule 7(6) a Licence continues only if renewal application is filed before expiry or within one year with additional fee. Rule 7(5) prescribed that after one year from expiry, the licence “shall cease to exist” and application is treated as fresh. No renewal application was filed before 07-07-2021

by M/s Hafiz Pharma or 22-06-2023 by M/s Uniferoz. The 2024 applications are therefore fresh applications, not renewals. The licences lapsed more than one year ago.

f. Now, whether the firms’ reliance on the issuance date (as written on Form-3) protects the validity? The answer is No. The firms’ argument and reliance on “Date of issue” + Form-3 condition (a) is understandable but legally incorrect on the following grounds:

Statutory rules i.e Rule 7(4) prevail over any wording in the prescribed form. The form is only the vehicle; the Rules define the legal effect. The MDB’s internal record (and the “Renewal Date” field) consistently shows the true validity cycle. Firms cannot claim protection by misreading a standard clause that applies primarily to initial grants. Good faith reliance does not extend the statutory validity period or prevent lapse under Rule 7(5).

g. Therefore, it is opined that the file may be processed as fresh applications for grant of new Establishment Licences under Rule 5. The firms should be informed in writing that their previous licences lapsed on the dates tied to the “Renewal Date” field and that no automatic renewal is possible. Any operations carried out after 07-07-2021 by M/s Hafiz and 22-06-2023 by Uniferoz are at their risk. Moreover, for the associated enlisted or registered products, the invalidation flows automatically from the license’s cessation pursuant to Rule 10(6), which provides that where an establishment license is cancelled, suspended, or (by extension) ceases to exist, the registrations or enlistments granted to that establishment shall automatically cease or remain suspended. No separate show-cause is mandated for this automatic effect, as it is consequential and linked to the license’s status under Rule 14(1), which requires a valid license for maintaining any product enlistment or registration. This opinion is based strictly on the provisions of the Medical Devices Rules, 2017.

h. Recommendation:

In order to prevent recurrence of such ambiguities in future renewal cases arising from the generic wording of condition (a) in Form-3, it is recommended that the Medical Device Board (MDB), in exercise of its powers under Rule 63(3) of the Medical Devices Rules, 2017, **may recommend the Authority** to amend Form-3 by substituting condition (a) as under:

“(a) The licence shall be in force for a period of five years from the date of issue in case of grant of a new licence. In case of renewal of an existing licence, the licence shall be in force for a period of five years from the date of expiry of the previous licence unless earlier suspended or cancelled.”

Additionally, Form-3 may be revised to clearly label the fields as “Date of Issue (Administrative)” and “Validity Commencement Date / Renewal Date” with an explicit note that the validity period for renewals is determined from the previous expiry date as per Rule 7(4). This amendment will ensure complete harmony between the prescribed Form and the statutory provisions of Rules 5 and 7, thereby eliminating any scope for misinterpretation by licence holders in future.

DECISION:

The board deliberated on the matter in detail and took following decision as per legal opinion provided by Legal Affairs Division.

- a. **M/s Sultan Health Care Rawalpindi (ELI No. 00489):** Establishment License to Import Medical Devices issued to the firm dated 04-02-2020 was declared invalid in the light of Rule 7(5) of Medical Devices Rules 2017 as the applicant failed to submit renewal application before expiry or within one year of expiry of license with late fee. However, the firm has made a new application with fee on Mar 24, 2026 using online portal therefore after fulfilment of all codal formalities/legal requirements a fresh license shall be issued with same license number. Similar procedure shall be adopted for registration/ enlistment of products if already granted to the applicant.
- b. **M/s Uniferoz (Pvt) Limited, Karachi (ELM No. 00284):** The board observed that the renewal of establishment license to manufacture medical devices issued to the firm was due on 22-06-2023 however the firm failed to apply for renewal in time in the light of Rule 7(5) of Medical Devices Rules 2017. Rather the firm applied for renewal on 04-11-2024 i.e more than one year after expiry of license. Therefore, in the light of opinion of legal affairs division the earlier license and registration/ enlistments issued to the firm had become invalid and any operations carried out after 22-06-2023 by M/s Uniferoz Karachi are at their risk. The board therefore considered the renewal application submitted by the firm on 04-11-2024 and differential fee submitted on 30-03-2026 and processed the application as fresh applications for grant of new Establishment License under Rule 7(5) of MDR 2017. The board also considered the inspection conducted for renewal of license and endorsed the recommendations and approved following sections for grant of establishment license to manufacture medical devices. The board also recommended that the same license number shall be issued to the firm and registrations/ enlistment of products which have also become invalid shall also be treated on similar grounds. Details of sections are as below:
 - First Aid Adhesive Bandages (Class-A)
 - Wound Dressing adhesive (sterile) (Class-B)
 - Surgical Tapes (Class-A)
 - Saniswab Alcohol Pad IPA 70% (Class-A)
- c. **M/s Hafiz Pharm, Gujranwala (ELM No. 0012):** The board observed that the renewal of establishment license to manufacture medical devices issued to the firm was due on 07-07-2021, however the firm failed to apply for renewal in time in the light of Rule 7(5) of Medical Devices Rules 2017. Rather the firm applied for renewal on 31-10-2024 i.e more than one year after expiry of license. Therefore, in the light of opinion of legal affairs division the earlier license and registration/ enlistments issued to the firm had become invalid and any operations carried out after 07-07-2021 by M/s Hafiz Pharm, Gujranwala are at their risk. To further process the application the firm needs to submit differential fee for grant of license in the light of opinion of legal affairs division and registration/ enlistment applications of the firm shall also be treated on same analogy.
- d. Additionally, the board also endorsed recommendations made by legal affairs division that in order to prevent recurrence of such ambiguities in future renewal cases arising from the generic wording of condition (a) in Form-3, it is recommended that the Medical Device Board (MDB), in exercise of its powers under **Rule 63(3)** of the Medical

Devices Rules, 2017, recommends the Authority to amend Form-3 by substituting condition (a) as under:

- **“(i) The licence shall be in force for a period of five years from the date of issue in case of grant of a new licence. In case of renewal of an existing licence, the licence shall be in force for a period of five years from the date of expiry of the previous licence unless earlier suspended or cancelled.”**
 - **(ii) Additionally, Form-3 may be revised to clearly label the fields as “Date of Issue (Administrative)” and “Validity Commencement Date / Renewal Date” with an explicit note that the validity period for renewals is determined from the previous expiry date as per Rule 7(4). This amendment will ensure complete harmony between the prescribed Form and the statutory provisions of Rules 5 and 7, thereby eliminating any scope for misinterpretation by license holders in future.**
- e. The board advised the division to take further steps and forward the case to authority in the light of above recommendations/ decision of the board.**



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

Evaluator: Saadat Ali Khan (Deputy Director)

Imported products Agenda.

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: Y6W-2Z1-U1A6	Legal Manufacturer & Site (as per Form-7A): M/s. Hollister ULC Foxford Road. Rehins, Ballina. Co. Mayo, Ireland. Legal Manufacturer (as per FSC-HPRA): Hollister Incorporated, 2000 Hollister Drive, Libertyville II, 60048, USA. Manufacturing Site (as per FSC-HPRA): Blomed Laboratories, LLC 8181 Eastpoint Drive, Suite 500 Dallas, TX 75227, USA. 0 LOA: Type: Scan copy of notarized copy. Date of issuance: 16-06-2020 Validity: 31-12-2021 FSC Type: Scan copy of notarized copy Issued By: HPRA, Ireland Issuance Date: 14-05-2019 Validity: 14-05-2024 ISO 13485: Type: Scan copy of non-notarized copy Validity: 09-09-2021	Inview Sheath Male External Sheath Class A Applied as Family. Shelf life: 5 years Code/Model/Size: 25mm, 29mm, 32mm, 36mm	Deferred for submission of the following: - Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. - Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. - R&I DRAP receiving & verifiable copy of fee slip for the applied product. - Properly filled Form-6A along all the required annexures duly signed by the authorized person. - Justification of the Class of the Product. - Justification of the grouping along with catalog & family fee. - Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
2.	Iqbal Enterprise, Karachi. ELI-00638	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou	Seton Collafoam Cervical Collar Class A	Deferred for submission of the following: Valid notarized Letter of Authorization (LOA) issued by

	R&I Details Not attached. Fee evidence not attached. Tracking ID: 1SW-X88-AEQ8	District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Applied as Single. Shelf life: 5 years Code/Model/Size: S, M, L	the legal manufacturer of the applied product. - Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. - R&I DRAP receiving & verifiable copy of fee slip for the applied product. - Properly filled Form-6A along all the required annexures duly signed by the authorized person. - Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
3.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: X8Z-NAX-SZE7	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Seton Polysling Polysling Class A Applied as Single. Shelf life: 5 years Code/Model/Size: Seton21015	Deferred for submission of the following: - Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. - Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. - R&I DRAP receiving & verifiable copy of fee slip for the applied product. - Properly filled Form-6A along all the required annexures duly signed by the authorized person. - Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
4.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached.	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China.	Seton Skin Traction Kit Skin Traction Kit (Adhesive) Class A Applied as Single.	Deferred for submission of the following: - Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. - Valid Legalized Free Certificate

	Fee evidence not attached. Tracking ID: X8Z-NAX-SZE7	China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Shelf life: 5 years Code/Model/Size: Child, Adult	issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
5.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: HE9-D9Q-LRWH	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Seton Stockinette Tubular Bandage Stockinette Tubular Bandage Class A Applied as Single. Shelf life: 5 years Code/Model/Size: (cmxm) 5x20, 7.5x20, 10x20	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
6.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China.	Seton Tubigrip Tubular Support Bandage Tubular Bandage Class A Applied as Single.	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the

	attached. Tracking ID: HE9-D9Q-LRWH	LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Shelf life: 5 years Code/Model/Size:	all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded Sizes as per FSC. It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
7.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: ZAT-H86-3U9N	Legal Manufacturer & Site (as per Form-6A): M/s. Hollister ULC Foxford Road. Rehins, Ballina. Co. Mayo, Ireland. Legal Manufacturer & Manufacturing Site (as per FSC): Blomed Laboratories, LLC 8181 Eastpoint Drive, Suite 500 Dallas, TX 75227, USA. Manufacturer. LOA: Type: Scan copy of notarized copy. Date of issuance: 16-06-2020 Validity: 31-12-2021 FSC Type: Scan copy of notarized copy Issued By: HPRA, Ireland Validity: 10-10-2024 ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026	Adapt Ostomy Belt Ostomy Belt Class A Applied as Single. Shelf life: 5 years Code/Model/Size: 7300	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
8.	Iqbal Enterprise, Karachi. ELI-00638	M/s. Hollister ULC Foxford Road. Rehins, Ballina. Co. Mayo, Ireland.	Pouch Clamp Pouch Clamp Class A	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the

	R&I Details Not attached. Fee evidence not attached. Tracking ID: V9U-XPG-L4G5	LOA: Type: Scan copy of notarized copy. Date of issuance: 16-06-2020 Validity: 31-12-2021 FSC Type: Scan copy of notarized copy Issued By: Zhejiang Medical Product Administration, China Validity: 24-11-2026 FSC Type: Scan copy of notarized copy Issued By: HPRA, Ireland Validity: 14-05-2024 ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026	Applied as Single. Shelf life: 5 years Code/Model/Size:	applied product. - Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. - R&I DRAP receiving & verifiable copy of fee slip for the applied product. - Properly filled Form-6A along all the required annexures duly signed by the authorized person. - Valid notarized ISO 13485 - Demanded Sizes/codes as per FSC It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
9.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: ZGM-XNH-DEE3	Tomato M&C Co. Ltd., 15-11, Suworam-gil. Seotan-myeon. Pyeongtaek-si, Gyeonggi-do, Republic of Korea. LOA: Type: Scan copy of notarized copy. Date of issuance: 01-11-2020 Validity: 01-11-2025. FSC Type: Scan copy of notarized copy Issued By: Mo FDS Korea Issuance Date: 22-02-2021 Validity: Not mentioned. ISO 13485: Not readable.	Tomato Super Cast Orthopedic Bandage Class A Applied as Single. Shelf life: 5 years Code/Model/Size: 2" x 4 Yards 3" x 4 Yards 4" x 4 Yards 5" x 4 Yards 6" x 4 Yards	Deferred for submission of the following: - Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. - Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. - R&I DRAP receiving & verifiable copy of fee slip for the applied product. - Properly filled Form-6A along all the required annexures duly signed by the authorized person. - Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
10.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China.	Seton Tubigrip Tubular Support Bandage Tubular Bandage Class A Applied as Single.	Deferred for submission of the following: - Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. - Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the

	attached. Tracking ID: A23-6BX-2JYH	LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Shelf life: 5 years Code/Model/Size:	all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded codes/sizes It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
11.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: HE9-D9Q-LRWH	M/s. Leonhard Lang Gmbh Archenweg 56 AT-6020 Innsbruck, Austria. LOA: Type: Scan copy of notarized copy. Date of issuance: 18-11-2020 Validity: Not mentioned FSC Type: Scan copy of notarized copy Issued by: Austria. Issuance Date: 02-06-2020 Validity: 28-05-2022 ISO 13485: Type: Scan copy of notarized copy Validity: 04-05-2021 EC (FQA) Certificate Type: Scan copy of notarized copy Validity: 15-06-2021	Skintect Neutral Electrodes Class B Applied as Family. Shelf life: 5 years Code/Model/Size: Skintact Neutral pre-connected RS23A30 RS26A30 RS27 A30	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Justification of the Class of the Product. 6. Justification of the grouping along with catalog & family fee. 7. Valid notarized ISO 13485 It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
12.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not	M/s. Tomato M&C Co. Ltd 15-11, Suworam-gil, Seotan-myeon, Pyeongtaek-si, Gyeonggi-do, Republic of Korea 17704 LOA:	Tomato Super Pad Orthopedic Bandage Class A Applied as Family. Shelf life:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the

	attached. Tracking ID: 7RA-2SN-N9MA	Type: Scan copy of notarized copy. Date of issuance: 01-11-2020 Validity: 01-11-2025 FSC Type: Scan copy of notarized copy Issued by: Mo FDS Korea Issuance Date: 22-02-2021 Validity: not mentioned ISO 13485: Valid upto 16-05-2022	Code/Model/Size: 5cm x 2.7mtr-2 Inch 7.5cm x 2.7mtr- 3Inch 10cm x 2.7mtr -4 Inch	all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded codes/sizes It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
13.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: LAP-1ZW-NJ78	M/s. Tomato M&C Co. Ltd 15-11, Suworam-gil, Seotan-myeon, Pyeongtaek-si, Gyeonggi-do, Republic of Korea 17704 LOA: Type: Scan copy of notarized copy. Date of issuance: 01-11-2020 Validity: 01-11-2025 FSC Type: Scan copy of notarized copy Issued by: Mo FDS Korea Issuance Date: 22-02-2021 Validity: not mentioned ISO 13485: Valid upto 16-05-2022	Tomato Super Splint Orthopedic Bandage Class A Applied as Family. Shelf life: Code/Model/Size: 3" x 12n 3" x 35" 4" x 15" 4" x 30"	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded codes/sizes It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
14.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID:	M/s. Turkuaz Saghk Hizmetleri San. ve Tic. Ltd. Sti. Beysan Sanayi Sitesi. Birlik caddesi. No:34 Beylikdüzü / Istanbul Turkey. LOA: FSC ISO 13485:	Skintact Ultrasonic Gel Ultrasonic Gel Class A Applied as Family. Shelf life: 5 years Code/Model/Size: Gel - 250ml Bottle Gel – 5 ltr. Can	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all

	JTE-SZT-QYZE			the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded codes/sizes It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
15.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: THA-GJL-E84B	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 02-08-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.	Seton Wrist Brace Right & Left Wrist Orthosis Class A Applied as Single. Shelf life: 5 years Code/Model/Size:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded codes/sizes It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
16.	Iqbal Enterprise, Karachi. ELI-00638 R&I Details Not attached. Fee evidence not attached. Tracking ID: QGD-Z7S-QJHZ.	Jiangxi Handasen Industry Co., Ltd Shaxi Avenue, Zhennan New District, Shaxi Town, Xinzhou District, Shangrao City, Jiangxi, China. LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 01-09-2027 FSC Type: Scan copy of notarized copy Issued by: Shangrao Food	Philadelphia Original Cervical Collar Class A Applied as Single. Shelf life: 5 years Code/Model/Size: S,M,L	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-6A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 It is further advised that same product

		and Drug Administration, China. Issuance Date: 13-08-2022 Validity: 12-08-2024 ISO 13485: Not attached.		shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.
17.	M/s Three Stars Medical Supplies, Lahore. (ELI-00353) Date of R&I 12-08-2021 Fee Details: Paid Fee: 25,000/- Challan No. 775660166246 dated 06-09-2021 Tracking 6XQ-V56-MV55	M/s DFI Co., Ltd. 388-255 Gomo-ro, Jillymyeon, Gimhae-si, Gyoengsangnam-do, 50875 Republic of Korea. Authorization Letter for Distribution: Type: Scan copy of non-notarized copy. Date of Issuance: 12-06-2021 Validity: Not mentioned FSC Korea Type: Scan copy of non-notarized copy Date of Issue: 15-02-2021 Validity: Not mentioned FSC Germany Type: Scan copy of non-notarized copy Date of Issue: 27-05-2021 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 05-11-2022	DFI ComboStik 3, DFI Combostik 4SG, DFI Combostik 10, DFI Combostik 10M Urine Reagent Strips Applied as Cluster. Class-B Model/Codes/Size: Shelf Life: 2 Years	Deferred for submission of the following: 1. Justification of the grouping along with catalog & fee. 2. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 3. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 4. Properly filled Form-7A along all the required annexures duly signed by the authorized person. 5. Valid notarized ISO 13485 6. Demanded codes/sizes

18.	M/s. Sind Medical Stores, Karachi. Lic. No.: ELI-00010 DRAP (R&I) Dated: 24-05-2024 Fee Challan No.: 553744454035 PKR: 50,000/- Dated: 22-05-2024 BGE-MRH-AUGH	M/s. Medtrade Products Ltd Electra House, Crewe Business Park, Crewe, Cheshire, CW1 6GL, England, UK LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 26-06-2029 Termination letter of previous Importer (M/s Healthline Pharmaceutical Corporation): Type: Scan copy of non-notarized copy. Date of issuance: 20-05-2024 FSC Type: Scan copy of notarized copy Issued by: MHRA, UK Issuance Date: 18-05-2024 Validity: 15-03-2028 ISO 13485 Certificate: Type: Scan copy of non-notarized copy. Validity: 26-04-2027 EU Technical Documentation Assessment Certificate: Type: Scan copy of notarized copy. Validity: 15-03-2027	Celox RAPID Gauze Hemostatic Gauze Class: D [Size & Codes] FG08839021 MDIR-0000307 Applied as : Single Shelf life: 5 Years	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 2. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 3. Clarification of the difference in the name of the Registration holder (Previous) in the termination letter. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Healthline Pharmaceuticals Pvt. Limited, Lahore, to M/s Sind Medical Stores, Karachi.
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19.	M/s. Sind Medical Stores, Karachi. Lic. No.: ELI-00010 DRAP (R&I) Dated: 24-05-2024 Fee Challan No.: 553744454035 PKR: 50,000/- Dated: 22-05-2024 BGE-MRH-AUGH	M/s. Medtrade Products Ltd Electra House, Crewe Business Park, Crewe, Cheshire, CW1 6GL, England, UK LOA: Type: Scan copy of notarized copy. Date of issuance: 03-08-2023 Validity: 26-06-2029 Termination letter of previous Importer (M/s Healthline Pharmaceutical Corporation): Type: Scan copy of non-notarized copy. Date of issuance: 20-05-2024 FSC Type: Scan copy of notarized copy Issued by: MHRA, UK Issuance Date: 18-05-2024 Validity: 15-03-2028 ISO 13485 Certificate: Type: Scan copy of non-notarized copy. Validity: 26-04-2027 EU Technical Documentation Assessment Certificate: Type: Scan copy of notarized copy. Validity: 15-03-2027	Celox Granules 15g Hemostatic Granules Class: D MD group: Single Shelf life: 5 Years [Size & Codes] FG08830181 MDIR-0000308	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder (M/s Healthline Pharmaceutical Corporation). 2. Evidence of submission of renewal Application by the Registration Holder (M/s Healthline Pharmaceutical Corporation). 3. Clarification of the difference in the name of the Registration holder (Previous) in the termination letter. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Healthline Pharmaceuticals Pvt. Limited, Lahore, to M/s Sind Medical Stores, Karachi.
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20.	Hospital Services & Sales 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 5,000/- Challan No.: 825361398	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Three-way Stopcocks for single use (with or without extension tube) (MDIE-0000246) MD group: Single Class: A Shelf life: 5 Years [Size & Codes] (with or without extension tube)	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder). 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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21.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 705185019	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Blood Transfusion Set for single use (With filter, with or without needle) (MDIR-0002349) MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (With filter, with or without needle)	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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22.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 6529966520	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Sterile Disposable Infusion Set for single use MDIR-0002350 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] Model No. (YW-1, YW-2, YW-3, YW-4, YW- 5, YW-6, YW-7, YW-8), Needle Gauge: 0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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23.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Challan No.: 32939800653	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Sterile Insulin Syringe for single use (0.5ml, 1ml) MDIR-0002351 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 0.5ml, 1ml	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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24.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 476679555849	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Syringe for single use (1ml, 10ml, 20ml) MDIR-0002352 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 1ml, 10ml, 20ml	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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25.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 5152544986	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Infusion Enteral Giving Sets for single use MDIR-0002353 MD group: Single Class: B Shelf life: 5 Years [Size & Codes]	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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26.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 7822539123	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Hypodermic Needles for single use MDIR-0002354 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (All Gauge) – (16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G)	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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27.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN. Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 556971023733	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Intravenous Needle for single use MDIR-0002355 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (with wings) – (0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm)	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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28.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 8534910348	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Connecting Extension Tubes for single use MDIR-0002356 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 50cm, 100cm, 150cm, 200cm	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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29.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 4698764238	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Infusion set with Burette Chamber for single use MDIR-0002357 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 80ml, 100ml, or 150ml	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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30.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 8389179456	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Scalp Vein Set for single use MDIR-0002358 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 14g, 15g, 16g, 18g, 19g, 20g, 21g, 22g, 23g, 24g, 25g, 26g, 27g, 28g, 29g, 30g.	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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31.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 713015758	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Syringe for single use MDIR-0002359 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 30ml, 50ml, 60ml, 100ml	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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32.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 271268731329	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Irrigating and Feeding Syringes for single use MDIR-0002360 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] 5ml, 10ml, 20ml, 50ml, 60ml, 100ml, 150ml, 200ml, 250ml, 300ml, 350ml, 500ml	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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33.	HOSPITAL SERVICES & SALES 13-C Annexe, Block 6, PECHS, Karachi – 75400, PAKISTAN Lic. No.ELI-00081 Date of R&I: 30-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No.: 351979891	Anhui Easyway Medical Supplies CO., LTD., Address: No.737, East Jianshe Road, Tianchang City, Anhui Province, P. R. CHINA. LOA Type: Scan copy of notarized copy. Validity: 22-01-2029 Termination letter of previous Importer (M/s Mars Enterprises, Karachi): Type: Scan copy of notarized copy. Date of issuance: 22-01- 2024. Copy of NOC for transfer of Registration of the products by M/s Mars Enterprises, Karachi on its letter head dated 15-08-2023. FSC Type: Scan copy of notarized copy. Issued by: NMPA - China Validity: 19-06-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 06-07-2026 EC PQA Certificate: Type: Scan copy of notarized copy. Validity: 26-05-2024	I Care Disposable Sterile Blood Transfusion Set for single use MDIR-0002824 MD group: Single Class: B Shelf life: 5 Years [Size & Codes] (with Filter) TS- 01, TS-02, TS-03, TS-04, TS-05, TS- 06	Deferred for submission of the following: 1. Valid notarized NOC from the Registration holder. 2. Evidence of submission of renewal Application by the Registration Holder. 3. Properly filled Form-7A along all the required annexures duly signed by the authorized person. Furthermore, both parties shall be called upon for a personal hearing in the matter, to determine whether they agree to the transfer of registration of the applied products from M/s Mars Enterprises, Karachi to Hospital Services & Sales, Karachi
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34.	M/s Battla Brothers Karachi (ELI- 00441) R& I Date: (01/01/2025) Fee details: Amount paid: PKR 31000/- Paid Slip / Challan No.: 0358485258 Dated: (23/12/2024)	M/s Super Health Medical(Qingdao) Co.,Ltd Address:No.236,Heyuan Road,High-Tech Zone,Qingdao, People's Republic of China. LOA Validity: (30-11-2029) FSC Country of Origin: CHINA Validity: (27-04-2025) FSC Reference Country: MHRA, UK Validity:31-12-2029 EC certificate & Notified Body Confirmation Letter Validity: ISO 13485 validity: (29-03-2026)	OEM Healcare I .V Catheters Type IB, (16G, 18G, 20G, 22G, 24G) Applied as system/single Class-B Shelf life: 3 years Models / Sizes: I.V Catheters Type IB,(16G, 18G, 20G, 22G, 24G)	Approved the I.V Catheter Type IB,(16G, 18G, 20G, 22G, 24G) (Regular/Straight Type)
35.	M/s Battla Brothers Karachi (ELI- 00441) R& I Date: (15/07/2025) Fee details: Amount paid: PKR 31000/- Paid Slip / Challan No.: 7187917230	M/s Super Health Medical(Qingdao) Co.,Ltd Address:No.236,Heyuan Road,High-Tech Zone,Qingdao, People's Republic of China. LOA Validity: (30-11-2029) FSC Country of Origin: CHINA Validity: (27-04-2025) FSC Reference Country: MHRA, UK Validity:31-12-2029 EC certificate & Notified Body Confirmation Letter Validity: ISO 13485 validity: (29-03-2026)	OEM Healcare I .V Catheters Type IC, (16G, 18G, 20G, 22G, 24G) Applied as system/single Class-B Shelf life: 3 years Models / Sizes: I.V Catheters Type IC ,(16G, 18G, 20G, 22G, 24G)	Approved the I.V Catheter Type IC ,(16G, 18G, 20G, 22G, 24G) (Regular/Straight Type)

36.	M/s Ferozsons Laboratories Limitad, Nowshera. (ELI-00120) Date of R&I: 18-11-2022 Fee Details: Paid Fees: 50,000/- Challan No. 7733094603 Tracking Id: U18-MY7-27AA	<u>Legal Manufacturer:</u> Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA <u>Manufacturing Site:</u> Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA 47460 LOA Type: Scan copy of notarized copy. Validity: 31-12-2025 FSC Type: Scan copy of notarized copy. Issued by: USFDA Validity: 21-11-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 01-09-2026	Advanix Biliary Stent-Duodenal Bend (Polymeric Biliary Stent, non-bioabsorbable (Endoscopic stent-placement system)) Applied as Single Class-C Shelf life: 25 months Models / Sizes: M00532870 M00532880 M00532890 M00532900 M00532910 M00532920 M00532930 M00532940 M00532950 M00532960 M00532970 M00532980 M00532990 M00533000 M00533010 M00533020 M00533030 M00533040	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. Justification of the grouping along with catalog & required fee. Different model shall be applied separately. 4. Shelf life evidence/study.
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37.	M/s Ferozsons Laboratories Limitad, Nowshera. (ELI-00120) Date of R&I: 27-03-2025 Fee Details: Paid Fees: 50,000/- Challan No. 234831585270. Tracking Id: 5J7-4Q3-M7U8	<u>Legal Manufacturer:</u> Boston Scientific Neuromodulation Corporation 25155 Rye Canyon Loop Valencia, CA 91355, USA <u>Manufacturing Site(s):</u> Boston Scientific Corporation Boston Scientific de Costa Rica, S.R.L. 2546 First First Street Propark, EI Coyol, Alajuela, Costa Rica LOA Type: Scan copy of notarized copy. Validity: 31-12-2025 FSC Type: Scan copy of notarized copy. Issued by: USFDA Validity: 13-02-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 30-11-2026	RF Ablation Electrodes for Central Nervous System (CNS) Percutaneous radio- frequency ablation system Generator Applied as Family Class-C Shelf life: 48 months Models / Sizes: CU-6520U-P CU-10520U-P CU-101020U-P CU-15520U-P CU-151020U-P CUR-101020U-P CC5222-P CC 10222-P CC10520-P CC101020-P CC101021-P CC101022-P CC15220-P CC15520-P CC10520U-P CC10521U-P CC101020U-P CC101021U-P CC15520U-P RFK-C10520S-P RFK-C101020S-P RFK-C101022S-P	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. Justification of the grouping along with catalog & required fee. Different model shall be applied separately. 4. Shelf life evidence/study.
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38.	M/s Ferozsons Laboratories Limitad, Nowshera. (ELI-00120) Date of R&I: 18-11-2022 Fee Details: Paid Fees: 50,000/- Challan No. 7733094603 Tracking Id: U18-MY7-27AA	<u>Legal Manufacturer:</u> Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA <u>Manufacturing Site:</u> Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA 47460 LOA Type: Scan copy of notarized copy. Validity: 31-12-2025 FSC Type: Scan copy of notarized copy. Issued by: USFDA Validity: 21-11-2025 ISO 13485: Type: Scan copy of notarized copy. Validity: 01-09-2026	Advanix Biliary Stent-Duodenal Bend (Polymeric Biliary Stent, non-bioabsorbable (Endoscopic stent-placement system)) Applied as Single Class-C Shelf life: 25 months Models / Sizes: M00532870 M00532880 M00532890 M00532900 M00532910 M00532920 M00532930 M00532940 M00532950 M00532960 M00532970 M00532980 M00532990 M00533000 M00533010 M00533020 M00533030 M00533040	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. Justification of the grouping along with catalog & required fee. Different model shall be applied separately. 4. Shelf life evidence/study.
39.	M/s Medtronic Pakistan Private Limited License number: ELI-00273 Ocean Tower, 21st floor Plot No. G3, Khayaban-e-Iqbal, Block 9, Clifton.	Legal manufacturer: Medtronic Perfusion System 7611, Northland DR Minneapolis, MN USA, 55432. Manufacturing site: Medtronic Mexico S. de RL de CV , Av. Paseo Cucupah 10510 EL Lago Tijuana, Baja California, Mexico C.P. 22210. FSC: Copy attached. USFDA Issuance Date: 03-08-	Paediatric Aortic Root Cannula Class: B Shelf life: 3 years Size & Model:	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. 3. R&I DRAP receiving & verifiable copy of fee slip for the applied product. 4. Properly filled Form-7A along all the required annexures duly signed by the authorized person. 5. Demanded sizes/codes

	R&I Dated: Not attached. Fee Challan No.: Not attached.	2022 Validity Date: 02-08-2024 ISO: Issuance Date: 11-02-2022 Validity Date: 20-12-2024 2. Copy attached of Perfusion System, USA Issuance date: 01-01-2023 Validity date: 31-03-2024 LOA: Not attached		
40.	M/s Sadqain Healthcare Pvt.Ltd. ELI -00020 R&I Receiving: 15-08-2022 Fee: Rs. 25000/- Fee challan no. 32636790428 Challan Date 12/8/2022	Legal Manufacturer M/s. Intersurgical Limited. Crane House ,MollyMillars Lane, Wokingha,Berkshire,United Kingdom Manufacturing site: UAB Intersurgical Arnioniu60, Pabrade, LT-18170, Lithuania Non notarized copy of LOA: Validity: 1-3-2026 FSC Type: Scan copy of notarized copy. Issued by: MHRA UK Validity: 30-6-2029 ISO 13485: Type: Scan copy of notarized copy. Validity: 26-11-2023	10mm flextube single heated wire breathing system with neo water trap monitor line and limb > 1.6m Generic name BREATHING SYSTEM Applied as system Class-B Product code:4506850 Shelf life : 5 years	Deferred for submission of the following: 1. Valid Legalized Free Certificate issued by the concerned Regulatory Authority wherein the all manufacturers along with the free sale status of the product shall be mentioned. It is further advised that same product shall not be applied multiple times (through online MDMC portal) in such case one application (manual or online) shall be withdrawn by the applicant.

41.	M/s Mediland Pakistan Pvt. Ltd., Rawalpindi. ELI:00202 R&I Receiving: 12-08-2022 Fee: Rs. 25000/- Fee challan no. 6632301451 for Euroclinic ENT Unit.	Manufacturer as per FSC: Medi-Care Solutions s.r.l Via Della Zecca, 1-40121 Bologna (BO) – Italy. Site Address: Via P. Nenni, 3 40026 Imola (BO), Italy. LOA: Type: Scan copy of notarized copy. Validity: 31-21-2025 FSC Type: Scan copy of notarized copy. Issued by: Italy Issuance Date: 20-03-2025 Validity: without expiry date ISO 13485 not provided Instead copy of ISO 9001:2015 attached.	Otocompact Otocompact professional Otocompact professional EVO Otocompact professional TS Otocompact STEEL Otoplus ENT Unit Applied as Family Class-B Product code: Otocompact Professional Otocompact Professional Evo Otocompact Steel OtoPlus Otocompact Plus Shelf life: N/A	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Clarification of the difference in the name of the manufacturer in FSC & Form-7A. 3. Justification of the grouping along with catalog & family fee. Different System/model shall be applied separately via online MDMC portal. 4. Valid notarized ISO 13485 Furthermore, both parties (M/s Mediland Pakistan Pvt. Ltd., Rawalpindi, and M/s Biologic Medical Systems, Karachi) shall be called upon for a personal hearing in the matter to determine the authorization of the applied product.
42.	M/s Mediland Pakistan Pvt. Ltd., Rawalpindi. ELI:00202 R&I Receiving: 24-06-2022 Fee challan not attached. Tracking ID: X7W-GGS-9WT9	Manufacturer (as per Form-7A): Getinge AB Lindholmspiren 7A P.O. Box 8861 SE-417 56 Göteborg Sweden. Legal Manufacturer as per FSC: MaquetGmbH Kehler StraBe 31 76437 Rastatt Germany Manufacturing Site as per FSC: Getinge IC Production, Poland Sp. z O.O., Szkolna 3D, 62-064 Plewiska, Poland. LOA: Type: Scan copy of	Getinge Poladus 150 Low Temperature Sterilizer Applied as Family Class-C Product code: 6034510000, 6034510001, 6034510002, 6034510003, 6034510004, 6034510005, 6034510006	Deferred for submission of the following: 1. Valid notarized Letter of Authorization (LOA) issued by the legal manufacturer of the applied product. 2. Verifiable copy of fee slip 3. Clarification of the difference in the name of the manufacturer in FSC & Form-7A. 4. Justification of the grouping along with catalog & family fee. Different System/model shall be applied separately via online MDMC portal. 5. Valid notarized ISO 13485 6. Clarification of the class of the product in light of DOC & MDR 2017. Furthermore, both parties (M/s Mediland Pakistan Pvt. Ltd., Rawalpindi, and M/s Biologic Medical

		notarized copy. Validity: 31-10-2025 FSC Type: Scan copy of notarized copy. Issued by: Germany Issuance Date: 01-08-2024 Validity: without expiry date ISO 13485: Type: Scan copy of notarized copy. Validity: 15-10-2027	Shelf life: N/A	Systems, Karachi) shall be called upon for a personal hearing in the matter to determine the authorization of the applied product.
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Item No. III:

MISCELLANEOUS CASES

Evaluator: Sadaf Ahmad (Deputy Director)

Agenda Item No. 1

Imported products Agenda, Transfer cases from M/s Intek Corporation Office. 517, Kohistan Towers, Mehfooz Road, Saddar, Rawalpindi. Godown Address: 25 A Nagi Road Westridge 1, Rawalpindi. (ELI: 00034) to M/s Intek Coporation (Pvt) Ltd., Office No. 501, Kohistan Tower, Opp AFIC, The Mall, Rawalpindi. Office No.502, Kohistan Tower, Opp AFIC, The Mall, Rawalpindi (ELI-00794). M/s Intek Corporation Office. 517, Kohistan Towers, Mehfooz Road, Saddar, Rawalpindi. Godown Address: 25 A Nagi Road Westridge 1, Rawalpindi. (ELI: 00034) has submitted the undertaking/ declaration for deregistration of all the below mentioned products.

S. No.	Name of Applicant	Name of Manufacturer	Medical Device
1.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 37379090345 Amount:	NuMED, Inc. Located at NuMED, Inc.2880 Main Street Hopkinton, NY 12965 USA NUMED CANADA, INC. 45 Second Street West CORNWALL, Ontario CANADA K6J 1G3 • FSC Type: US FDA Issued By: USA Food & Drug	Brand Name: BIB Stent Placement Catheter. Generic Name: Balloon in Balloon Catheter Class: D Models/Code/sizes: BB014 BB016 BB017 BB019

	62,030.00 Differential Fee Challan: 445966501 Amount: 42,530	Administration Legalization: Yes Validity: 22-12-2027 • ISO 13485: Type: Notarization: Yes Validity: 09-06-2027 • CE certificate (FQA): Type: Full Quality Assurance Certificate Notarization: YES Validity: 28-02-2024 EC Design Examination: Notarization: YES Validity: 04-12-2023 • Extension letter Type: Notarization: Yes Validity: 31-12-2027	BB021 BB023 BB025 BB027 BB029 BB031 BB032 BB033 BB034 BB035 BB037 BB038 BB039 BB040 BB041 BB042 Shelf Life: 5 years
2.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 27850682280 Amount: 62,030.00 Differential Fee Challan: 41463786783 Amount: 42,530	NuMED , Inc. Located at NuMED, Inc.2880 Main Street Hopkinton, NY 12965 USA NUMED CANADA, INC. 45 Second Street West CORNWALL, Ontario CANADA K6J 1G3 • FSC Type: US FDA Issued By: USA Food & Drug Administration Legalization: Yes Validity: 22-12-2027 • ISO 13485: Type: Notarization: Yes Validity: 09-06-2027 • CE certificate (FQA):	Brand Name: Cp Stent Generic Name: CP Stent (Sterile Cheatham Platinum Stent) “. Class: D Models/Code/sizes: CP8Z16, CP8Z22, CP8Z28, CP8Z34, CP8Z39, CP8Z45, CP8Z50, CP8Z55, CP8Z60, CP10Z39, CP10Z45, CP10Z50, CP10Z55, CP10Z60. Shelf Life: 5 years

		Type: Full Quality assurance Certificate Notarization: YES Validity: 28-02-2024 EC Design Exaimnation: Notarization: YES Validity: 22-01-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2027	
3.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 173212673 Amount: 62,030.00 Differential Fee Challan: 77248759821 Amount: 42,530	NuMED , Inc. Located at NuMED, Inc.2880 Main Street Hopkinton, NY 12965 USA NUMED CANADA, INC. 45 Second Street West CORNWALL, Ontario CANADA K6J 1G3 • FSC Type: US FDA Issued By: USA Food & Drug Administration Legalization: Yes Validity: 22-12-2027 • ISO 13485: Type: Notarization: Yes Validity: 09-06-2027 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 28-02-2024 EC Design Exaimnation: Notarization: YES Validity: 22-01-2024 • Extension letter Type: Notarization: Yes	Brand Name: Covered Cp Stent Generic Name: Covered Cp Stent Class: D Models/Code/sizes: CVRDCP8Z16, CVRDCP8Z22, CVRDCP8Z28, CVRDCP8Z34, CVRDCP8Z39, CVRDCP8Z45, CVRDCP8Z50, CVRDCP8Z55, CVRDCP8Z60, CVRDCP10Z39, CVRDCP10Z45, CVRDCP10Z50, CVRDCP10Z55, CVRDCP10Z60. Shelf Life: 5 years

		Validity: 31-12-2027	
4.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 30648456383 Amount: 62,030.00 Differential Fee Challan: 439879038 Amount: 42,530	NuMED , Inc. Located at NuMED, Inc.2880 Main Street Hopkinton, NY 12965 USA NUMED CANADA, INC. 45 Second Street West CORNWALL, Ontario CANADA K6J 1G3 - FSC Type: US FDA Issued By: USA Food & Drug Administration Legalization: Yes Validity: 22-12-2027 - ISO 13485: Type: Notarization: Yes Validity: 09-06-2027 - CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 28-02-2024 - EC Design Exaimnation: Notarization: YES Validity: 25-02-2024 - Extension letter Type: Notarization: Yes Validity: 31-12-2027	Brand Name: Z-MED II-X PTV Catheter, Generic Name: PTV Catheter, Class: D Models/Code/sizes: PDZ716, PDZ717, PDZ720, PDZ721, PDZ724, PDZ725, PDZ728, PDZ729, , PDZ732, PDZ733, PDZ736, PDZ737, , PDZ740, PDZ741, PDZ744, PDZ745, PDZ748, PDZ749, PDZ752, PDZ753 Shelf Life: 5 years
5.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 48382012	NuMED , Inc. Located at NuMED, Inc.2880 Main Street Hopkinton, NY 12965 USA NUMED CANADA, INC. 45 Second Street West CORNWALL, Ontario CANADA K6J 1G3 FSC Type: US FDA	Brand Name: <u>Tyshak X PTV Catheter “.</u> Generic Name: PTV Catheter “. Class: D Models/Code/sizes: PDC400 PDC401

	Amount: 62,030.00 Differential Fee Challan: 2905347873 Amount: 42,530	Issued By: USA Food & Drug Administration Legalization: Yes Validity: 22-12-2027 • ISO 13485: Type: Notarization: Yes Validity: 09-06-2027 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 28-02-2024 EC Design Exaimnation: Notarization: YES Validity: 25-02-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2027	PDC402 PDC403 PDC404 PDC301 PDC302 PDC305 PDC306 PDC310 PDC311 PDC312 PDC316 PDC317 PDC320 PDC321 PDC324 PDC325 PDC328 PDC329 Shelf Life: 5 years
6.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 39779999645 Amount: 62,030.00 Differential Fee Challan: 2198518041 Amount: 42,530	NuMED , Inc. Located at NuMED, Inc.2880 Main Street Hopkinton, NY 12965 USA NUMED CANADA, INC. 45 Second Street West CORNWALL, Ontario CANADA K6J 1G3 • FSC Type: US FDA Issued By: USA Food & Drug Administration Legalization: Yes Validity: 22-12-2027 • ISO 13485: Type: Notarization: Yes Validity: 09-06-2027 • EU MDR: Yes	Brand Name: “Z-5 Atrioseptostomy Catheter“. Generic Name: Atrioseptostomy Catheter“. Class: D Models/Code/sizes: SPT002, SPT003. Shelf Life: 5 years

		Notarization :Yes Validity:06-06-2029	
7.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 03-07-2025 Challan: 8091714809 Amount: 31030 Diff Fee Challan: 1628437687 Amount: 21230	Lepu Medical Technology (Beijing) Co., Ltd Address: No. 37 Chaoqian Road, Changping District, Beijing, China 102200 P.R China • FSC Type: EU FSC Issued By: Minsistry of health , Welfare & Sport CIBG Legalization:Yes Validity: 31-12-2028 • ISO 13485: Type: Notarization: Yes Validity: 10-09-2026 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 26-05-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2028	Brand Name: Shoocin Introducer Kit Generic Name: Introducer Kit Class: B Models/Code/sizes: LS062338-SJ70-IN18-K-S LS072338-SJ70-IN18-K-S LS082338-SJ70-IN18-K-S RS040721-SS45-IN20-K-S RS041121-SS45-IN20-K-S RS051121-SS45-IN20-K-S RS061121-SS45-IN20-K-S RS071121-SS45-IN20-K-S FS041135-SJ45-IN18-K-S FS051135-SJ45-IN18-K-S FS061135-SJ45-IN18-K-S FS071135-SJ45-IN18-K-S FS081135-SJ45-IN18-K-S FS091138-SJ45-IN18-K-S FS091138-SS45-IN18-K-S FS101138-SJ45-IN18-K-S FS111138-SJ45-IN18-K-S Shelf Life: 3 years
8.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 03-07-2025 Challan: 22749045 Amount: 31030	Lepu Medical Technology (Beijing) Co., Ltd Address: No. 37 Chaoqian Road, Changping District, Beijing, China 102200 P.R China • FSC Type: EU FSC Issued By: Minsistry of health , Welfare & Sport CIBG Legalization:Yes Validity: 31-12-2028	Brand Name: Angiopower Inflation Device Generic Name: Inflation Device Class: B Models/Code/sizes: LP-P-30 LP-P-30S LP-Z-30X LP-P-40 LP-P-40S

	Diff Fee Challan: 9885624771 Amount: 21230	• ISO 13485: Type: Notarization: Yes Validity: 10-09-2026 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 26-05-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2028	Shelf Life: 3 years
9.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 03-07-2025 Challan: 6824746558 Amount: 31030 Diff Fee Challan: 59766856851 Amount: 21230	Lepu Medical Technology (Beijing) Co., Ltd Address: No. 37 Chaoqian Road, Changping District, Beijing, China 102200 P.R China • FSC Type: EU FSC Issued By: Ministry of health , Welfare & Sport CIBG Legalization: Yes Validity: 31-12-2028 • ISO 13485: Type: Notarization: Yes Validity: 10-09-2026 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 26-05-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2028	Brand Name: Brilliant Introducer Kit Generic Name: Introducer Kit Class: B Models/Code/sizes: RSC041121-HS45-IC22-K-S RSC061121-HS45-IC22-K-S RSC040725-HW45-IC20-K-S RSC041121-HW45-IC22-K-S RSC061121-HW45-IC22-K-S RSC051121-HS45-IC22-K-S RSC071121-HS45-IC22-K-S RSC051121-HW45-IC22-K-S RSC071121-HW45-IC22-K-S RSC041121-HS45-IC22-K-S RSC051121-SS45-IN20-K-S RSC040721-SS45-IN20-K-S RSC041121-SS45-IN20-K-S RSC071121-SS45-IN20-K-S RSC061121-SS45-IN20-K-S RSC051121-SJ45-IN20-K-S RSC041121-SJ45-IN20-K-S RSC071121-SJ45-IN20-K-S RSC071121-SS45-IN20-K-S RSC061121-SJ45-IN20-K-S Shelf Life: 3 years

10.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 03-07-2025 Challan: 809704003 Amount: 31030 Diff Fee Challan: 312910786971 Amount: 21230	Lepu Medical Technology (Beijing) Co., Ltd Address: No. 37 Chaoqian Road, Changping District, Beijing, China 102200 P.R China • FSC Type: EU FSC Issued By: Minsistry of health , Welfare & Sport CIBG Legalization:Yes Validity: 31-12-2028 • ISO 13485: Type: Notarization: Yes Validity: 10-09-2026 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 26-05-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2028	Brand Name: CONTRAST MEDIUM INJECTIONS MANIFOLD KIT Generic Name: MANIFOLD KIT Class: B Models/Code/sizes: MK-001 MK-002 MK-003 MK-004 MK-005 MK-006 MK-007 MK-008 MK-009 MK-010 MK-011 MK-012 MK-013 MK-014 MK-015 MK-016 MK-017 MK-018 MK-019 MK-020 Shelf Life: 3 years
11.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 03-07-2025 Challan: 806877148399 Amount: 31030 Diff Fee Challan:	Lepu Medical Technology (Beijing) Co., Ltd Address: No. 37 Chaoqian Road, Changping District, Beijing, China 102200 P.R China • FSC Type: EU FSC Issued By: Minsistry of health , Welfare & Sport CIBG Legalization:Yes Validity: 31-12-2028 • ISO 13485:	Brand Name: Angioway Manifold Generic Name: Manifold Class: B Models/Code/sizes: LPJD253N LPJD253F Shelf Life: 3 years

	756324095650 Amount: 21230	Type: Notarization: Yes Validity: 10-09-2026 • CE certificate (FQA): Type: Full Quality assurance Certificate Notarization: YES Validity: 26-05-2024 • Extension letter Type: Notarization: Yes Validity: 31-12-2028	
	<i>The Board decided to approve the transfer of above-mentioned products from M/s Intek Corporation Office. 517, Kohistan Towers, Mehfooz Road, Saddar, Rawalpindi. Godown Address: 25 A Nagi Road Westridge 1, Rawalpindi. (ELI: 00034) to M/s Intek Coporation (Pvt) Ltd., Office No. 501, Kohistan Tower, Opp AFIC, The Mall, Rawalpindi. Office No.502, Kohistan Tower, Opp AFIC, The Mall, Rawalpindi (ELI-00794). The firm will submit previous original registration letters to MDMC division before the issuance of new registration letters.</i>		

New Applications			
1.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 25-02-2025 Challan: 5448915805 Amount: 62,030.00 Extra codes Fee: Challan: 23122700550 Amount :88430 Challan: 607290629 Amount : 42530	<u>Legal Manufacturer:</u> MicroVention, Inc. 35, Enterprise Alsio Viejo, CA 92780 USA <u>Manufacturing site:</u> MicroVention Costa Rica S.R.L Edificio B33 Zona Franca Coyol Alajuela, Costa Rica - FSC France Legalization: Yes Issued on: 20-06-2023 - ISO 13485: Type: Notarization: Yes Validity: 26-09-2027 - CE certificate (FQA): Type: Full Quality Assurance Certificate Notarization: YES Validity: 26-05-2024 - Extension letter Type: Notarization: Yes Validity: 31-12-2027	Brand Name: MICROPLEX HYPERSOFT 3D COIL SYSTEM. Generic Name: Hypersoft Coil Class: D Models/Code/sizes: 100102HS3D-V , 100409HS3D-V 100103HS3D-V, 100412HS3D-V 100106HS3D-V, 100415HS3D-V 100115HS3D-V, 100510HS3D-V 100152HS3D-V, 100515HS3D-V 100153HS3D-V, 100520HS3D-V 100154HS3D-V, 100620HS3D-V 100155HS3D-V, 101510HS3D-V 100202HS3D-V, 102510HS3D-V 100203HS3D-V, 102512HS3D-V 100204HS3D-V, 100408HS3D-V 100206HS3D-V, 100208HS3D-V 100210HS3D-V, 100212HS3D-V 100254HS3D-V, 100256HS3D-V 100258HS3D-V, 100304HS3D-V 100306HS3D-V, 100308HS3D-V 100310HS3D-V, 100312HS3D-V 100355HS3D-V, 100358HS3D-V 100406HS3D-V Shelf Life: 5 years
2.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 9725347847 Amount: 25000 Differential Fee Challan: 94074524128 Amount: 27200	Beijing Demax Medical Technology Co. Ltd Located at 13-7A Jingshengnansi Street, Majuqiao, Tong Zhou District, 101102 Beijing, P.R. China - FSC Type: Australian FSC Issued by: Australian Government Department of Health and Aged Care Legalization: Yes Issue:20-06-2024 - ISO 13485: Type: Notarization: Yes Validity: 06-06-2026 EU QMS Certificate: Notarization : Yes Validity:28-11-2028	<u>Brand Name:</u> <u>Twist Y Connector Kit</u> <u>Generic Name:</u> Twist Y Connector Kit Class: B Models/Code/sizes: DRY01, DDY01, DRY01B, DHDY01B, DRY02, DRY03, DHRY02, DHRY03, DDY02, DDY03, DHDY03, DRY02B, DRY03B, DHRY02B, DHRY03B, DDY02B, DDY03B, DHDY03B, DDT03, DHDT02B, Shelf Life: 3 Years

3.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 26-06-2025 Challan: 8773033494 Amount: 25000 Differential Fee Challan: 528752230375 Amount: 27200	Beijing Demax Medical Technology Co. Ltd Located at 13-7A Jingshengnansi Street, Majuqiao, Tong Zhou District, 101102 Beijing, P.R. China • FSC Type: Australian FSC Issued by: Australian Government Department of Health and Aged Care Legalization: Yes Issue:20-06-2024 • ISO 13485: Type: Notarization: Yes Validity: 06-06-2026 EU QMS Certificate: Notarization : Yes Validity:28-11-2028	Brand Name: <u>Push-Click Y Connector Kit</u> Generic Name: Push-Click Y Connector Kit Class: B Models/Code/sizes: DPY01, DPY01B, DPY02, DPY03, DPY02B, DPY03B, Shelf Life: 3 Years
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Decision: The Board approved the above-mentioned 03 new cases of M/s Intek Corporation Pvt ltd.

ADDITIONAL AGENDA CASES

Evaluator: RANA AHSAN UL HAQ ATHAR (DEPUTY DIRECTOR)

DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Briogene Pvt Ltd, 196-A, Sindhi Muslim Cooperative Housing Society, Shahrah-e- Faisal, Karachi (ELI-00015) Evaluator AD VI	Legal Manufacture Xiamen Zeesan Pvt.Ltd Building 1#, 4F and include complete address, telephone number, fax number area 3F of Building 11#, No.3701 North and its official website: Xiang'an Road, (Xiang An) Industrial Area, Torch High-Tech Zoiie, Xiamen City, Fujian Province, 361101, P.R. China FSC: China DATE OF FSC: July 22, 2020.	Lab-Aid Virus RNA Extraction Kit • Class -B • Claimed Shelf life: 12 Months • Codes as per FSC • Code#606104	Approved.
2.	Applicant Name: M/s. Acme Intertrade Health Care, Vision Clifton Shopping Arcade, Shop # 28, Khayaban-e-Roomi Road, Clifton Block 5, Karachi. (ELI-01097) R&I detail 04-04-2025 Fee: 6000 Slip: 25681892920 Dated: 15-03-2025	Name of Manufacturer: M/s Vacsax Limited, Western Wood Way Language Science Park Plymouth UK. LOA validity: 03-04-2025 FSC issuance (UK): 12-07-2023 ISO Validity: 09-07-2027	Brand name: Vacsax Bacticlear Liner Generic Name: suction liners Class: A Codes/Sizes: VAL-201 Shelf life: 05 Years	Approved Vacsax Bacticlear Liner 2L standard (VAL-201).
3.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708)	Name of Manufacturer: As per application form: Sir Trang Gloves (Thailand) Public Company Limited Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand As per FSC:	Brand Name: Axelis Generic Name: Latex Powdered Examination Gloves, Non Sterile Applied as: -- Class: A Models/Code/sizes (as per FSC	Approved.

	R&I No. & Date: 19304; 01-Jul-2025 Fee: 6,000/- Slip # 16513711435	Sir Trang Gloves (Thailand) Public Company Limited Address: 110 Kanjavanit road, Pahtong, Hat yai, Songkhla 90230, Thailand LOA: Type: Original Legalization: Legalized Validity: 06-05-2030 FSC: Type: Original Issued By: Food And Drug Administration, Thailand Legalization: Legalized Validity: 01-04-2027 ISO – Certificate: Legalization: Legalized Validity: 31-10-2026	& application Model: Shelf Life: 5 years	
4.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19302; 01-Jul-2025 Fee: 6,000/- Slip # 69326591	Name of Manufacturer: As per application form: Sir Trang Gloves (Thailand) Public Company Limited Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand As per FSC: Sir Trang Gloves (Thailand) Public Company Limited Address: 110 Kanjavanit road, Pahtong, Hat yai, Songkhla 90230, Thailand LOA: Type: Copy Legalization: Legalized Validity: 06-05-2030 FSC: Type: Copy Issued By: Food And Drug Administration, Thailand Legalization: Legalized Validity: 01-04-2027 ISO – Certificate: Legalization: Legalized Validity: 31-10-2026	Brand Name: Axelis Generic Name: Nitrile Powder Free Examination Gloves Applied as: -- Class: A Models/Code/sizes (as per FSC & application Model: Shelf Life: 5 years	Approved.

5.	Roys & Roys International, 1st Floor Rehman Centre-2, Service Lane Ring Road, Near Askari-11, Lahore. (ELI-00708) R&I No. & Date: 19303; 01-Jul-2025 Fee: 6,000/- Slip # 762763089096	Name of Manufacturer: As per application form: Sir Trang Gloves (Thailand) Public Company Limited Address: 10 Soi 10 Phetkasem Road, Hat Yai, Songkhla 90110 Thailand As per FSC: Sir Trang Gloves (Thailand) Public Company Limited Address: 110 Kanjanavanit road, Pahtong, Hat yai, Songkhla 90230, Thailand LOA: Type: Copy Legalization: Legalized Validity: 06-05-2030 FSC: Type: Copy Issued By: Food And Drug Administration, Thailand Legalization: Legalized Validity: 01-04-2027 ISO – Certificate: Legalization: Legalized Validity: 31-10-2026	Brand Name: Axelis Generic Name: Latex Powder Free Examination Gloves, Non Sterile Applied as: -- Class: A Models/Code/sizes (as per FSC & application) Model: Shelf Life: 5 years	Approved.
6.	Intek Corporation Pvt Ltd ELI-00794 Validity 19-10-2026 R&I Date: 08-07-2025 Fee: Rs 62030 Slip No: 263246980794 Date: 07-7-2025	Lepu Medical Technology (Beijing) Co., Ltd No. 37 Chaoqian Road, Changping District, Beijing, China 102200 LOA Type: Copy Notarization: No Issuance Date: 13-06-2025 Validity date: Not mentioned • FSC Type: Copy Issued By: Beijing Drug Administration. Legalization/ Apostille: No Validity: 09-01-2027	Thorcrack Peripheral IVL Balloon Dilatation Catheter Applied as: Kit Class: C Shelf Life: 24 months Models/Code/sizes: LPAW3040, LPAW3060, LPAW3540, LPAW3560, LPAW4040, LPAW4060, LPAW4540, LPAW4560, LPAW5040, LPAW5060, LPAW5540, LPAW5560, LPAW6040, LPAW6060, LPAW6540, LPAW6560, LPAW7040, LPAW7060	Approved following codes: LPAW3040, LPAW3060, LPAW3540, LPAW3560, LPAW4040, LPAW4060, LPAW4540, LPAW4560, LPAW5040, LPAW5060, LPAW5540, LPAW5560, LPAW6040, LPAW6060

		• ISO 13485: Type: Copy Notarization: No Validity: 6-3-2026 • CE certificate (FQA): Not provided		
7.	Applicant Name: Intek Corporation Pvt. Ltd., Office No. 501, Kohistan Towers, Opp. AFIC The Mall Rawalpindi ELI-00794 Date of R&I 18-07-2025 Fee Details: Paid Fee: 62,000/- Fee Challan No: 9747548897	Name of Manufacturer: Lepu Medical Technology (Beijing) Co, No. 37 Chaoqian Road, Changping District Beijing 102200, China Manufacturing site: Lepu Medical (Europe) Cooperatief U.A Abe Lenstra Boulevard 36,8448 JB Heerensven the, Netherlands LOA Validity: 12-06-2028 (Original notarized) FSC: CCPIT Validity:09-01-2027 (Apsotilled) ISO Validity: 06-03-2026 DOC Certificate Not specified	Brand name: VessCrack Generic Name: Coronary IVL Balloon Dilatation Catheter Class-D Shelf life: 03 years Models/ Specification 2.5 * 12 2.75 * 12 3 * 12 3.25 * 12 3.5 * 12 3.75 * 12 4 * 12	Approved.
8.	M/s AL Madina International Co., Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00661) R&I Date: 05-06-2025 Fee: 31,000/- Slip # 06508755	Name of Manufacturer: Xiantao Daoqi Plastic Co., Ltd., Address: No. 83 Wagou New District, Pengchang Town, Xiantao City, Hubei Province, china LOA Type: Copy Notarization: No Issue Date: 02-05-2025 Validity: 31-12-2025 FSC:	Brand Name: Green Disposable Shoe Cover Generic Name: Disposable Shoe Cover Applied as: Single Class: A Models/Code/sizes (as per FSC & application Model: Non-woven, Plastic Size: S/M/L Shelf Life: 5 years (Room temperature; 25°C)	Approved.

		Type: Copy Issued By: Not mentioned Legalization: No Validity: 05-12-2025 ISO – Certificate: Type: Copy Notarization: No Validity: 21-05-2025		
9.	M/s AL Madina International Co., Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00661) R&I Date: 05-06-2025 Fee: 31,000/- Slip # 52141358962	Name of Manufacturer: Xiantao Daoqi Plastic Co., Ltd., Address: No. 83 Wagou New District, Pengchang Town, Xiantao City, Hubei Province, china LOA Type: Copy Notarization: No Issue Date: 02-05-2025 Validity: 31-12-2025 FSC: Type: Copy Issued By: Not mentioned Legalization: No Validity: 13-01-2027 ISO – Certificate: Type: Copy Notarization: No Validity: 21-05-2025	Brand Name: Green Disposable Isolation Gown Generic Name: Disposable Isolation Gown Applied as: Single Class: A Models/Code/sizes (as per FSC & application) Model: Model: Gown style: S CLHIOXWI3S) M CLHISXWI37. L (LI20XW140) . XL (L160 XW125) XXL (LI65XW130) . XXXL M (L99XW66) 、 L (102XW68) 、 XL (LI70XW135): Separate stylet S L96XW64).) (L105XW70) XKL (Li0gwx72). XXXL (L111 x W74); Jumpsuit: S (LI65XW120) . M(LI69XW125) . L (LI73XW130) . XL (L78XW135) . XXL (L18]XW140), XXXL (LIS8XW145) units cm. (As per Free sale) Shelf Life: 5 years (Room temperature; 25°C)	Approved.
10.	M/s AL Madina International Co., Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi (ELI-00661) R&I Date: 05-06-2025 Fee: ,000/- Slip # 46851722	Name of Manufacturer: Xiantao Daoqi Plastic Co., Ltd., Address: No. 83 Wagou New District, Pengchang Town, Xiantao City, Hubei Province, china LOA Type: Copy Notarization: No Issue Date: 02-05-2025 Validity: 31-12-2025 FSC: Type: Copy Issued By: Not mentioned Legalization: NO Validity: 05-12-2025	Brand Name: Green Disposable Caps Generic Name: Disposable Caps Applied as: Family Class: A Models/Code/sizes (as per FSC & application) Model: Strip cap (45cm,48cm,50cm,53cm,61cm), Round cap (45cm,48cm,50cm,53cm,61cm); Strapped cap (62cm,64cm; Elastic cap (62cm, 64cm) (As per free sale) Specification: 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5	Approved Strip cap (45cm,48cm,50cm, 53cm,61cm)

		ISO – Certificate: Type: Copy Notarization: No Validity: 21-05-2025	Shelf Life: 5 years	
11.	M/s Al Madina International Co., Office No. 306/11, Trade Tower, Altaf Hussain Road, New Chali, Karachi. ELI-00661 Date of R& I 30-06-2025 Fee: PKR 6,000/- Slip No. 5089986160	Name of Manufacturer: Guangdong Dayang Medical Technology Co. Ltd., Xingxian Development Zone, Changhongling Industrial Park (2 nd Phase), Shishan, Nanhai District, Foshan, Guangdong, China. • LOA Type: Copy Notarization: Not notarized Validity: 25-06-2030 • FSC (China) Type: Copy Issued By: Chamber of Commerce Legalization: Not legalized. Validity: 16-07-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 23-06-2028	Brand name: Comfort Care Walking Stick Generic Name: Walking Stick Class: A Models/Codes/Sizes (as per FSC & Application: Multiple mentioned in FSC, not specified. Applied as: Single Service life: Not mentioned The codes as per FSC are following: DY05910L, DY05911, DY05911L, DY05911LB, DY05911LH, DY05920L, DY059201LB, DY059201L-M1, DY059201L-M2, DY059201L-M3, DY059201L-M4, DY059201L-M5, DY059201L-M6, DY059201L-M7, DY059201L-M10, DY05921, DY05922, DY05924, DY05924L, DY059241, DY059241B, DY059242, DY059243, DY05926, DY05926B, DY05926(2), DY059261, DY05927L-M2, DY05927L-M4, DY05927L-M8, DY05927L-M9, DY05928L, DY059282L, DY05929L, DY05930L, DY05931, DY05931V, DY05932, DY05932L, DY05932LG, DY05932L(2), DY05932L(2)B, DY05932L(2)H, DY05934, DY05934(3), DY05934V, DY05934(3)V, DY05936L, DY05936L(S), DY05938LB,	Approved only one code DY05911.

			DY05940L, DY05940LB, DY05940L(2), DY05940L(2)G, DY05940L(2)H, DY05940(2)B, DY05941, DY05942L-BK, DY05942L-P, DY05942L-GN, DY05942LH-BK, DY05942L-RD, DY05942L-Y, DY05939L, DY05944, DY05947	
12.	M/s Al Madina International Co., Office No. 306/11, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI-00661 Date of R& I 30-06-2025 Fee: PKR 6,000/- Slip No. 830366514	Name of Manufacturer: Guangdong Dayang Medical Technology Co. Ltd., Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, China. • LOA Type: Copy Notarization: Not notarized Validity: 25-06-2030 • FSC (China) Type: Copy Issued By: Chamber of Commerce Legalization: Not legalized. Validity: 16-07-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 23-06-2028	Brand name: Comfort Care Walker/Rollator Generic Name: Walker/Rollator Class: A Models/Codes/Sizes (as per FSC & Application): Multiple mentioned in FSC, not specified. Applied as: Single Service life: Not mentioned	Approved Comfort Care Walker with code (DY04915L/adu)
13.	M/s Al Madina International Co., Office No. 306/11, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI-00661 Date of R& I 30-06-2025 Fee: PKR 6,000/- Slip No. 170145044	Name of Manufacturer: Guangdong Dayang Medical Technology Co. Ltd., Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, China. • LOA Type: Copy Notarization: Not notarized Validity: 25-06-2030	Brand name: Comfort Care Manual Wheel Chair Generic Name: Manual Wheel Chair Class: A Models/Codes/Sizes (as per FSC & Application): Multiple mentioned in FSC, not specified. Applied as: Single	Approved only one code DY01201LQ

		• FSC (China) Type: Copy Issued By: Chamber of Commerce Legalization: Not legalized. Validity: 16-07-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 23-06-2028	Service life: Not mentioned Codes as per FSC are DY01201LQ, DY01700LQ, DY01802E, DY01809, DY01863, DY01864, DY01868, DY01872, DY01875, DY019001, DY01903, DY01908, DY01902GC, DY01951, DY01950, DY01953, DY01954, DY01980, DY01958, DY01959, DY01973, DY01990, DY02608, DY02609, DY02608GC, DY02609GC, DY02681, DY02683, DY01805, DY01871	
14.	M/s Al Madina International Co., Office No. 306/11, Trade Tower, Altaf Hussain Road, New Challi, Karachi. ELI-00661 Date of R& I 30-06-2025 Fee: PKR 6,000/- Slip No. 08575982641	Name of Manufacturer: Guangdong Dayang Medical Technology Co. Ltd., Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, Foshan, Guangdong, China. • LOA Type: Copy Notarization: Not notarized Validity: 25-06-2030 • FSC (China) Type: Copy Issued By: Chamber of Commerce Legalization: Not legalized. Validity: 16-07-2026 • ISO Certificate Type: Copy Notarization: Not notarized Validity: 23-06-2028	Brand name: Comfort Care Commode Chair Generic Name: Commode Chair Class: A Models/Codes/Sizes (as per FSC & Application): Multiple mentioned in FSC, not specified. Applied as: Single Service life: Not mentioned	Rejected the application as product was not mentioned in the FSC.
15.	AL Madina International Co., Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yinhai Street, Qiantang New Area,	Brand Name: Comfort Care Pregnancy (hCG) Rapid Test Generic Name: Pregnancy (hCG) Rapid Test Applied as: Family Class: A	Approved in class B

	ELI-00661 R&I Date: 18-07-2025 Fee: Rs. 31,000 vide deposit slip no. 19482864	Hangzhou, Zhejiang China LOA: Not submitted FSC: Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: No Validity: 27-11-2026 ISO – Certificate: Type: Copy Notarization: No Validity: 17-06-2027	Models/Code/sizes (as per FSC & application) Shelf Life: 3 years	
16.	Ghazali Brothers 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240) R&I Date 18/07/2025 Fee Challan No. Slip No. 5201468013 Rs 6,000.00, Dated 17-02-25 R&I Date: 13-11-2025	Legal Manufacturer: Hospital & Homecare IMP. & EXP. Co., Ltd, Nanjing Room no. 608-611 No.5 Zhongtai International Plaza, No. 311 Middle of Jiangdong Road, Central Business District, Nanjing, Jiangsu Province, 210019, China <u>Tel:</u>+86 25 87783278 Website: www.aline-medical.com LOA validity: 2028-02-10 FSC Valid till: 10-01-2027 ISO-13485 Validity 2028-05-31	Brand &Name: Hospital & Homecare IV Cannula Fixation Class A Shelf Life: 5 Years Codes/Sizes: MC179	Approved.
17.	Ghazali Brothers 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240) R&I Date 12-05-2025 Fee Challan No. Slip No. 73198873	Legal Manufacturer: Guangzhou AXD Electronic Co., Ltd Factory 3, No.9 Changxin Road, Changshapu, Zhongluotan Town, 510550, Baiyun District, Guangzhou City, Guangdong Province, China	Brand &Name: Accumax Minor Compressor Nebulizer Machine Class B Shelf Life: 5 Years Codes/Model: AXD-308	Approved only code/model AXD-308.

	Rs 31,000.00, Dated 19-05-2025 R&I Date: 04-09-2025	http://www.axdgz.com LOA validity: 2035-04-17 FSC Valid till: 2027-07-24 ISO-13485 Validity 2028-03-25		
18.	Ghazali Brothers 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240) R&I Date 12-05-2025 Fee Challan No. Slip No. 0571992883 Rs 31,000.00, Dated 19-05-2025 R&I Date: 04-09-2025	Legal Manufacturer: Guangzhou AXD Electronic Co., Ltd Factory 3, No.9 Changxin Road, Changshapu, Zhongluotan Town, 510550, Baiyun District, Guangzhou City, Guangdong Province, China http://www.axdgz.com LOA validity: 2035-04-17 FSC Valid till: 2027-07-24 ISO-13485 Validity 2028-03-25	Brand &Name: Care Compressor Nebulizer Machine Class B Shelf Life: 5 Years Codes/Model: AXD-305.	Approved only code/model AXD- 305.
19.	Ghazali Brothers 1st Floor, Azzainab Court, Campbell Street Karachi (ELI- 00240) R&I Date 14-04-2025 Fee Challan No. Slip No. 1036755964 Rs 31,000.00, Dated 19-05-2025 R&I Date: 03-11-2025	Legal Manufacturer: Guangdong Baihe Medical Technology Co., Ltd No.89, Taoyuan East Road, Nanhai Foshan Guangdong P.R. China LOA validity: 2027-01-19 FSC Valid till: 18-06-2027 ISO-13485 Validity 2027-08-06	Brand &Name: Hospital & Homecare Disposable Fistula Needles Class C Codes/Sizes: 14G, 15G, 16G, 17G	Approved in class B.

20.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: 31000/- Slip # 8781383526	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yinhai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: -- Validity: 28-08-2029 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Brand Name: Accurate Pregnancy (hCG) Rapid Test Generic Name: Pregnancy (hCG) Rapid Test Applied as: Family Class: B Models/Code/sizes (as per FSC & application Pregnancy (HCG) test strips Pregnancy (HCG) test Cassette Shelf Life: 3 years	Approved
21.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Not submitted	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yinhai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Brand Name: Accurate Typhoid Rapid Test Generic Name: Typhoid Rapid Test Applied as: Family Class: B Models/Code/sizes (as per FSC & application Shelf Life: 2 years	Approved in class C.

22.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Not submitted	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yinhai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Brand Name: Accurate Malaria P.f/P.v Rapid Test. Generic Name: Malaria P.f/P.v Rapid Test. Applied as: Family Class: B Models/Code/sizes (as per FSC & application Shelf Life:	Approved in class C.
23.	New Pakistan Traders, Office No. 306/II, Trade Tower, Altaf Hussain Road, New Challi, Karachi ELI-00661 R&I Date: 18-07-2025 Fee: Not submitted	Name of Manufacturer: Actest Biotech (Hangzhou) Co., Ltd., Address: Office Room 408, Building 5, #600 Yinhai Street, Qiantang New Area, Hangzhou, Zhejiang China LOA Type: Copy Notarization: No Validity: 31-12-2035 • FSC Type: Copy Issued By: China Chamber of Commerce for Import & Export of Medicines and Health Products Legalization: Apostille Validity: 27-11-2026 • ISO – Certificate: Not submitted Type: Notarization	Brand Name: Accurate Dengue NS1 Rapid Test Generic Name: Dengue NS1 Rapid Test. Applied as: Family Class: B Models/Code/sizes (as per FSC & application Shelf Life:	Approved in class C.

CASE NO. 1

Name Address of Importer	Name : M/S Briogene Pvt Ltd Address of Importer 196-A, Sindhi, Muslim Cooperative Housing Society, Shahrach-e-Faisal, Karachi
Detail of ELM/ELI	ELI-00015
Name Address of Manufacturer	(LEGAL MANUFACTUREUR) Qiagen GmbH, Qiagen Strasse 1, 40724, Helden, Germany (Manufacturing site) Veracyte SAS, 163, Avenue de Luminy, 13009, Marseille, France
Brand Name	IPSOGEN® BCR-ABL 1 MBCR IS-MMR DX Kit Cat # 670823 (24)
Country of origin FSC	FSC: Embassy attested free sale certificate from Germany, Issuance date: 25-07-2022
Whether the product is applied on CE certificate basis or free sale in reference country	Free Sale in reference country.
Date of application received along with Fee	Date : 21 December 2023 Fee: Rs. 50,000/ through slip no. 14537699678, dated 14.12.2023
Class of medical device	C
Stability data/ service life	Shelf Life: 36 months
Documents submitted Marketing Authorization Letter: Production Quality Management System Certificate (ISO 13485) Production Quality Assurance Certificate or Equivalent Full Quality Assurance Certificate or Equivalent Design Examination Declaration of Conformity (Doc) provided/not provided	Marketing Authorization Letter: issuance date 24.03.2022 Production Quality Management System Certificate (Iso 13485) Iso 13485 Notifying Body TUV Rheinland LGA Valid till 14-June-24 issuance date 19-Aug-21 Production Quality Assurance Certificate or Equivalent N/A Full Quality Assurance Certificate or Equivalent: The product falls in Class C and is currently classified as a General IVD, under Self-Assessment Route of the In Vitro Diagnostic Directive (IVDD) 98/79/EC. the product is General IVD class, it does not require EC Design Examination Certificate, or a Full Quality Management System EC Certificate. Design Examination The product falls in Class C and is currently classified as a General IVD, under Self-Assessment Route of the In Vitro Diagnostic Directive (IVDD) 98/79/EC. the product is General IVD class, it does not require EC Design Examination Certificate, or a Full Quality Management System EC Certificate. Declaration of Conformity (Doc): Provided
Codes/ sizes	670823/ pack size: 24
Decision	Approved.

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