

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

DECISIONS OF 117th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 14th JANUARY-2026 MANUAL APPLICATIONS PART-II

117th 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 14th January, 2026. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

S. No.	Name and Designation/Department	Position in the MDB
1.	Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad.	Chairman
2.	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)
3.	Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian.	Member
4.	Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab.	Member (attended meeting through videolink)
5.	Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist).	Member (attended meeting through videolink)
6.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
7.	Mr. Wajahat Ali, Biomedical Manager, Liaquat College of Medicine and Dentistry & Darul Sehat Hospital, Karachi.	Member (attended meeting through videolink)
8.	Ms. Tazeen Saeed Bukhari, Biomedical Engineer	Co-Opted Expert (attended meeting through videolink)
9.	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.

Item No. I(A): SITE VERIFICATION APPLICATIONS:

S.#	Name of Establishment	Name of Panel Inspector (s)	Decision
1.	M/s Sinopak United Industries, Plot No. F/2B, SITE, Karachi.	Abdul Waheed Deputy Director DRAP Karachi.	Approved

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

(FRESH CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Dante Health Care (Pvt) Ltd Office: Ground Floor, Plot 44-W Alay Plaza Fazlal e Haq Road, Blue Area, Islamabad Islamabad	Dr Maria Gulzaman Pharm D	Rejected. The board considered the report of the inspector that the firm is not interested in grant of ELI therefore decided to reject application for ELI.
2.	M/s GLOBAL MANAGEMENT TEAM (PRIVATE) LIMITED Office / godown: UNIT 05, MASCO PLAZA, 64-E, JINNAH AVENUE, BLUE AREA, ISLAMABAD Islamabad	Usman Khan Biomedical Engineer	Approved. Office/ Godown: Unit 05, Masco Plaza, 64-E, Jinnah Avenue, Blue Area, Islamabad

(FRESH RENEWAL CASES-ELI)

S.#	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Molecular biology products, Office/godown: 7B-1, 7 Floor, fakhri trade centre, shahrah-e- liaquat, Karachi. ELI-00493	Heeba shahid BS biotechnology	Mufaddal cutierywala CEO	Approved. The firm shall submit an undertaking that the premises shall not be used for residential purposes and could be inspected anytime without hindrance.
2.	M/s Bright vision, Office/godown: FL-1/10, block 3, KDA scheme no. 24, gulshan-e- iqbal, Karachi. ELI-00474	Fasiha barlas Pharm D	M mazhar ismail Umair bin asrar	Approved
3.	M/s Hospital services & sales, Office/godown: 13-C, annex, Block 6, PECHS, Shahrah-e-Faisal, Karachi. ELI-00081	M. Nasir Khatib B-Pharm	M Younus biloo Kishwar Billoo Miss Tasmia Abeer billoo	Approved
4.	M/s Bio life, Office/Godown: office No 4, wnd floor, ahmed center, I-8 markaz, Islamabad. ELI-00223	Tehzeeba riaz Pharm D	Sohail akram CEO	Deferred for submission of fee and documents for approval of new godown and technical staff. The applicant shall also submit a written statement on not obtaining registrations/ enlistment of products despite lapse of more than 5 years since grant of license.
5.	M/s GULF MARKETING INTERNATIONAL, Office/godown: Gulf House 10&11-B/2 , Satellite Town Abdullah Jan Masjid Street Near Kali Tanki , Rawalpindi Rawalpindi	Malik Asad Zaman Medical laboratory technology	Muhammad Shafiq Aakfa Batool	Deferred for re-inspection of the applicant with following panel: Dr. Ghayour Ahmad, DD, DRAP, Isb.

	ELI-00194			
6.	<p>M/s Nisa Impex, Office: Office 1, First Floor, Maxim Arcade, Plot 13 14, Usman Block, Jeddah Town Ph1, GT road, Islamabad</p> <p>Godown: office No. 2, 1st floor, akbar khan plaza college road, tehsil & district Rawalpindi.</p> <p>ELI-00064</p>	Babar Hamid Pharm D	M Inayat ullah Rakshanda anjum M wassi shan	<p>Deferred for re-inspection of the applicant with following panel:</p> <p>Mr. Asif Iqbal, DD, DRAP, Isb.</p> <p>However the board took serious notice on not informing the board on change of godown and qualified person and asked to be careful in future in conduct of business in accordance with Medical Devices Rules 2017.</p>
7.	<p>M/s Mediland Pakistan (pvt) ltd, Office: Office B-09, 2nd floor Masood Arcade, I.J.P Road Near Saidpur Road, Rawalpindi Islamabad</p> <p>Godown: SHOP B-16, LOWER GROUND FLOOR, MASOOD ARCADE, IJP ROAD, RAWALPINDI</p> <p>ELI-00202</p>	Naveed Akhtar	Ghulam murtaza tariq Abdul shakoor Afrat javeed Naveed Akhtar Shahid mehmood.	<p>Deferred for re-inspection of the applicant with following panel:</p> <p>Mr. Ahsan ul Haq Athar, DD, DRAP, Isb</p>

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

(DEFERRED CASES FOR RENEWAL OF -ELI):

1.	<p>M/s Organs Pharma</p> <p>Office/Godown: Block-A, 6th Floor, Plot No. FD 35-36,A7, ST-1, Sector 38, National Industrial Park, Korangi Creek, Karachi.</p> <p>ELI-00403</p>	Rehana Yousaf Pharm D	Kashif Rahman Saif Ur Rehman Atiq Ur Rehman	Approved
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2.	<p>M/s Business Medical International, Suit No 203, 2nd Floor Hafeez Center, Shahrah e faisal Karachi.</p> <p>Godown:</p> <p>Plot No. C-16, Block 7/8, K.A.E.C.H.S, Karachi</p> <p>New Office address and godown: Suite 101 & 102, Trade Centre, Plot No. 23/F, Commercial Area, Mohammad Ali Society, Karachi (ELI-00262)</p>	<p>Jamshed Iqbal</p> <p>BS</p> <p>Biotechnology</p>	<p>Muhammad Nadeem</p> <p>CEO</p>	Approved
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Item No. I(E): ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES - INVALID

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

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

S.NO.	Name of Firm	Renewal Due Date	Date of Renewal Application	Decision
1.	<p>M/s Shamco trader (Pvt)</p> <p>Office/Godown: 174-A, Ahmed Block, new garden town, Lahore.</p> <p>ELI No. 00102</p>	03-08-2023	Not submitted	<p>The board observed that the firm has applied for renewal of license even after expiry of one year grace period given in the medical devices rules 2017 (Rule 7(5) of Medical Devices Rules 2017) therefore it was decided to declare the license invalid. Accordingly, all the enlistment / registrations granted to the firm have also become invalid and fresh applications need to be submitted for both the purposes.</p> <p>Therefore the Board decided to issue show cause</p>

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

Evaluator: Saadat Ali Khan (Deputy Director)

CASES RECEIVED ON CASE MANAGEMEMTN SYSTEM:

S. No	Name of Applicant(s)	Name of Manufacturer	Medical Device	Decision
1.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 0863713915.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 10-12-2022</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>	<p>Mindray Carbohydrate Antigen 242 (CLIA) Kit with Carbohydrate 242 Calibrators and controls</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: Reagent: 2×50 tests, 2×100 tests Calibrators: C0: 1×1.2ml C1: 1×1.0ml C2: 1×1.5ml</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA).
2.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p>	<p>Mindray Carbohydrate antigen CA50 Kit with calibrator (CLIA)</p> <p>Applied as Kit: Class-C</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory

	<p>Date of R&I 22-02-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 785233881.</p>	<p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Western Drug Supervision Network Bureau (as translated by Google through online) Validity: 11-02-2023 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>	<p>Shelf life: 18 months Codes/Model/Sizes:</p>	<p>authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). 3. Demanded codes as per FSC.</p>
3.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 30-12-2022 Fee Details: Paid Fee: 50,000/- Fee Challan No: 7347560139.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p>	<p>Mindray Brain natriuretic peptide (BNP) Calibrator Kit Applied as Kit: Class-C Shelf life: 18 months Codes/Model/Sizes:</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of Germany with demanded codes.</p>

		<ul style="list-style-type: none"> • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 		
4.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 30-12-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 305787905970.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>	<p>Mindray Brain natriuretic peptide (BNP) Kit B-type Natriuretic peptide (CLIA). Applied as Kit: Class-C</p> <p>Shelf life: 18 months Codes/Model/Sizes:</p>	<p>Deferred for the following: Valid legalized Free Sale Certificate of Germany with demanded codes.</p>
5.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2023 Fee Details: Paid Fee: 5,000/- Fee Challan No: 0863713915.</p>	<p>Name of manufacturer (as per Form-7A): M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of</p>	<p>Mindray Endoscope camera system. Applied as Cluster: Class-A Shelf life: 18 months Codes/Model/Sizes: HD-3</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). 3. Clarification of the difference in address of manufacturer in</p>

		<p>notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 09-04-2023</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> • EU QMS certificate (IVDR): <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 14-12-2025.</p>		<p>FSC & application.</p> <p>4. Justification of the class of the applied product.</p>
6.	<p>MR Medical Pakistan Private Limited</p> <p>Address:</p> <p>Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan.</p> <p>(ELI-01008)</p> <p>Date of R&I 12-10-2023</p> <p>Fee Details:</p> <p>Paid Fee: 5,000/- Fee Challan No: 5516241223.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 09-04-2023</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> • EU QMS certificate (IVDR): <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 14-12-2025.</p>	<p>Mindray</p> <p>Endoscope camera system (U1)</p> <p>Applied as Cluster: Class-A</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: U1</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). 3. Clarification of the difference in address of manufacturer in FSC & application. 4. Justification of the class of the applied product.

7.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 12-10-2023</p> <p>Fee Details: Paid Fee: 5,000/- Fee Challan No: 811140894037</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 19-02-2023</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>	<p>Mindray</p> <p>Endoscope camera system (R1)</p> <p>Applied as Cluster: Class-A</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: R1</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). Justification of the class of the applied product.
8.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 12-10-2023</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 6632336464.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network</p>	<p>Mindray</p> <p>Endoscope Light source.</p> <p>Applied as Kit: Class-B</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: HB300R</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). Justification of the class of the applied product.

		<p>Bureau (as translated by Google through online)</p> <p>Validity: 19-02-2023</p> <ul style="list-style-type: none"> ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> EU QMS certificate (IVDR): <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 14-12-2025.</p>		
9.	<p>MR Medical Pakistan Private Limited</p> <p>Address:</p> <p>Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan.</p> <p>(ELI-01008)</p> <p>Date of R&I 12-10-2023</p> <p>Fee Details:</p> <p>Paid Fee: 5,000/- Fee Challan No: 9135636507.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 19-02-2023</p> <ul style="list-style-type: none"> ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> EU QMS certificate (IVDR): <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 14-12-2025.</p>	<p>Mindray</p> <p>Endoscope Light source.</p> <p>Applied as Cluster: Class-B</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: HB3000L, HB2000L</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). 3. Clarification of the difference in address of manufacturer in FSC & application. 4. Justification of the class of the applied product. 5. Justification grouping along with submission catalog & fee as per current SRO.
10.	<p>MR Medical Pakistan Private Limited</p> <p>Address:</p> <p>Office no: 1101, 11th</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th</p>	<p>Mindray</p> <p>Diagnostic ultrasound system.</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Justification of the class of the applied

	<p>floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 26-10-2023</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 0258402104.</p>	<p>Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Germany</p> <p>Issuance Date: 21-08-2023</p> <p>Validity: Not mentioned</p> <p>• ISO 13485:</p> <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR):</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 14-12-2025.</p>	<p>Applied as Kit: Class-B</p> <p>Shelf life: 10 years</p> <p>Codes/Model/Sizes: DC-60EXP</p>	<p>product.</p> <p>2. Justification grouping along with submission catalog & fee for system as per current SRO.</p>
11.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 12-10-2023</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 4286774954.</p>	<p>Legal Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>Manufacturer:</p> <p>M/S Nanjing Mindray Bio-Medical Electronics Co., Ltd.</p> <p>666# Middle Zhengfang Road Jiangning 211111 Nanjing, Jiangsu People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Embassy</p>	<p>Mindray Insufflator</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: HS -50F</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA).

		<p>attested copy Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 09-04-2023</p> <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 		
12.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 26-10-2023 Fee Details: Paid Fee: 25,000/- Fee Challan No: 4102275683.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Western Drug Supervision Network Bureau (as translated by Google through online) <p>Validity: 12-10-2022</p> <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	<p>Mindray Diagnostic ultrasound system.</p> <p>Applied as System: Class-B</p> <p>Shelf life: 10 years</p> <p>Codes/Model/Sizes: ME-7, MX7</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). Justification of the class of the applied product. Justification grouping along with submission catalog & fee as per current SRO for system. One system shall be considered in the current application for the rest the firm shall apply separately via online MDMC portal.

13.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 26-10-2023</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 280096341543</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Germany</p> <p>Issuance Date: 21-08-2023</p> <p>Validity: Not mentioned</p> <p>ISO 13485:</p> <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <p>EU QMS certificate (IVDR):</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 14-12-2025.</p>	<p>Mindray</p> <p>Diagnostic ultrasound system.</p> <p>Applied as System: Class-B</p> <p>Shelf life: 10 years</p> <p>Codes/Model/Sizes: TEX20</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Justification of the class of the applied product. Justification grouping along with submission catalog & fee as per current SRO for system.
14.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 23-02-2023</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 268158915.</p>	<p>Name of manufacturer (as per Form-7A):</p> <p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by</p>	<p>Mindray</p> <p>Hematology Control</p> <p>Applied as Kit: Class-B</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes: BC-5D:</p> <p>H : 3mL×1 , 3mL×6 ;</p> <p>N : 3mL×1 , 3mL×6 ;</p> <p>L : 3mL×1 , 3mL×6 ;</p> <p>H : 3mL×1 , N : 3mL×1 , L : 3mL×1 ;</p> <p>H : 3mL×2 , N : 3mL×2 , L : 3mL×2</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA).

		<p>Google through online)</p> <p>Validity: 07-01-2027</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>		
15.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 23-12-2023</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 572569866.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>	<p>Mindray Auto-Hematology Analyzer BC-5800 and its Reagent Applied as Cluster: Class-B Shelf life: Analyzer: 5 years Reagents 24 Months Model M-58 LEO (I) Lyse M-58 LEO (II) Lyse M-58 LH Lyse M-58 LBA Lyse M-58 D Diluent.</p>	<p>Deferred for the followings: Justification grouping along with submission catalog & fee as per current SRO for cluster.</p>
16.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p>	<p>Name of manufacturer (as per Form-7A): M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan,</p>	<p>Mindray Anti Mullerian hormone kit with AMH calibrators Applied as System: Class-B Shelf life: 18 months</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE</p>

	<p>Date of R&I 30-12-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 33802351257.</p>	<p>518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 31-08-2026</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025.</p>	<p>Codes/Model/Sizes: 2 × 50 tests , 2 × 100 tests</p>	<p>(FQA).</p> <p>2. Justification grouping as applied as system along with submission catalog & fee as per current SRO for system.</p>
17.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2022 Fee Details: Paid Fee: 5,000/- Fee Challan No: 878129065738.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p>	<p>Mindray Reagents for BC-6000 -6200 Hematology Analyzer. Applied as Cluster: Class-B Shelf life: M-6 LH Lyse: 2 years M-6 LB Lyse: 2 years M-6 LN Lyse: 2 years M-6 LD Lyse: 2 years M-6 DR Diluent: 2 years M-6 DS Diluent: 2 years M-6 FD Dye: 1 year M-6 FN Dye: 1 year M-6FR Dye: 1 year DS Diluent: 2 years Model M-6 DR Diluent M-6 LD Lyse M-6LN Lyse M-6LB Lyse M-6LH Lyse</p>	<p>Deferred for the followings:</p> <p>1. Justification grouping along with submission catalog & fee as per current SRO for cluster.</p>

		<ul style="list-style-type: none"> • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	M-6 FN Dye M-6 FR Dye M-6 FD Dye DS Diluent Probe Cleanser	
18.	MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008) Date of R&I 20-12-2022 Fee Details: Paid Fee: 25,000/- Fee Challan No: 91488995.	Name of manufacturer (as per Form-7A): M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China. LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Drug Supervision Network Bureau (as translated by Google through online) Validity: 04-05-2026 • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	Mindray Total Protein Kit (Biuret Method) with Calibrator (Multi Sera Calibrators) and Controls (ClinChem Multi Control) Applied as Kit: Class-B Shelf life: 18 months Codes/Model/Sizes: Reagents: 196ml R1:4×38ml, R2:4×11ml 308ml: R1:4×60ml, R2: 4×17ml 900ml: R1:3×240ml, R2: 1×180ml multi sera calibrator: 2×30ml, 1×30ml ClinChem Multi Controls: level 20×5ml, 10×5ml, 6×5ml, 1×5ml Level 2: 20×5ml, 10×5ml, 6×5ml, 1×5ml	Deferred for the followings: 1. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA).

19.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 01-08-2022</p> <p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 16072766.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 19-02-2023</p> <ul style="list-style-type: none"> ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> EC (FQA) certificate: <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 26-05-2024.</p>	<p>Mindray</p> <p>Central Monitoring System</p> <p>Applied as Family: Class-C</p> <p>Shelf life: 10 years</p> <p>Codes/Model/Sizes: BENEVISION / HYPERSIPORX</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). 3. Justification grouping along with submission catalog & fee as per current SRO for system. One system shall be considered in the current application for the rest the firm shall apply separately via online MDMC portal.
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20.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 20-12-2022</p> <p>Fee Details: Paid Fee: 25,000/- Fee Challan No: 87673134456.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 13-12-2023</p> <ul style="list-style-type: none"> ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> EC (FQA) certificate: <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 26-05-2024.</p>	<p>Mindray</p> <p>Albumin Kit (Bromcresol Green Method) with calibrators (Multi Sera Calibrator) and controls (ClinChem Multi Control)</p> <p>Applied as Family: Class-C</p> <p>Shelf life: 18 months</p> <p>Calibrator Shelf life: 24 months</p> <p>Control Shelf Life: 24 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. 2. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). 3. Justification grouping along with submission catalog & fee as per current SRO for Family. 4. Codes as per FSC.
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21.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2022 Fee Details: Paid Fee: 50,000/- Fee Challan No: 98082370669.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	<p>Mindray Anti TP Control Applied as Cluster: Class-C Shelf life: 24 months Codes/Model/Sizes:</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of any Reference Regulatory authority with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO for that group.</p>
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22.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2022</p> <p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 7419503044.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	<p>Mindray Squamous Cell Carcinoma Antigen - SccA Kit Applied as Kit: Class-C Shelf life: 21 months for each kit & calibrator Codes/Model/Sizes:</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of any Reference Regulatory authority with applied codes. 2. Justification grouping along with submission catalog</p>
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23.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 34318069748.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 • EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	<p>Mindray proGRP Assay (CLIA)</p> <p>Applied as : Class-C</p> <p>Shelf life: Form-7A not present</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of any Reference Regulatory authority with applied codes 2. Form-7A dully signed by the company authorized person. 3. Justification grouping along with submission catalog.
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24.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2023</p> <p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 596387764.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA</p> <p>Type: Scan copy of non-notarized copy.</p> <p>Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC <p>Type: Scan copy of notarized & Embassy attested copy</p> <p>Issued By: Western Drug Supervision Network Bureau (as translated by Google through online)</p> <p>Validity: 13-12-2023</p> <ul style="list-style-type: none"> ISO 13485: <p>Type: Scan copy of non-notarized copy</p> <p>Validity: 31-08-2026</p> <ul style="list-style-type: none"> EC (FQA) certificate: <p>Type: Scan copy of non-notarized copy.</p> <p>Validity: 26-05-2024.</p>	<p>Mindray</p> <p>Human Epididymal Protein 4 HE4 Kit with calibrator (CLIA).</p> <p>Applied as Kit: Class-C</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority. Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA). Justification grouping along with submission catalog Codes as per FSC.
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25.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 22-02-2023 Fee Details: Paid Fee: 50,000/- Fee Challan No: 82290741606.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027 • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 02-02-2021 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026</p> <p>• EC(FQA) certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 06-05-2024.</p>	<p>Mindray Glucose kit (GOD-POD METHOD) Applied as :Kit Class-C Shelf life: 18 months Codes/Model/Sizes:</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of any Reference Regulatory authority with codes 2. Justification grouping along with submission catalog.</p>
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26.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 28-12-2023</p> <p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 22938648265.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 07-02-2024 Validity: Not mentioned <p>Validity: 13-12-2023</p> <ul style="list-style-type: none"> • ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 • EC (FQA) certificate: Type: Scan copy of non-notarized copy. Validity: 26-05-2024. 	<p>Mindray Electrosurgical Platform</p> <p>Applied as family: Class-C</p> <p>Shelf life: 10 years</p> <p>Codes/Model/Sizes: EP 300 EP 300B EP 300C EP 300D</p>	<p>Deferred for the followings: 1. Justification grouping along with submission catalog & fee as per current SRO for system. One system shall be considered in the current application for the rest the firm shall apply separately via online MDMC portal.</p>
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27.	<p>MR Medical Pakistan Private Limited Address: Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. (ELI-01008)</p> <p>Date of R&I 01-08-2022</p> <p>Fee Details: Paid Fee: 50,000/- Fee Challan No: 26511406800.</p>	<p>M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</p> <p>Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, People's Republic of China.</p> <p>LOA Type: Scan copy of non-notarized copy. Validity date: 04-04-2027</p> <ul style="list-style-type: none"> FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Drug Supervision Network Bureau (as translated by Google through online) <p>Validity: 16-07-2026</p> <ul style="list-style-type: none"> ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-08-2026 EU QMS certificate (IVDR): Type: Scan copy of non-notarized copy. Validity: 14-12-2025. 	<p>Mindray Antigen and antibodies to human immunodeficiency virus (CLIA)</p> <p>Applied as Kit: Class-D</p> <p>Shelf life: 18 months</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> Valid legalized Free Sale Certificate of any Reference Regulatory authority or valid notarized CE (FQA) plus Design Examination Certificate. Justification grouping along with submission catalog Codes as per FSC.
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28.	<p>M/S Global Marketing Services (ELI- 00109)</p> <p>Date of R&I 23-09-2022</p> <p>Fee Details: Paid Fee: 50,000/- Fee</p> <p>Challan No: 26511406800.</p>	<p>Legal Manufacturer: BioMérieux Inc. 100 Rodolphe Street Durham, North Carolina 27712 – USA</p> <p>Manufacturing Site: BioMérieux, Inc. 595 Anglum Road, Hazelwood, Missouri 63042 USA</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-03-2026</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: CCIP France Issued date: 02-07-2024 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 17-12-2027</p>	<p>VITEK DENSICHEK Bacterial Suspension Turbidity Meter</p> <p>Apply as: System</p> <p>Shelf life: N/A</p> <p>Class: A</p> <p>Codes: VITEK DENSICHEK pod 423000 VITEK DENSICHEK Display Base 422220 VITEK DENSICHEK Connectivity Base 422221</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO for system. 3. Form-7A duly signed by company authorized person.
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29.	<p>M/S Global Marketing Services (ELI- 00109)</p> <p>Date of R&I 16-12-2021</p>	<p>Legal Manufacturer: Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA</p> <p>Manufacturer: Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France</p> <p>Manufacturer: COPAN ITALIA VIA F. PEROTTI, 10, 18 BRESCIA, Lombardy ITALY 25125</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-03-2026</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: CCIP France Issued date: 20-08-2018 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 18-12-2027 	<p>Xpert Nasal Sample Collection Kit.</p> <p>Apply as : Kit</p> <p>Shelf life: 18 months</p> <p>Class: A</p> <p>Codes: SWAB/F-100</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO. 3. Form-7A duly signed by company authorized person. 4. Fee evidence
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30.	<p>M/S Global Marketing Services (ELI- 00109)</p> <p>Date of R&I 16-12-2021</p>	<p>Legal Manufacturer: Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA</p> <p>Manufacturer: Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA</p> <p>Manufacturer: COPAN ITALIA VIA F. PEROTTI, 10, 18 BRESCIA, Lombardy ITALY 25125</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-03-2026</p> <ul style="list-style-type: none"> • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: CCIP France Issued date: 20-08-2018 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 18-12-2027 	<p>Xpert Nasopharyngeal Sample Collection Kit</p> <p>Apply as : Kit</p> <p>Shelf life: 18 months</p> <p>Class: A</p> <p>Codes: SWAB/B-100</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO. 3. Form-7A duly signed by company authorized person. 4. Fee evidence
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31.	<p>M/s Radiant Medical Private Limited Address: 06-Sher Shah Block New Garden Town Lahore, Pakistan Lic. No: ELI-00135</p> <p>Date of R&I 13-06-2024 Fee Details: Paid Fee: 50,000/- Fee Challan No: 59192959891.</p>	<p>M/S Livetec Ingenieurbüro GmbH Marie-Curie-Strasse 8 79539 Lorrach Germany.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2026.</p> <ul style="list-style-type: none"> FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Germany Issuance Date: 16-10-2023 Validity: Not mentioned ISO 13485: Type: Scan copy of notarized copy Validity: 14-04-2028 	<p>Pace T20 Pacemaker External Cardiac Pacemaker</p> <p>Applied as family: Class-C</p> <p>Shelf life: 7 years</p> <p>Codes/Model/Sizes: 103722.</p>	<p>Deferred for provision of shelf life studies. Further more the MDB decided to call for personal hearing to both the firms i.e M/S Novatek Pakistan and M/s Radiant Medical Lahore for clarification about the valid Letter of Authorization about the said product.</p>
32.	<p>M/s Radiant Medical Private Limited Address: 06-Sher Shah Block New Garden Town Lahore, Pakistan Lic. No: ELI-00135</p> <p>Date of R&I 28-01-2025 Fee Details: Paid Fee: 6000/- Fee Challan No: 593740134.</p>	<p>Legal Manufacturer: M/s Inami & Co. Ltd., 24-2, Hongo 3- Chome, Bunkyo-ku, Tokyo 113-0033, Japan.</p> <p>Manufacturing Site (as per FSC): M/s Inami & Co. Ltd., Bijyogi Research Institute, No.14-13, Bijyogi3-chome, Toda City, Saitama Prefecture, Japan.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 01-10-2025.</p> <ul style="list-style-type: none"> FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Japan Issuance Date: 26-02-2020 Validity: Not mentioned 	<p>L-5110 Applanation Tonometer</p> <p>Applied as family: Class-A</p> <p>Shelf life: 7 years</p> <p>Codes/Model/Sizes: L-5110</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Valid notarized LOA 3. Justification of Class 4. Justification grouping along with submission catalog & fee as per current SRO.

		<ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy Validity: 31-07-2027</p>		
33.	<p>M/s Radiant Medical Private Limited Address: 06-Sher Shah Block New Garden Town Lahore, Pakistan Lic. No: ELI-00135</p> <p>Date of R&I 27-05-2024 Fee Details: Paid Fee: 25,000/- Fee Challan No: 8532063569.</p>	<p>M/s Carestream Health Inc 150 Verona Street, Rochester, New York, USA 14608</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 02-10-2025.</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: USFDA Validity: 12-06-2026</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 02-10-2025</p>	<p>DRX Plus Detectors Digital Imaging System</p> <p>Applied as family: Class-B</p> <p>Shelf life: NA</p> <p>Codes/Model/Sizes: .</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Valid notarized LOA 3. Justification of Class 4. Justification grouping along with submission catalog & fee as per current SRO.
34.	<p>Perfect Medical System, D-442, D block, Satellite Town, Rawalpindi ELI-00964</p> <p>Date of R&I 09-02-2024 Slip No.: 68942658: Fee :31000/-</p>	<p>Spinreact S.A.U CR Santa Coloma NO. 7 SantEsteve, Spain.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 03-03-2026.</p> <p>• FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Spain Issuance Date: 11-07-2024 Validity: Not mentioned</p> <p>• ISO 13485:</p>	<p>Spinreact IVD (Serology Cluster)</p> <p>Applied as Cluster: Class-B</p> <p>Shelf life: 1.5 Years</p> <p>Codes/Model/Sizes: .</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO. 3. Form-7A with complete description of the applied product duly signed by company authorized person. 4. Valid notarized ISO

		Type: Scan copy of notarized copy Validity: 29-05-2025		13485 5.Stability Study data/evidence
35.	Perfect Medical System, D-442, D block, Satellite Town, Rawalpindi ELI-00964 Date of R&I 09-02-2024 Slip 600165423932: :31000/- No.: Fee	Spinreact S.A.U CR Santa Coloma NO. 7 SantEsteve, Spain. LOA Type: Scan copy of notarized copy. Validity date: 03-03-2026. • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Spain Issuance Date: 11-07-2024 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 29-05-2025	Spinreact IVD (Immuno turbidimetry Serum Proteins Cluster) Applied as Cluster: Class-B Shelf life: 1.5 Years Codes/Model/Sizes: .	Deferred for the followings: 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO. 3. Form-7A with complete description of the applied product duly signed by company authorized person. 4. Valid notarized ISO 13485 5.Stability Study data/evidence
36.	Perfect Medical System, D-442, D block, Satellite Town, Rawalpindi ELI-00964 Date of R&I 09-02-2024 Slip 456772508437: :31000/- No.: Fee	Spinreact S.A.U CR Santa Coloma NO. 7 SantEsteve, Spain. LOA Type: Scan copy of notarized copy. Validity date: 03-03-2026. • FSC Type: Scan copy of notarized & Embassy attested copy Issued By: Spain Issuance Date: 11-07-2024 Validity: Not mentioned • ISO 13485: Type: Scan copy of notarized copy Validity: 29-05-2025	Spinreact IVD (Turbilatex Cluster) Applied as Cluster: Class-B Shelf life: 1.5 Years Codes/Model/Sizes: .	Deferred for the followings: 1. Valid legalized Free Sale Certificate of the country of origin or any RRA with applied codes. 2. Justification grouping along with submission catalog & fee as per current SRO. 3. Form-7A with complete description of the applied product duly signed by company authorized person. 4. Valid notarized ISO 13485 5.Stability Study data/evidence

37.	<p>Tech Zone Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore ELI- 00040</p> <p>Date of R&I 26-06-2024 Slip No.: 8433902103: Fee :5000/-</p>	<p>Zhejiang Longterm Medical Technology Co., Ltd., Shuang Shan Road 277, Fuxi Substrict, Deqing County, 313200 Huzhou City, Zhejiang Province, People's Republic of China</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 21-10-2028.</p> <p>• FSC Not attached</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 31-03-2025</p> <p>EU Quality Assurance Certificate (MDR) Type: Scan copy of notarized copy Validity: 10-04-2028</p>	<p>INNOMED Hydrocolloid Dressing Applied as Cluster: Class-A Shelf life: 3 Years Codes/Model/Sizes: 5cm×5cm, 5cm×10cm, 5cm×15cm, 5cm×20cm, 6cm×7.6cm, 7.5cm×7.5cm, 8 cm×12cm , 10cm×10cm , 10cm×11cm , 10cm×12cm , 10cm×15cm , 10cm×20cm , 10cm×25cm , 10cm×30cm , 10cm×35cm , 12cm×14cm, 14.3cm×15.6cm, 15cm×15cm, 15cm×18cm , 15cm×20cm , 20cm×20cm , 20cm×25cm, 20cm×30cm</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of the country of origin issued by concerned regulatory authority or any RRA with applied codes. 2. Justification of class 3. Justification grouping along with submission catalog & fee as per current SRO. 4. Form-7A with complete annex of the applied product duly signed by company authorized person. 5. Valid notarized ISO 13485</p>
38.	<p>Tech Zone Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore ELI- 00040</p> <p>Date of R&I 28-04-2025 Slip No.:</p>	<p>Zhejiang Haisheng Medical Device Co.,Ltd No.8 Zhenyuan Road, Yuecheng District, Shaoxing City, Zhejiang Province, China.</p> <p>LOA Type: Scan copy of not</p>	<p>HISERN Disposable Electrosurgical Pencil Applied as Single: Class-B Shelf life: 5 Years Codes/Model/Sizes:</p>	<p>Deferred for the followings: 1. Valid legalized Free Sale Certificate of any RRA or valid notarized CE (FQA). 2. Justification of class 3. Justification grouping along with</p>

	939909009173: Fee :31,000/-	<p>notarized copy. Validity date: 21-01-2028.</p> <ul style="list-style-type: none"> FSC Type: Scan copy of notarized & Apostille copy Issued by: Zhejiang Medical Product Administration Validity: 11-05-2026 ISO 13485: Type: Scan copy of notarized copy Validity: 30-11-2026 <p>EC (Full Quality Assurance) Type: Scan copy of notarized copy Validity: 03-03-2024</p>	HEP4、HEP7、HEP8、 HEP10、HEP12、 HEP14、HEP16	submission catalog & fee as per current SRO.
39.	Tech Zone Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore ELI- 00040 Date of R&I 28-04-2025 Slip No.: 5586528103: Fee :31,000/-	<p>Zhejiang Haisheng Medical Device Co.,Ltd No.8 Zhenyuan Road, Yuecheng District, Shaoxing City, Zhejiang Province, China.</p> <p>LOA Type: Scan copy of not notarized copy. Validity date: 21-01-2028.</p> <ul style="list-style-type: none"> FSC Type: Scan copy of notarized & Apostille copy Issued by: Zhejiang Medical Product Administration Validity: 11-05-2026 ISO 13485: Type: Scan copy of notarized copy Validity: 30-11-2026 <p>EC (Full Quality Assurance) Type: Scan copy of notarized copy Validity: 03-03-2024</p>	<p>HISERN Anesthesia Mask</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 5 Years</p> <p>Codes/Model/Sizes: Inflatable、Non-Inflatable</p> <p>Size: Newborn、 Infant、Child、Adult (Small/S)、Adult (Medium/M)、 Adult(Large/L)</p>	Deferred for the followings: 1. Valid legalized Free Sale Certificate of any RRA or valid notarized CE (FQA). 2. Justification grouping along with submission catalog & fee as per current SRO.

40.	<p>Tech Zone Ground Floor, Weal House, 8 Faiz Road Old Muslim Town Lahore ELI- 00040</p> <p>Date of R&I 28-04-2025</p> <p>Slip 164375843165:</p> <p>Fee :31,000/-</p>	<p>Zhejiang Haisheng Medical Device Co.,Ltd</p> <p>No.8 Zhenyuan Road, Yuecheng District, Shaoxing City, Zhejiang Province, China.</p> <p>LOA</p> <p>Type: Scan copy of not notarized copy.</p> <p>Validity date: 21-01-2028.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized & Apostille copy</p> <p>Issued by: Zhejiang Medical Product Administration</p> <p>Validity: 11-05-2026</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy</p> <p>Validity: 30-11-2026</p> <p>EC (Full Quality Assurance)</p> <p>Type: Scan copy of notarized copy</p> <p>Validity: 03-03-2024</p>	<p>HISERN</p> <p>Disposable Pressure Transducer</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 5 Years</p> <p>Codes/Model/Sizes:</p> <p>DBPT-0103, DBPT-0130, DBPT-0203, DBPT-0230, DBPT-0303, DBPT-0330, DBPT-0403, DBPT-0430, DBPT-0503C3, DBPT-0503C5, DBPT-0503C10, DBPT-0530C3, DBPT-0530C5, DBPT-0530C10, DBPT-0603C3, DBPT-0603C5, DBPT-0603C10, DBPT-0630C3, DBPT-0630C5, DBPT-0630C10, DBPT-0703C3, DBPT-0703C5, DBPT-0703C10, DBPT-0730C3, DBPT-0730C5, DBPT-0730C10, DBPT-0803C3, DBPT-0803C5, DBPT-0803C10, DBPT-0830C3, DBPT-0830C5, DBPT-</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized Free Sale Certificate of any RRA or valid notarized CE (FQA). 2. Justification of class 3. Justification grouping along with submission catalog & fee as per current SRO.
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			0830C10、DBPT-0903、DBPT-0930.	
41.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I 15-03-2023 Slip No.: 35719974110 Fee :25,000/-</p>	<p>Shenzhen Lifotronic Technology Co., Ltd.</p> <p>Address as per Form-7A & Germany FSc:</p> <p>Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>Address as per FSC (China):</p> <p>No. 2, Changhua Road, Songshan Lake Park, 523828 Dongguan City, Guangdong Province, P.R China.</p> <p>LOA Type: Scan copy of not notarized copy. Validity date: 31-12-2027.</p> <p>• FSC Type: Scan copy of not notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 10-09-2026.</p> <p>• FSC Type: Scan copy of notarized copy Issued by: Germany Issuance date: 03-08-2023 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 12-12-2026</p>	<p>Lifotronic Air Compression Therapy System</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 10 Years</p> <p>Codes/Model/Sizes: Airpro-300, Airpro-600</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Justification of class 2. Clarification of difference in manufacturing address in FSC (China) & FSC (Germany) 3. Justification grouping along with submission catalog & fee as per current SRO. If the product is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal. 4. Valid Notarized LOA
42.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p>	<p>Shenzhen Lifotronic Technology Co., Ltd.</p> <p>Address as per Form-7A & Germany FSc:</p> <p>Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City,</p>	<p>Lifotronic Airway Clearance System.</p> <p>Applied as Single: Class-B</p> <p>Shelf life: 10 Years</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Justification of class 2. Clarification of difference in manufacturing address in FSC (China) & FSC

	<p>Date of R&I 15-03-2023 Slip No.: 93575398519 Fee :25,000/-</p>	<p>Guangdong Province, 518055, P.R China.</p> <p>Address as per FSC (China): No. 2, Changhua Road, Songshan Lake Park, 523828 Dongguan City, Guangdong Province, P.R China.</p> <p>LOA</p> <p>Type: Scan copy of not notarized copy.</p> <p>Validity date: 31-12-2027.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of not notarized copy</p> <p>Issued by: Not confirmed as it is in Chinese Language</p> <p>Validity: 10-09-2026.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of not notarized copy</p> <p>Issued by: Germany</p> <p>Issuance date: 03-08-2023</p> <p>Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of not notarized copy</p> <p>Validity: 12-12-2026</p>	<p>Codes/Model/Sizes: PV-100</p>	<p>(Germany)</p> <p>3. Justification grouping along with submission catalog & fee as per current SRO. If the product is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal.</p> <p>4. Valid Notarized LOA</p>
43.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I 15-03-2023 Slip No.: 95277264679 Fee :5,000/-</p>	<p>Shenzhen Lifotronic Technology Co., Ltd.</p> <p>Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>LOA</p> <p>Type: Scan copy of not notarized copy.</p> <p>Validity date: 31-12-2027.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of not notarized copy</p> <p>Issued by: Not confirmed</p>	<p>Lifotronic Canister</p> <p>Applied as Family: Class-A</p> <p>Shelf life: 3 Years</p> <p>Codes/Model/Sizes: CS300 CS500 CL500 CL1000</p>	<p>Deferred for the followings:</p> <p>1. Justification of class</p> <p>2. Justification grouping along with submission catalog & fee as per current SRO. If the product is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal.</p> <p>3. Valid Notarized LOA</p>

		<p>as it is in Chinese Language Validity: 04-01-2026.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized copy Issued by: Germany Issuance date: 03-08-2023 Validity: Not mentioned</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy Validity: 12-12-2026</p>	
44.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I 15-03-2023 Slip No.: 7981694475 Fee :25,000/-</p>	<p>Shenzhen Lifotronic Technology Co., Ltd. Address as per Form-7A & EC: Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>Legal manufacturer Address as per FSC (China): No. 2, Changhua Road, Songshan Lake Park, 523828 Dongguan City, Guangdong Province, P.R China.</p> <p>LOA Type: Scan copy of not notarized copy. Validity date: 31-12-2027.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of not notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 10-09-2026.</p> <ul style="list-style-type: none"> • EU QMS (MDR) <p>Type: Scan copy of notarized copy Issued by: TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123. Validity: 16-10-2028</p>	<p>Lifotronic High-flow Humidification Device Applied as Family: Class-B Shelf life: 10 Years Codes/Model/Sizes: <input type="checkbox"/> Hi-800 <input type="checkbox"/> Hi-600</p> <p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Clarification of difference in manufacturing address in FSC (China) & FSC (Germany) 2. Justification grouping along with submission catalog & fee as per current SRO. If the product is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal. 3. Valid Notarized LOA

		<ul style="list-style-type: none"> • ISO 13485: Type: Scan copy of notarized copy Validity: 12-12-2026 		
45.	Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926) Date of R&I 15-03-2023 Slip No.: 42209637677 Fee :25,000/-	<p>Shenzhen Lifotronic Technology Co., Ltd.</p> <p>Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>LOA Type: Scan copy of not notarized copy. Validity date: 31-12-2027.</p> <p>• FSC Type: Scan copy of not notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 04-01-2026.</p> <p>• FSC Type: Scan copy of notarized copy Issued by: Germany Issuance date: 03-08-2023 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 12-12-2026</p>	<p>Lifotronic Patient Interfaces (Nasal Cannula)</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 3 Years</p> <p>Codes/Model/Sizes: Hi-NAL-L Hi-NAL-M Hi-NAL-S</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of any RRA or valid legalized FSC of country of original wherein the product with applied codes shall be mentioned plus valid notarized CE. 2. Justification grouping along with submission catalog & fee as per current SRO. If the product is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal. 3. Valid Notarized LOA
46.	Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926) Date of R&I 15-03-2023 Slip No.: 69286570 Fee :5,000/-	<p>Shenzhen Lifotronic Technology Co., Ltd.</p> <p>Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>LOA Type: Scan copy of not notarized copy. Validity date: 31-12-2027.</p>	<p>Lifotronic Sleeve</p> <p>Applied as Family: Class-A</p> <p>Shelf life: Reusable: 2 years storage, Single Use: 1 year storage</p> <p>Codes/Model/Sizes:</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of any RRA or valid legalized FSC of country of original wherein the product with applied codes shall be mentioned. 2. Justification grouping along with submission catalog & fee as per current SRO. If the product

		<ul style="list-style-type: none"> FSC Type: Scan copy of not notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 04-01-2026. FSC Type: Scan copy of notarized copy Issued by: Germany Issuance date: 03-08-2023 Validity: Not mentioned ISO 13485: Type: Scan copy of notarized copy Validity: 12-12-2026 		is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal. 3. Valid Notarized LOA
47.	Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926) Date of R&I 15-03-2023 Slip No.: 6499500019 Fee :5,000/-	Shenzhen Lifotronic Technology Co., Ltd. Address as per Form-7A & FSC (Germany): Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China. Legal manufacturer Address as per FSC (China): No. 2, Changhua Road, Songshan Lake Park, 523828 Dongguan City, Guangdong Province, P.R China. LOA Type: Scan copy of not notarized copy. Validity date: 31-12-2027. <ul style="list-style-type: none"> FSC Type: Scan copy of not notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 10-09-2026. FSC Type: Scan copy of notarized copy 	Lifotronic Warming Blanket Applied as Family: Class-A Shelf life: 3 Years Codes/Model/Sizes: UP-121, LW-150, FU-221, UN-321, UN-332, SU-322, SR-521, LT-417, MA-421, PU-215, PL-314, PS-309, UL-415, US-409, LL-420, RL-420, ST-112, D-112	Deferred for the followings: 1. Clarification of difference in manufacturing address in FSC (China) & FSC (Germany) 2. Justification grouping along with submission catalog & fee as per current SRO. 3. Valid Notarized LOA

		<p>Issued by: Germany Issuance date: 03-08-2023 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 12-12-2026</p>		
48.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I 15-03-2023 Slip No.: 090786467. Fee :25,000/-</p>	<p>Shenzhen Lifotronic Technology Co., Ltd. Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 31-12-2027.</p> <p>• FSC Type: Scan copy of notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 4-01-2026.</p> <p>• FSC Type: Scan copy of notarized copy Issued by: Germany Issuance date: 03-08-2023 Validity: Not mentioned</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 12-12-2026</p>	<p>Lifotronic Tube and Chamber Kit</p> <p>Applied as Family: Class-B</p> <p>Shelf life: 3 Years</p> <p>Codes/Model/Sizes: Hi-OT1 Hi-OT2 Hi-OT3</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. Valid legalized FSC of any RRA or valid legalized FSC of country of original wherein the product with applied codes shall be mentioned plus valid notarized CE. 2. Justification grouping along with submission catalog & fee as per current SRO. If the product is system, one system will be considered in current application while firm shall apply separately for other via online MDMC portal. 3. Valid Notarized LOA
49.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I</p>	<p>Shenzhen Lifotronic Technology Co., Ltd. Unit A, 4th Floor, Building 15, Yijing Estate, No 1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R China.</p> <p>LOA Type: Scan copy of not</p>	<p>Lifotronic Lateral Flow Immunoassay Analyzer FA 160</p> <p>Applied as Kit: Class-A</p> <p>Shelf life: 5 Years</p> <p>Codes/Model/Sizes: FA 160</p>	<p>Deferred for the followings:</p> <ol style="list-style-type: none"> 1. R&I receiving of the application. 2. Evidence of submission of fee 3. Valid Notarized LOA

	<p>Not attached</p> <p>Slip No.: 6408462870.</p> <p>Fee :5,000/-</p>	<p>notarized copy.</p> <p>Validity date: 31-12-2027.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of not notarized copy</p> <p>Issued by: Not confirmed as it is in Chinese Language</p> <p>Validity: 28-09-2025.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of notarized copy</p> <p>Issued by: The Netherlands</p> <p>Validity: 01-02-2028</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy</p> <p>Validity: 12-12-2026</p>		
50.	<p>Moody Global Services</p> <p>Address:</p> <p>No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I 15-03-2023</p> <p>Slip No.: 2792023500</p> <p>Fee :5,000/-</p>	<p>Wheisman Medical technology Co., Ltd</p> <p>District 1101A, 16th Bldg., Tongfu Industrial Park, Houdikeng Shijia Community, Matian Street, , Guangdong District, Shenzhen City Guangdong Province, P.R China.</p> <p>LOA</p> <p>Type: Scan copy of notarized copy.</p> <p>Validity date: 15-05-2030.</p> <ul style="list-style-type: none"> • FSC <p>Type: Scan copy of not notarized copy</p> <p>Issued by: Not confirmed as it is in Chinese Language</p> <p>Validity: 02-04-2026.</p> <p>CE Extension letter attached.</p> <ul style="list-style-type: none"> • ISO 13485: <p>Type: Scan copy of notarized copy</p> <p>Validity: 06-03-2028</p>	<p>Lifotronic</p> <p>Auto 3-part Hematology Analyzer</p> <p>Applied as Kit: Class-A</p> <p>Shelf life: 30 months</p> <p>Codes/Model/Sizes: AC 310</p>	Deferred for clarification & justification of class and valid CE(FQA)

51.	<p>Moody Global Services Address: No 14, 2nd Floor, Mujahid Plaza, Jinnah Avenue, Blue Area, Islamabad 44000, Pakistan (ELI-00926)</p> <p>Date of R&I 15-03-2023 Slip No.: 1005179225 Fee :5,000/-</p>	<p>Wheisman Medical technology Co., Ltd District 1101A, 16th Bldg., Tongfu Industrial Park, Houdikeng Shijia Community, Matian Street, , Guangdong District, Shenzhen City Guangdong Province, P.R China.</p> <p>LOA Type: Scan copy of notarized copy. Validity date: 15-05-2030.</p> <p>• FSC Type: Scan copy of not notarized copy Issued by: Not confirmed as it is in Chinese Language Validity: 02-04-2026.</p> <p>CE Extension letter attached.</p> <p>• ISO 13485: Type: Scan copy of notarized copy Validity: 06-03-2028</p>	<p>Lifotronic Auto 5-part Hematology Analyzer Applied as Kit: Class-A Shelf life: 30 months Codes/Model/Sizes: AC 610</p>	Deferred for clarification & justification of class and valid CE(FQA)
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Evaluator: Ghavour Ahmad (Deputy Director):

1	<p>Global Health Care Midway Commercial Plaza No 20, back Side of Prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. ELI-00086</p> <p>R&I Date:26-05-2025</p> <p>Fee: 37000 fee challan No. 9639692607 & 25000 fee challan No. 1900268</p>	<p>M/s OK Biotech Co., Ltd No 91 Sec 2 Gongdao 5th Road, 30070 Hsinchu City Taiwan +886- 3-5160258 Fax +886-3-5160028 www.okbiotech.com</p> <p>LOA Expiry: 02-06-2027</p> <p>EC Certificate Expiry : 26- 05-2025</p> <p>FSC : Taiwan</p> <p>Expiry: 10-02-2030</p>	<p>Brand Name: OK meter Optima Blood Glucose Monitoring System, OEM Brand Easy Gluco Ultra Plus Blood Glucose strip</p> <p>Generic Name: Blood Glucose strip</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Models/Code/sizes (as per FSC & application): Ok-10H-0</p> <p>Shelf Life: 24 months</p>	Approved the product with code Ok-10H-0 subject to submission of differential fee.
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