

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

DECISIONS OF 125th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 16th MARCH 10, 2026 (MANUAL APPLICATIONS PART-II)

125th meeting of the Medical Device Board (MDB) was held in the committee room of Drug Regulatory Authority of Pakistan (DRAP), Prime Minister Health Complex, Chak Shahzad, Islamabad on 16th March, 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
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 (attended meeting through videolink)
9.	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member (attended meeting through videolink)
10.	Prof. Dr. Syed Mohsin Naveed Abbas, Consultant Nephrologist & Transplant Physician, Head of Department of Nephrology & Dialysis, Cantt General Hospital, Rawalpindi.	Member (attended meeting through videolink)
11.	Mrs. Tazeen Saeed Bukhari, 192 Cavelry Ground, Street 4, Shami Road Khalid Yaqoob Chowk, Lahore	Co-opted expert (attended meeting through videolink)
12.	Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad.	Member-cum-Secretary

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

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



EVALUATOR: MR. MUHAMMAD AMIN (DEPUTY DIRECTOR)

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

FRESH CASES-ELM:

S.No	Name and Address of Establishment	Name of Production Incharge	Name of QC Incharge	Decision
1	M/s Novamed Pharmaceuticals (Pvt.) Ltd, Office/godown: 28 KM Ferozepur Road Lahore.	Shahid Amin	Hafiz Nasrullah Khan	Rejected. The board considered the request of the firm as reported by inspector and decided to reject application of the firm for establishment license to manufacture medical devices.
2	M/s Bridge Surgical, office/godown: Khan Mehal road, Sialkot	Muhammad Jameel	Muhammad Arshad	Deferred. The board considered the request of the firm as reported by inspector and decided to grant 02 months time for panel inspection. The board further directed Mr. Abdul Rasheed Shaikh DD DRAP Lahore to present site verification report in the meanwhile and obtain all relevant documents/ prerequisites in this regard.
3	M/s MM Surgical, 63-A, M-3, Industril Estate, Sahianwal, Chak Jumra, Faisalabad.	Sawera Saleem Khan	Mr. Ghulam Mustafa	Deferred. The board considered the request of the firm as reported by inspector and decided to grant 02 months time for panel inspection. The board further directed Mr. Abdul Rasheed Shaikh DD DRAP Lahore to present site verification report in the meanwhile and obtain all relevant documents/ prerequisites in this regard.
4	M/s Medigar, Chak No. 78G, Stiana road, Khanuana bypass Faisalabad.	Tayyiba Zaib	Fazilat Mehboob	Deferred. The board considered the request of the firm as reported by inspector and decided to grant 02 months time for panel inspection. The board further directed Mr. Abdul Rasheed Shaikh DD DRAP Lahore to present site verification report in the meanwhile and obtain all relevant documents/ prerequisites in this regard.

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 Azan Trading Co. Office/godown: Plot No. 91, Street No. 08, Faisal town , Koral, Islamabad.	Muhammad Mugheera Popalzai Pharmacist	Approved
2.	M/s Perform Leo, Office/godown: Office No. 708, 7th Floor, Ashrafi Heights 2-E, Main Market Road Gulberg-II, Lahore.	Muhammad Hassan Butt Pharm D	Rejected. The board considered the report of the inspector, “the undersigned visited the premises M/s Perform Leo, Office/godown: Office No. 708, 7th Floor, Ashrafi Heights 2-E, Main Market Road Gulberg-II, Lahore thrice and always found closed the inspection cannot be conducted” and took a serious note of the applicant’s response towards conducting inspection of the storage facility. The board therefore decided to reject application of the firm for establishment licesne to import medical devices. The applicant may apply afresh once ready for inspection.

**Item No. I(C): APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT
MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017****(DEFERRED CASES FOR GRANT OF ELI)**

S.#	Name of Establishment	Name of Qualified Technical Person	Decision
1.	M/s Saqib Traders, Office/godown: Lawyers Club Complex,Near DPO Office,Opp.Ladies Club,Bhimber Road Gujrat	Old Technical person: Muaaz Raheel BS computer Science New Technical Person: Hassam Danish Bs Biotechnology	Approved

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

(FRESH RENEWAL CASES-ELI):

S.No	Name of Establishment	Name of Qualified Technical Person	Name of Management	Decision
1.	M/s Hospicare Systems, Office: Plot 8-B, Block-A, 09 th Floor, Emarah suites, SMCHS, Shahrah-e-Faisal, Karahchi. Godown: St-20/1, KDA Scheme 16, Block 7, Federal B Area, Karachi. ELI-00274	Miss Laraib Bio Medical Engineer	Masood Ahmed CEO	Approved
2.	M/s Euronano Diagnostics (Pvt) Ltd., Office/godown: Plot No 225/1/F, Block-2, PECHS Society, Jamshed Town, Karachi ELI-00461	Waqas Khan Bs Medical Laboratory Technology	Mr. Abdullah Abdul Waheed Mr. Alper Akyoz Ms. Elif Akyoz	Approved
3.	M/s MSB Medical, Office/godown: F-2, 1st Floor, 51-1/C, Block-6, PECHS, Karachi ELI-00035	Shahnila Fatima Pharm D	Attaullah Bhatti CEO	Approved
4.	M/s Schazoo SPL Consumer Healthcare, Office/godown: 71-B/C2, Gulberg-III, Lahore ELI-00095	Muhammad Nabeel Asad Pharm D	Mujtaba Shuja ur Rehman Mian Ahmad Shuja ur Rehman Mian Asad Shuja Ansar Sohail Malik Ahmer Malik	Approved
5.	M/s Health Tec, Office: House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi Godown: House No. 31, Street 27, Valley Road, Westridge 1,	Syed Adnan Haider Pharmacist	Ahmed Ali Aslam CEO	Approved

	Rawalpindi. ELI-00046			
6.	M/s Decent Traders, Office/godown: 1st floor, KH 2312, Tape Road, Sheesh Mehal, Near UVAS, Lahore ELI-00516	Afsheen Asghar Pharm D	Mr. Mohammad Waseem Tipu CEO	Approved
7.	M/s AL-Haram Traders, Office/godown: D-18/19 4th Floor Karachi Market Khyber Bazar, Peshawar. ELI-00503	Sareed Khan Medical Lab technologist	Syed Rizwan Ali Shah	Deferred. The board deferred the case for fee and documents regarding appointment of new qualified person.
8.	M/s Usmanco International, Office: 220,Block -3,DMCHS, S.Abdul Tawwab Road, Karachi. godown: Plot No. 43, sector 27, Korangi industrial area, Karachi. ELI-00121	Dr. Faryal Ali Pharm D	Qammar Usman CEO	Deferred. The board deferred the case for fee and documents regarding appointment of new qualified person and change of godown.

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

(DEFERRED CASES FOR RENEWAL OF -ELI):

1.	M/s Labserv, House No. B-165/2, Block -3A, Gulistan-e-Johar, Scheme 36, Karachi ELI-00105	Sumaria Rafiq Pharm-D	Irshad Bano	Decision: Approved
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Item No. I(F): CHANGE OF QUALIFIED PERSON

The qualified person of below mentioned firms has informed that they are no more working with these companies. These firms were intimated and advised in writing to appoint a qualified person in accordance with medical devices under MDR, 2017. However, no response in this regard has been received so far.

S.#	Name of Establishment	Director/Proprietor/ partners	Name of Qualified Person	Decision of MDB
1.	M/s Health Prior (SMC-Private) Limited, 502, Flat No.03, 5 th Floor, Gulberg Green, Islamabad. ELI-01006	Muhammad Faizan	Rabia Ruby 37301-0479859-8	The board took serious notice for not complying with conditions of medical devices rules 2017 by not appointing a qualified person and seeking approval of Medical Devices Board once the previously approved staff member has resigned. Conducting business activity without appointing a qualified person is a serious contravention of law despite communicating the same in writing. The board therefore decided to issue show cause notice and personal hearing to the license holder.
2.	M/s Perfect Traders, 72 Harley Street, Lane No 2, Rawalpindi. ELI-01394	Mr. Nafees-ur-Rehman, Deputy Director, DRAP, Islamabad.	Shaiza Khan 37401-8606292-7	The board took serious notice for not complying with conditions of medical devices rules 2017 by not appointing a qualified person and seeking approval of Medical Devices Board once the previously approved staff member has resigned. Conducting business activity without appointing a qualified person is a serious contravention of law despite communicating the same in writing. The board therefore decided to issue show cause notice and personal hearing to the license holder.

Item No. I(G): LICENSING MISCELLANEOUS AGENDA.

Agenda Item: Issuance of Duplicate Licenses in Case of Lost or Stolen Hard-Form Licenses.

Currently, the Medical Devices Rules do not provide any provision for the issuance of duplicate licenses in cases where licenses issued in hard form are lost, misplaced, or stolen. This creates administrative difficulties for license holders who require valid documentary evidence of their authorization. In order to facilitate such cases and ensure continuity of regulatory compliance, it is proposed that the Board consider allowing the issuance of duplicate licenses subject to appropriate verification and documentation.

2. The Board is requested to authorize the Secretary, Medical Devices Board, to issue duplicate licenses in such cases after obtaining the following documents from the license holder:

- (i) a copy of the FIR in case of loss or theft of the original license.
- (ii) an undertaking from the owner stating that the information provided is correct and that, if the original license is found, it will be returned to the Board; and
- (iii) payment of the prescribed fee applicable for change of particulars.

The matter is placed before the Board for consideration and approval.

Decision: The board deliberated on the matter in detail and devised following mechanism for issuance of duplicate establishment license.

- **The applicant shall make a request to Medical Devices Board in writing for issuance of duplicate license with the reasons thereof.**
- **A copy of police report in case of loss or theft of the original license.**
- **If original license is defaced/ damaged the same shall be returned to Medical Devices Board with the application.**
- **Fee in Misc head and fee challan shall be submitted.**
- **An undertaking from the owner stating that the information provided is correct and that, if the original license is found, it will be returned to the Board.**
- **The Secretary Medical Devices Board shall issue duplicate license once all formalities are met. The word duplicate shall be written on duplicate license.**

Item No. I(H): PERSONAL HEARING CASES.

APPLICATION FOR RENEWAL OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.

S.No .	Name of Establishment	Name of Qualified Technical Person	Name of Management	Reply of the firm	Decision
1.	M/s Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd, Office: 65 Main Boulevard Gulberg Lahore Godown: Kot Abdul Malik Ferozwala, District Sheikhpura. ELI-00179	Mrs. Anila Zareen	Nicolas C.Marie Joseph Bouts Pierre Albert Paul Dussaud	Reference to the subject mentioned above, we were issued the license no. ELI-00179 to import the registered medical devices on 25-Feb-2019 with the validity period of 5 years. We are no more interested in the renewal of the said license. A copy of the license is hereby enclosed for your kind reference. We remain available for any additional information, if needed. Thanking you in advance for your kind cooperation and understanding	No person appeared before the board in person however the firm submitted a response in writing and reiterated the same stance that due to business decisions they do not intend to maintain this license therefore their establishment license for import of medical devices (ELI 00179) be cancelled. The board considered the request and decided to cancel establishment license for import of medical devices (ELI 00179) issued in favour of M/s Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd, Lahore.
2.	M/s Don Valley Pharmaceuticals (Pvt) Ltd, Office/Godown: 15-C/2, Vogue Tower, Gulberg III, MM Alam Road, Lahore ELI-00561	Mr. Mukhtar Ahmed	Dr. Shahla Javed Akram Mr. Saad Javed Akram Mr. Abdul Shabbir Khokhar	We respectfully inform your esteemed office that Don Valley Pharmaceuticals (Pvt.) Ltd., located at 15-C/2, Vogue Tower, MM Alam Road, Gulberg III, Lahore (as per the licence details on page 1 of our existing Form-4, License for Import of Medical D), has decided not to proceed with	No person appeared before the board in person however the firm submitted a response in writing and reiterated the same stance that after reviewing operational and regulatory strategies, they have concluded that they

				the renewal of its Licence to Import Medical Devices, Licence No. ELI-00561, originally issued on 13 February 2020 and due for renewal on 12 February 2025. After reviewing our operational and regulatory strategies, we have concluded that we will no longer continue activities related to the import of registered medical devices. Therefore, we kindly request DRAP to consider this letter as our official notification of withdrawal from the license renewal process. We appreciate the cooperation extended by the MDMC Division throughout the period of our licensing and remain available for any clarification DRAP may require.	no longer intend to continue activities related to the import of registered medical devices. therefore, their establishment license for import of medical devices (ELI 00561) be cancelled. The board considered the request and decided to cancel establishment license for import of medical devices (ELI 00561) issued in favour of M/s Don Valley Pharmaceuticals (Pvt) Ltd, Lahore.
3.	M/s FABNOS INTERNATIONAL Office/Godown: Building # 26 - C, 3rd Floor, Touheed Commercial Area, Street # 26, Phase – V, D.H.A Karachi ELI No. 00149	22-10-2023	08-12-2025	The board discussed the case in detail and provided opportunity of personal hearing to the firm. Mr. Uzair Ahmad cnic no. 61101-9544496-7 holding authority letter from the company appeared before the board. He reiterated the same stance that the non-submission of the renewal application within the prescribed timeline was unintentional and occurred due to administrative and operational constraints, including some internal restructuring, appointment of new qualified person and delay in required documentations. Keeping in view the position of Medical Devices Rules 2017 in the subject matter the board declared the license invalid as renewal application was made after one year of expiry of license. The registrations/ enlistments granted to the firm shall also become invalid. However, the firm may apply afresh for grant of license and registrations/ enlistment of products. The board shall decide on such applications and if approved same license number and registration/ enlistment numbers shall be issued to avoid any confusion in conducting business	

				activities.
4.	M/s Analytical Measuring system (Pvt) Ltd, Office/Godown: AMH House 14-C, main sehar , commercial avenue , lane no. 4, Khayaban e sehar, DHA, Phase VII , Karachi ELI No. 00413	26-05-2024	03-07-2025	The board discussed the case in detail and provided opportunity of personal hearing to the firm. Representative of the firm appeared before the board and reiterated the stance that they admit that the application for renewal of our establishment license could not be submitted within the prescribed time and the grace period as stipulated under the Medical Devices Rules, 2017. This delay occurred inadvertently and without any mala file intention, and they regret the lapse. Keeping in view the position of Medical Devices Rules 2017 in the subject matter, the board declared the license invalid as renewal application was made after one year of expiry of license. The registrations/ enlistments granted to the firm shall also become invalid. However, the firm may apply afresh for grant of license and registrations/ enlistment of products. The board shall decide on such applications and if approved same license number and registration/ enlistment numbers shall be issued to avoid any confusion in conducting business activities.

**Item No. II(A):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.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 13-08-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944817 dated 17-	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Randox Laboratories Limited. 55, Diamond Road Crumlin County	Atellica TIBC Kit CH Total Iron Binding Capacity, CH Special Chemistry Calibrator, Atellica Iron Kit CH Iron 2, CH Chemistry Calibrator, Applied as Cluster.	Deferred for submission of the followings: 1.Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The

	07-2020 Tracking ID: WTJ-WJG-B4WP	Antrium, BT29 4QY, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Class-B Model/Codes/Size: TIBC Kit : CH Total Iron Binding Capacity (Code: 11097525): Shelf Life: 12 months CH Special Chemistry Calibrator (Code: 11099438): Shelf Life: 18 months Iron Kit CH Iron 2 (Code: 11097601): Shelf Life: 12 months CH Chemistry Calibrator (Code: 11099411): Shelf Life: 18 months	manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevent grouping. 4.Shelf life evidence/study for the applied product.
2.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 13-08-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944809 dated 17-07-2020 Tracking ID: 8Z2-ZVH-31RN	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Randox Laboratories Limited. 55, Diamond Road Crumlin County Antrium, BT29 4QY, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485:	Atellica CH Complement C3, CH Liquid Specific Protein Calibrators, CH Complement C4, CH Liquid Specific Protein Calibrators, (Complement C3) & (Complement C4) [Cluster for immunochemistry of component for Atellica Chemistry System] Applied as Cluster. Class-B Model/Codes/Size: CH Complement C3 (Code: 11097624): Shelf Life: 12 months CH Liquid Specific Protein Calibrators (Code: 11099434):	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevent grouping. 4.Shelf life evidence/study for the applied product.

		Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Shelf Life: 24 months CH Complement C4 (Code: 11097623): Shelf Life: 12 months CH Liquid Specific Protein Calibrators (Code: 11099434): Shelf Life: 24 months	
3.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 13-08-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944812 dated 17-07-2020 Tracking ID: JPV-HDY-EYN2	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Randox Laboratories Limited. 55, Diamond Road Crumlin County Antrim, BT29 4QY, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica CH Fructosamine (Fruc), CH Fructosamine Calibrator (FRUC CAL), CH Hemoglobin Alc_3 (Alc_3), CH Ale 3 Calibrator (Ale 3 CAL). (Fructosamine (Fruc),) & (Hemoglobin Alc_3 (Alc_3)) [Cluster of Immuno Chemistry Diabetic Assays for Atellica Chemistry System] Applied as Cluster. Class-B Model/Codes/Size: CH Fructosamine (Fruc) (Code: 11097637): Shelf Life: 12 months CH Fructosamine Calibrator (FRUC CAL). (Code: 11099432): Shelf Life: 12 months CH Hemoglobin Alc_3 (Alc_3). (Code: 11097500): Shelf Life: 12 months CH Ale 3 Calibrator (Ale 3 CAL). (Code: 11099328): Shelf Life: 24 months	Deferred for submission of the followings: 5. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 6. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 7. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. Shelf life evidence/study for the applied product.
4.	M/s. Hoorah	Legal Manufacturer:	Atellica	Deferred for submission of

Pharma (Pvt.) Ltd. Karachi (ELI-00037)	Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Randox Laboratories Limited. 55, Diamond Road Crumlin County Antrim, BT29 4QY, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica CH Immunoglobulin A_2, Atellica CH Liauid Soecific Protein calibrators, Atellica CH Immunoglobulin G_2 (IgG_2), Atellica CH Liauid Soecific Protein calibrators, Atellica CH Immunoglobulin M_2, Atellica CH Liquid Soecific Protein calibrators. (Irrnimmunoglobulin A 2 Kit), (Immunoglobulin G 2 Kit) & (Irrnimmunoglobulin M 2 Kit) [Cluster of Immuno Chemistry Immunoglobulin for Atellica Chemistry System] Applied as Cluster. Class-B Model/Codes/Size: Atellica CH Immunoglobulin A_2 (Code: 11097619): Shelf Life: 12 months Atellica CH Liquid Specific Protein calibrators (Code: 11099434): Shelf Life: 12 months Atellica CH Immunoglobulin G_2 (IgG_2) (Code: 11097616): Shelf Life: 12 months Atellica CH Liquid Specific Protein calibrators (Code: 11099434): Shelf Life: 24 months	the followings: 8. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 9. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 10. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. Shelf life evidence/study for the applied product.
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			Atellica CH Immunoglobulin M_2 (Code: 11097620): Shelf Life: 24 months Atellica CH Liquid Specific Protein calibrators (Code: 11099434): Shelf Life: 24 months	
5.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 13-08-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944808 dated 17- 07-2020 Tracking ID: VGD- 8D7-YY1G	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Randox Laboratories Limited. 55, Diamond Road Crumlin County Antrim, BT29 4QY, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica CH Apolipoprotein A-1 (APO AI), CH Apolipoprotein A-1 & B Calibrator, CH Apolipoprotein B (APO B), CH Apolipoprotein A-1 & B Calibrator, CH Lipoprotein(a), CH Lipoprotein(a) Calibrator. (Apolipoprotein Kit) & (Lipo Protein Kit) [Cluster for Immuno Chemistry Lipoproteins for Atellica Chemistry System] Applied as Cluster. Class-B Code: 11097625 Code: 11099329 Code: 11097626 Code: 11099329 Code: 11097627 Code: 11099433 Model/Codes/Size: Apolipoprotein Kit: CH Apolipoprotein A-1 (APO AI), (Code: 11097625): Shelf Life: 15 months CH Apolipoprotein A-1 & B Calibrator, (Code: 11099329): Shelf Life: 24 months	Deferred for submission of the followings: 11. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 12. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 13. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. Shelf life evidence/study for the applied product.

			CH Apolipoprotein B (APO B), CH (Code: 11097626): Shelf Life: 15 months CH Apolipoprotein A-1 & B Calibrator (Code: 11099329): Shelf Life: 24 months Lipo Protein Kit: CH Lipoprotein(a), (Code: 11097627): Shelf Life: 15 months CH Lipoprotein(a) Calibrator. (Code: 11099433): Shelf Life: 36 months	
6.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 06-08-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944814 dated 17-07-2020 Tracking ID: SSH-QE6-83Q9	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. Manufacturing Site (as per CMS) Siemens Healthcare Diagnostics Inc. Address: 700 GBC Drive Newark DE 19702 Glasgow, Delaware U.S LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of	1. Atellica CH Gentamicin Kit Atellica CH DRUG CAL II 2. Atellica CH Phenobarbital (Phnb) kit Atellica CH DRUG CAL 3. Atellica CH Phenytoin Kit Atellica CH DRUG CAL 4. Atellica CH Theophylline Kit Atellica CH DRUG CAL 5. Atellica CH Valproic Acid Kit Atellica CH DRUG CAL II 6. Atellica CH Vancomycin Kit Atellica CH DRUG CAL II 7. Atellica CH Carbamazepine Kit Atellica CH DRUG CAL II 8. Atellica CH Tobramycin Kit Atellica CH DRUG CAL II	Deferred for submission of the followings: 14. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 15. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 16. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. Shelf life evidence/study for the applied product.

		non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	9.Atellica CH Lithium Kit Atellica CH Chemistry Calibrator 10.Atellica CH Digoxin (Dgn) Kit Atellica CH TDM Calibrators 11.Atellica CH Procainamide (PROC) Kit Atellica CH DRUG CAL II 12.Atellica CH N-Acetylprocainamide (NAPA) Kit Atellica CH DRUG CAL II 13.Atellica CH Lidocaine (LIDO) Kit Atellica CH DRUG CAL II (Gentamicin Kit, Phenobarbital Kit, Phenytoin Kit, Theophylline Kit, Valproic Acid Kit, Vancomycin Kit, Carbamazepine Kit, Tobramycin Kit, Lithium Kit, Digoxin Kit, Procainamide Kit, N-Acetyl procain amide (NAPA) Kit, Lidocaine (LIDO) Kit) [Cluster of Immuno Chemistry Non-Immunosuppressive Therapeutic Drug Monitoring for Atellica Chemistry System] Applied as Cluster. Class-B Code: 11097516 Code: 11099405 Code: 11097514 Code: 11099336 Code: 11097510 Code: 11099336	
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			Code: 11097513 Code: 11099336 Code: 11097512 Code: 11099405 Code: 11097511 Code: 11099405 Code: 11097515 Code: 11099405 Code: 11097517 Code: 11099405 Code: 11097535 Code: 11099411 Code: 11097526 Code: 11099439 Code: 11097538 Code: 11099405 Code: 11097537 Code: 11099405 Code: 11097539 Code: 11099405 Model/Codes/Size: Model/Codes/Size: Atellica CH Gentamicin, (Code: 11097516): Shelf Life: 12 months Atellica CH DRUG CAL II, (Code: 11099405): Shelf Life: 12 months Atellica CH Phenobarbital (Phnb) (Code: 11097514): Shelf Life: 12 months Atellica CH DRUG CAL, (Code: 11099336): Shelf Life: 18 months Atellica CH Phenytoin (Code: 11097510): Shelf Life: 12 months Atellica CH DRUG CAL, (Code: 11099336): Shelf Life: 18 months Atellica CH Theophylline. (Code: 11097513): Shelf Life: 12 months Atellica CH DRUG CAL, (Code: 11099336): Shelf Life: 18 months	
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			Atellica CH Valproic Acid. (Code: 11097512): Shelf Life: 12 months Atellica CH DRUG CAL II, (Code: 11099405): Shelf Life: 12 months Atellica CH Vancomycin. (Code: 11097511): Shelf Life: 12 months Atellica CH DRUG CAL II, (Code: 11099405): Shelf Life: 12 months Atellica CH Carbamazepine. (Code: 11097515): Shelf Life: 12 months Atellica CH DRUG CAL II, (Code: 11099405): Shelf Life: 12 months Atellica CH Tobramycin. (Code: 11097517): Shelf Life: 12 months Atellica CH DRUG CAL II, (Code: 11099405): Shelf Life: 12 months Atellica CH Lithium. (Code: 11097535): Shelf Life: 12 months Atellica CH Chemistry Calibrator, (Code: 11099411): Shelf Life: 24 months Atellica CH Digoxin (Dgn). (Code: 11097526): Shelf Life: 12 months Atellica CH TOM Calibrators (TOM CAL), (Code: 11099439): Shelf Life: 18 months Atellica CH Procainamide	
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			(PROC) (Code: 11097538): Shelf Life: 06 months Atellica CH DRUG CAL II , (Code: 1099405): Shelf Life: 12 months Atellica CH N-Acetylprocainamide (NAPA) (Code: 097537): Shelf Life: 06 months Atellica CH DRUG CAL II , (Code: 1099405): Shelf Life: 12 months Atellica CH Lidocaine (LIDO) (Code: 11097539): Shelf Life: 06 months Atellica CH DRUG CAL II , (Code: 1099405): Shelf Life: 12 months	
7.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-07-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944807 dated 17-07-2020 Tracking ID: JJA-V6U-L32X	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. Manufacturing Site (as per CMS) Siemens Healthcare Diagnostics Inc. Address: 700 GBC Drive Newark DE 19702 Glasgow, Delaware U.S LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026	Atellica (Details are under codes) [Cluster of Immuno Chemistry Toxicology for Atellica Chemistry System] Applied as Cluster. Class-B Model/Codes/Size: Model/Codes/Size: 1. Atellica CH Salicylate Size: 1200 Tests Code: 11097523 Shelf life: 12 Months Atellica CH Toxicology Calibrator Size: 6 X 3.0 ml. Code: 11099440 Shelf life: 24 Months 2. Atellica CH Ethyl	Deferred for submission of the followings: 17. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 18. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 19. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. Shelf life evidence/study for the applied product.

		FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Alcohol Size: 1200 Tests Code: 11097501 Shelf life: 12 Months Atellica CH Toxicology Calibrator Size: 6 X 3.0 ml. Code: 11099440 Shelf life: 24 Months 3.Atellica CH Acetaminophen. Size: 1200 Tests Code: 11097522 Shelf life: 12 months Atellica CH Toxicology Calibrator Size: 6 X 3.0 ml. Code: 11099440 Shelf life: 24 Months 4.Atellica CH Amphetamines. Size: 1520 Tests Code: 11097506 Shelf life: 12 Months Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit Calibrator/ Control Level 1. Size: 14 ml Code: 10445407 Shelf life: 12 Months. Emit Calibrator/ Control Level 2. Size: 14 ml	
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			Code: 10445408 Shelf life: 09 Months. Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 09 months Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 09 Months. 5. Atellica CH Cocaine Metabolite Size: 1520 Tests Code: 11097504 Shelf life: 12 Months Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 09 Months. Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 09 months. Emit Calibrator/ Control Level 4. Size: 14 ml Code: 10445410 Shelf life: 09 Months	
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			Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 09 Months. 6.Atellica CH Opiates Size: 1520 Tests Code: 11097502 Shelf life: 06 Months. Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit Calibrator/ Control Level 1. Size: 14 ml Code: 10445407 Shelf life: 12 Months. Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 09 Months. Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 09 months. Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 09 Months 7.Atellica CH Cannabinoids THC Size: 1250 Tests Code:11097503 Shelf life: 12 Months. Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months	
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			Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 09 Months. Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 09 months. Emit Calibrator/ Control Level 4. Size: 14 ml Code: 10445410 Shelf life: 09 Months. Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 09 Months. 8.Atellica CH Barbiturates Size: 1250 Tests Code: 11097507 Shelf life: 12 Months Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 09 Months Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 09 months. Emit Calibrator/ Control Level 4.	
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			Size: 14 ml Code: 10445410 Shelf life: 09 Months. Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 09 Months 9.Atellica CH Benzodiazepines Size: 1250 Tests Code: 11097505 Shelf life: 12 Months Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 09 Months Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 09 months. Emit Calibrator/ Control Level 4. Size: 14 ml Code: 10445410 Shelf life: 09 months. Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 09 Months 10.Atellica CH Methadone Size: 1520 Tests Code: 11097520 Shelf life: 12 Months	
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			Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 12 months Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 12 months Emit Calibrator/ Control Level 4. Size: 14 ml Code: 10445410 Shelf life: 12 months Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 12 months. 11.Atellica CH Phencyclidine Size: 1250 Tests Code: 11097509 Shelf life: 12 Months. Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 12 months Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 12 months.	
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			Emit Calibrator/ Control Level 4. Size: 14 ml Code: 10445410 Shelf life: 12 months 12.Atellica CH Propoxyphene Size: 1520 Tests Code: 11097519 Shelf life: 12 Months Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit Calibrator/ Control Level 2. Size: 14 ml Code: 10445408 Shelf life: 12 months Emit Calibrator/ Control Level 3. Size: 14 ml Code: 10445409 Shelf life: 12 months Emit Calibrator/ Control Level 4. Size: 14 ml Code: 10445410 Shelf life: 12 months Emit Calibrator/ Control Level 5. Size: 14 ml Code: 10445411 Shelf life: 12 months. 13.Atellica CH Oxycodone Size: 1520 Tests Code: 11097541 Shelf life: 06 Months. Emit Calibrator/ Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months.	
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			Emit® II Plus Specialty Multi Drug Calibrators/Controls Level 1 Size: 10 ml Code: 10720807 Shelf life:08 months. Emit® II Plus Specialty Multi Drug Calibrators/Controls Level 2 Size: 10 ml Code: 10720813 Shelf life:08 months Emit® II Plus Specialty Multi Drug Calibrators/Controls Level 3 Size: 10 ml Code:10720814 Shelf life:08 months Emit® II Plus Specialty Multi Drug Calibrators/Controls Level 4 Size: 10 ml Code: 10720815 Shelf life:08 months Emit® II Plus Oxycodone Controls Negative 100 Size: 10 ml Code: 10720809 Shelf life:08 months. Emit® II Plus Oxycodone Controls Negative 100 Size: 10 ml Code: 10720810 Shelf life:08 months Emit® II Plus Oxycodone Controls Negative 300 Size: 10 ml Code: 10720811 Shelf life:08 months Emit® II Plus Oxycodone	
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			Controls Negative 300 Size: 10 ml Code: 10720812 Shelf life:08 months. 14.Atellica CH Methadone Metabolite Size: 2000 Tests Code: 11097527 Shelf life: 12 Months. Atellica CH Methadone Metabolite 1000 ng/mL Urine Calibrator Size: 1 x 10 mL Code: 11099437 Shelf life: 17 Months ◆ Atellica CH Multi-Drug Urine Controls Size: 3 x 5.0 ml Code: 11099406 Shelf life: 24 Months. 15.Atellica CH Ecstasy. Size: 400 Tests Code: 11097518 Shelf life: 12 Months Emit Calibrator/Control Level 0. Size: 14 ml Code: 10445406 Shelf life: 12 months. Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 1 ◆ Size: 10 ml. Code: 10470441 Shelf life: 12 Months. Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 2 Size: 10 ml. Code: 10470442 Shelf life: 12 Months Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 3 Size: 10 ml.	
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			Code: 10470443 Shelf life: 12 Months Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 4 Size: 10 ml. Code: 10470444 Shelf life: 12 Months	
8.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 04-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029858 dated 02-09-2020 Tracking ID: 75M-D2J-HLXG	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica (Details are under codes) [Cluster for Immuno Chemistry Anemia] Applied as Cluster. Class-B Model/Codes/Size: 1.Atellica IM Ferritin (Fer) Kit Size: 450 Tests Codes: 10995568 Shelf Life:08 months Atellica IM Ferritin (Fer) Size: 90 Tests Codes: 10995569 Shelf Life:08 months Atellica IM Calibrator C (CAL C) Size: 2 x 5.0 mL Codes: 10995506 Shelf Life:15months Atellica IM Calibrator C (CAL C) Size: 6 x 5.0 mL Codes: 110995507 Shelf Life:15months Atellica IM Multi-Diluent 1 Size2x25.0mL/ Pack Codes: 10995637 Shelf Life:12months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. Shelf life evidence/study for the applied product.

			Atellica IM Multi-Diluent 1 Size: 6x25.0mL/ Pack Codes: 10995638 Shelf Life:12months Atellica IM Multi-Diluent 1 Size: 50.0mL/vial Codes: 10995639 Shelf Life:12months 2.Atellica IM Folate (Fol) Size: 140 Tests Codes: 10995572 Shelf Life:09 months Atellica IM Folate (Fol) Size: 700 Tests Codes: 10995573 Shelf Life:09 months Atellica IM Folate DTT/Releasing Agent (Fol DTT/REL) Size: 3 x 8.0 mL/vial DTT Codes: 10995576 Shelf Life:15months Atellica IM RBC Folate Ascorbic Acid / Ascorbic Acid Diluent (RBC Fol) Size: 4 x 30.0 mL/vial Codes: 10995440 Shelf Life:12months Atellica IM Folate Diluent (Fol DIL) Size: 2 x 10.0mL/pack Codes: 10995574 Shelf Life:12months.	
9.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi	Legal Manufacturer: Siemens Healthcare Diagnostics Inc.	Atellica (Details are under codes) [Cluster for	Deferred for submission of the followings: 1. Valid Legalized Free

	(ELI-00037) Date of R&I 17-06-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2029857 dated 02-09-2020 Tracking ID: BTN-7DD-SWZ1	511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Immunochemistry Cancer Marker for ATTELICA Immunochemistry system] Applied as Cluster. Class-B Model/Codes/Size: CA 15-3 Kit Atellica IM CA 15-3 (CA 15-3) 10995485 12 months 100 Tests Atellica IM CA 15-3 (CA 15-3) 10995486 12 months 500 Tests Atellica I M CA 15-3 Calibrator (CA 15-3 CAL) 10995487 12 months 2 x 2.0mL Atellica IM Multi-Diluent 1 10995637 12 months 2x25.0 mL/pack Atellica IM Multi-Diluent 1 10995638 12months 6x25.0 mL/pack Atellica IM Multi-Diluent 1 10995639 12 months 50.0mL/ vial Atellica IM BR 27.29 (BR) 10995477 10 months	Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. Shelf life evidence/study for the applied product.
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			250Tests Atellica IM BR 27.29 (BR) 10995478 10 months 50Tests Atellica IM BR 27.29 Calibrator (BR CAL) 10995515 15 months 2 x 2.0 mL Atellica IM CA 19-9 (CA 19-9) 10995489 10 months 250 Tests Atellica IM CA 19-9 (CA 19-9) 10995490 10 months 50 Tests Atellica IM CA 19-9 Diluent (CA19-9 DIL) 10995491 15 months 2x5.0mL/ pack Atellica IM CA 12511 (CA 125II) 10995481 12 months 100 Tests Atellica IM CA 12511 (CA 125II) 10995482 12 months 500 Tests Atellica IM CA 12511 Calibrator (CA 125II CAL) 10995483 21 months 2 x 2.0 mL Atellica IM Carcinoembryonic Antigen (CEA) 10995523	
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			12 months 100 Tests Atellica IM Carcinoembryonic Antigen (CEA) 10995524 12 months 500 Tests Atellica IM Calibrator D (CAL D) 10995509 2 x 2.0 mL Atellica IM Calibrator D (CAL D) 10995510 6 x 2.0 mL Atellica IM Carcinoembryonic Antigen Diluent (CEA DIL) 10995525 12 months 2x5.0mL/pack Atellica IM HER-2/neu (H2n) 10995591 18 months 50 Tests Atellica IM HER-2/neu Calibrator (H2n CAL) 10995592 12 months 2 x 2.0 mL Atellica IM Her-2/neu Quality Control 10995594 12 months 2 x 2.0 mL	
10.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037)	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA	Atellica (Details are under codes) [Cluster For Immunochemistry Diabetic Assay For Immunoassay System]	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference

	Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029862 dated 02-09-2020 Tracking ID: 7ZN-VBU-54G9	Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Applied as Cluster. Class-B Model/Codes/Size: 1.Atellica IM C-peptide (CpS). Size: 100 tests Codes: 10995541 Shelf Life:12months Atellica IM C-peptide Calibrator (CpS CAL). Size: 2 x 1.0 mL Codes: 10995542 Shelf Life:18months Atellica IM Multi-Diluent 10 Size: 2x5.0mL/ pack Codes: 10995640 Shelf Life:12months 2.Atellica IM Insulin (IRI) Size: 100 Tests Codes: 10995628 Shelf Life:12months Atellica IM Insulin Calibrator (IRI CAL) Size: 2 x 1.0 mL Codes: 10995629 Shelf Life:18months Atellica IM Insulin Diluent (IRI DIL) Size: 2x10.0mL/ Pack Codes: 10995630 Shelf Life:12months	Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. Shelf life evidence/study for the applied product.
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			Atellica IM Insulin Diluent (IRI DIL) Size:20.0mL/ vial Codes: 10995631 Shelf Life:12months	
11.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029867 dated 02-09-2020 Tracking ID: YVS-UHE-RT9B	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica (Details are under codes) [Cluster for Endocrine hormones and peptides] Applied as Cluster. Class-B Model/Codes/Size: 1.Atellica IM DHEA SO4 (DHEAS) Size:50 Tests Codes: 10995555 Shelf Life: 18 months Atellica IM Multi-Diluent 1 Size:2 x 25 ml/ pack Codes: 10995637 Shelf Life:12months Atellica IM Multi-Diluent 1 Size: 6x 25 ml/ pack Codes: 10995638 Shelf Life:12months Atellica IM Multi-Diluent 1 Size: 50ml/ vial Codes: 10995639 Shelf Life:12months 2.Atellica IM Pregnancy-Associated Plasma Protein-A (PAPP-A) Size: 500 tests Codes: 10733020	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. Shelf life evidence/study for the applied product.

			Shelf Life: 09 months Atellica IM Pregnancy-Associated Plasma Protein-A (PAPP-A) Size: 100 tests Codes: 10733019 Shelf Life: 09 months Atellica IM Multi-Diluent 13 Size: 2 x 10 ml/ Pack Codes: 10995643 Shelf Life: 24 months. 3. Atellica IM Sex Hormone Binding Globulin (SHBG). Size: 50 Tests Codes: 10995672 Shelf Life: 18 months. Atellica IM Sex Hormone Binding Globulin Calibrator (SHBG CAL) Size: 2 x 2.0 ml Codes: 10995673 Shelf Life: 18 months. Atellica IM Multi-Diluent 1 Size: 2 x 25 ml/ pack Codes: 10995637 Shelf Life: 24 months. Atellica IM Multi-Diluent 1 Size: 6 x 25 ml/ Pack Codes: 10995638 Shelf Life: 24 months. Atellica IM Multi-Diluent 1 Size: 50ml/ vial Codes: 10995639	
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			Shelf Life: 24 months.	
12.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 20299879 dated 02-09-2020 Tracking ID: YVS-UHE-RT9B	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica (Details are under codes) [Cluster for Immuno Chemistry Liver Function for Atellica Immuno assay System] Applied as Cluster. Class-B Model/Codes/Size: 1.Atellica IM N-terminal Propeptide of Type III Procollagen (PIINP) Size: 50 Tests Codes: 10995653 Shelf Life: 27 months Atellica IM Enhanced Liver Fibrosis Calibrator (ELF CAL) Size: 2 x 2.0 mL Codes: 10995565 Shelf Life: 28 months Atellica IM Enhanced Liver Fibrosis Quality Control (ELF QC) Size: 3 x 2.0 mL Codes: 10995566 Shelf Life: 28 months Atellica IM Multi-Diluent 13 Size: 2x10.0mL/ pack Codes: 10995643 Shelf Life: 24 months 2.Atellica IM Hyaluronic acid (HA) Size: 50 Tests Codes: 10995595 Shelf Life: 27 months Atellica IM Enhanced Liver Fibrosis Calibrator (ELF CAL) Size: 2 x 2.0 mL	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. Shelf life evidence/study for the applied product.

			Codes: 10995565 Shelf Life: 28 months Atellica IM Enhanced Liver Fibrosis Quality Control (ELF QC) Size: 3 x 2.0 mL Codes: 10995566 Shelf Life: 28 months Atellica IM Multi-Diluent 13 Size: 2 x10.0mL/ pack Codes: 10995643 Shelf Life: 24 months 3. Atellica IM Tissue Inhibitor of Matrix Metalloproteinase 1 (TIMP-1) Size: 50 Tests Codes: 10995695 Shelf Life: 26 months Atellica IM Enhanced Liver Fibrosis Calibrator (ELF CAL) Size: 2 x 2.0 mL Codes: 10995565 Shelf Life: 28 months Atellica IM Enhanced Liver Fibrosis Quality Control (ELF QC) Size: 3 x 2.0 mL Codes: 10995566 Shelf Life: 28 months Atellica IM Multi-Diluent 10 Size: 2x5.0mL/ pack Codes: 10995640 Shelf Life: 10 months	
13.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as	Atellica (Details are under codes) [Cluster for] Applied as Cluster. Class-B	Deferred for submission of the followings: Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority

	14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029863 dated 02-09-2020 Tracking ID: 34B-AR7-5UVN	per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Model/Codes/Size: Atellica IM Cortisol (Cor) 10995537 Shelf Life: 15 months Size: 250 Tests Atellica IM Cortisol (Cor) 10995538 Shelf Life: 15 months Size: 50 Tests Atellica IM Calibrator E (CAL E) 10995512 Shelf Life: 16 months Size: 2x2.0mL Atellica IM Calibrator E (CAL E) 10995513 Shelf Life: 16 months Size: 6x2.0mL Atellica IM multi-diluent 3 10995645 Shelf Life: 12 months Size: 2x5.0mL/pack	wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
14.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029860 dated 02-09-2020 Tracking ID: E6S-6ZA-G5BP	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of	Atellica (Details are under codes) [Cluster for Immuno Chemistry Atellica IM Vitamin D Total (VitD)] Applied as Cluster. Class-B Model/Codes/Size: Atellica IM Vitamin D Total (VitD)- (10995719, 10995720) Shelf Life: 13 months Atellica IM Vitamin D Total Quality Control (VitD QC) (10995724) Shelf Life: 13 months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with

		non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica IM Vitamin D Total Diluent (VitD DIL) (10995721) Shelf Life: 12 months Atellica IM Vitamin B12 (VB12) (10995714, 10995715) Shelf Life: 11 months Atellica IM Calibrator C (CAL C) (10995506, 10995507) Atellica IM Vitamin B12 DTT/ Releasing Agent (VB12 DTT/REL) (10995718) Shelf Life: 11 months Atellica IM T3/T4/VB12 Ancillary Reagent (T3/T4/VB12 ANC) (10995682, 10995683) Shelf Life: 11 months Atellica IM Vitamin V12 Diluent (VB12 DIL) (10995716) Shelf Life: 12 months	submission of the fee for the releavent grouping. 4. Shelf life evidence/study for the applied product.
15.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1919501 dated 21-02-2019 Tracking ID: EGE-MT1-3TDX	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc.,	Atellica (Details are under codes) [Cluster for Immuno Chemistry Immunoglobulin for Dimension] Applied as Cluster. Class-B Model/Codes/Size: 1. Dimension Immunoglobulin A Flex reagent cartridge Dimension Special Protein Calibrator. 2.Dimension Immunoglobulin G Flex	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of grouping as per MDR 2017 with

		500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	reagent cartridge Kit Dimension Special Protein Calibrator. 3.Dimension Immunoglobulin M Flex reagent cartridge Kit. Dimension Special Protein Calibrator. 1. Dimension Immunoglobulin A Flex reagent cartridge Kit Size: 120 Tests Codes: 10444982 / DF74 Shelf Life: 12 months Dimension Special Protein Calibrator Size: 10 x 1.5 mL Codes: 10445028/ DC51 Shelf Life: 18 months 2.Dimension Immunoglobulin G Flex reagent cartridge Kit Size: 120 Tests Codes: 10444983 /DF76 Shelf Life: 12 months Dimension Special Protein Calibrator Size: 10 x 1.5 mL Codes: 10445028/ DC51 Shelf Life: 18 months 3. Dimension Immunoglobulin M Flex reagent cartridge Kit Size: 120 Tests Codes: 10444984 / DF81 Shelf Life: 12 months Dimension Special Protein Calibrator Size: 10 x 1.5 mL Codes: 10445028/ DC51 Shelf Life: 18 months	documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
16.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037)	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave.	Atellica (Details are under codes)	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of

	Date of R&I 13-11-2019 Fee Details: Paid Fee: 25,000/- Challan No. 1944786 dated 21-02-2019 Tracking ID: E6S-6ZA-G5BP	Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Chemistry Electrolyte Electrode for Dimension System] Applied as Cluster. Class-B Model/Codes/Size: 1. Dimension QuikLYTE Integrated Multisensor Size: 4 Sensors Codes: S600 / 10445058 Shelf Life: 12 months. 2. Dimension QuikLYTE Standard A Size: 3 x 1000 ml Codes: S620/10444878 Shelf Life: 12 months. 3. Dimension QuikLYTE Standard B Size: 3 x 300 ml Codes: S625/10444881 Shelf Life: 12 months. 4. Dimension QuikLYTE Flush Solution Size: 3 x 1000 ml Codes: S630/10445051 Shelf Life: 12 months 5. Dimension QuikLYTE Sample Diluent Size: 6 x 500 ml Codes: S630/10445051 Shelf Life: 12 months. 6. Dimension QuikLYTE Dilution Check Size: 1 x 60 ml Codes: S640/10444872 Shelf Life: 12 months. 7. Dimension IMT Probe Cleaner Size: 1 x 60 ml RD704/10445038	origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4. Shelf life evidence/study for the applied product.
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			Shelf Life: 12 months. 8. Dimension Salt Bridge Solution Size: 3 x 150 ml Codes: D105/10444873 Shelf Life: 12 months.	
17.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 19-03-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1919503 dated 19- 03-2019 Tracking ID: WTU- DH8-8W3G	Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica (Details are under codes) [Cluster for Immuno Chemistry Immunoglobulin for Dimension] Applied as Cluster. Class-B Model/Codes/Size: 1. Dimension Carbamazepine Flex reagent cartridge Size: 80 Tests Codes: DF87/10444930 Shelf Life: 12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 2. Dimension Digoxin Flex reagent cartridge Size: 80 Tests Codes: DF35A/ 10444941 Shelf Life: 12 months Dimension Drug Calibrator I Size: 10 x 3.0 mL Codes: DC22B /10445014 Shelf Life:18 months 3. Dimension Gentamicin Flex reagent cartridge Size: 80 Tests Codes: DF12/10444927	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. Shelf life evidence/study for the applied product.

			Shelf Life: 15 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 4. Dimension N-Acetylprocainamide Flex reagent cartridge Size: 80 Tests Codes: DF111/10444936 Shelf Life: 12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 5. Dimension Phenobarbital Flex reagent cartridge Size: 80 Tests Codes: DF60/ 10444933 Shelf Life: 12 months Dimension Drug Calibrator I Size: 10 x 3.0 mL Codes: DC22B /10445014 Shelf Life:18 months 6. Dimension Procainamide Flex reagent cartridge Size: 80 Tests Codes: DF110/ 10444937 Shelf Life:12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 7. Dimension Phenytoin Flex reagent cartridge Size: 112 Tests Codes: DF64/ 10444940 Shelf Life:12 months	
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			Dimension Drug Calibrator I Size: 10 x 3.0 mL Codes: DC22B /10445014 Shelf Life:18 months 8. Dimension Theophylline Flex reagent cartridge Size: 80 Tests Codes: DF71/ 10444942 Shelf Life:12 months Dimension Drug Calibrator I Size: 10 x 3.0 mL Codes: DC22B /10445014 Shelf Life:18 months 9. Dimension Tobramycin Flex reagent cartridge Size: 80 Tests Codes DF14/ 10444928 Shelf Life:12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 10. Dimension Vancomycin Flex reagent cartridge Size: 80 Tests Codes DF86/ 10444929 Shelf Life:12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 11. Dimension Valproic Acid Flex reagent cartridge Size: 80 Tests	
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			Codes DF78/ 10444943 Shelf Life:12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 12. Dimension Lithium Flex reagent cartridge Size: 80 Tests Codes DF132/ 10444939 Shelf Life:12 months Dimension Drug Calibrator I Size: 10 x 3.0 mL Codes: DC22B /10445014 Shelf Life:18 months 13. Dimension Lidocaine Flex reagent cartridge Size: 80 Tests Codes DF113/10444935 Shelf Life:12 months. Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months 14. Dimension Digitoxin Flex reagent cartridge Size: 80 Tests Codes DF36/ 10444932 Shelf Life:12 months Dimension Drug Calibrator II Size: 10 x 5.0mL Codes: DC49D /10445005 Shelf Life:12 months	
18.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 19-03-2020	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens	Dimension (Details are under codes) [Cluster for Immuno Chemistry of Anaemia for Dimension System] Applied as Cluster.	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall

	Fee Details: Paid Fee: 25,000/- Challan No. 1944787 dated 27-02-2019 Tracking ID: VD1-4SB-U5Y2	Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Class-B Model/Codes/Size: 1. Dimension Iron Flex reagent cartridge Kit Size: 240 Tests Codes: DF85/ 10444945 Shelf Life: 12 months Siemens Dimension Iron Calibrator Size: 4 x 1.2 mL Codes DC85/ 10445010 Shelf Life: 18 months 2. Dimension Total Iron Binding Capacity (IBCT) Flex reagent cartridge Size: 240 Tests Codes DF84/ 10444944 Shelf Life: 12 months Dimension Total Iron Binding Capacity (IBCT) Calibrator Size: 6 x 1.0 mL Codes DC84/ 10445006 Shelf Life: 18 months 3. Dimension Ferritin Flex reagent cartridge Size: 120 Tests Codes RF440/ 10444946 Shelf Life: 12 months Dimension Ferritin Calibrator Size: 10 x 2.0 mL Codes RC440/ 10445017 Shelf Life: 24 months 4.Dimension LOCI Folate Flex Reagent cartridge Size: 80 Tests Codes RF644/ 10463370 Shelf Life: 12 months	be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
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			Dimension LOCI Anemia Calibrator Size: 10 x 2.0 mL Codes RC640/ 10463372 Shelf Life: 12 months	
19.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 16-06-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944788 dated 16-06-2020 Tracking ID: 6EA-P5Y-HZ36	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate:	Dimension (Details are under codes) [Cluster of Immuno Chemistry Thyroid Function Marker for Dimension System] Applied as Cluster. Class-B Model/Codes/Size: Free T3 Kit 1. Dimension Free Thyroxine Flex reagent cartridge KIT Size: 120 Test Codes: 10444910 / RF410 Shelf Life: 12 months Dimension Thyroid Calibrator Size: 10 x 2.0 mL Codes: 10445018/RC410 Shelf Life: 18 months 2.Dimension Thyroxine Flex reagent cartridge Size: 120 Test Codes: 10444908 / DF65 Shelf Life: 12 months Dimension Thyroxine Calibrator Size: 10 x 1.0mL Codes: 10445029 / DC13 Shelf Life: 12 months 3.Dimension Thyroid Stimulating Hormone Flex reagent cartridge Size: 200 Tests Codes: 10444911 / RF412 Shelf Life: 12 months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.

		Type: Scan copy of non- notarized copy Validity: 15-09-2026	Dimension Thyroid Calibrator Size: 10 x 2.0 mL Codes: 10445018/RC410 Shelf Life: 18 months 4. Dimension Thyronine Uptake Flex reagent cartridge Size: 160 Tests Codes: 10444912 / DF75A Shelf Life: 12 months Dimension Thyronine Uptake Calibrator Size: 10 x 2.0 mL Codes: 10459406 / DC14 Shelf Life: 18 months 5. Dimension LOCI Free Triiodothyronine Flex reagent cartridge Size: 120 Tests Codes: 10483414 / RF616. Shelf Life: 12 months Dimension LOCI Thyroid Calibrator Size: 10 x 2.0mL Codes: 10484354/RC610A Shelf Life: 12 months	
20.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 11-05-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1919504 dated 08-05-2020 Tracking ID: JPM-UR6-YBVA	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare	Dimension (Details are under codes) [Cluster for Immuno Chemistry Fertility/Pregnancy/hormones/Protein] Applied as Cluster. Class-B Model/Codes/Size: 1. Dimension Human Chorionic Gonadotropin Flex reagent cartridge Kit Size: 120 Tests	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as

		Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Codes: 10444913/RF430 Shelf Life: 18 months Dimension Human Chorionic Gonadotropin Calibrator Size: 10 x 2.0 mL Codes: 10445019/RC430 Shelf Life: 24 months 2. Dimension Human Chorionic Gonadotropin Flex reagent cartridge Kit Size: 60 Tests Codes: 10444914/RF530 Shelf Life: 18 months Dimension Human Chorionic Gonadotropin Calibrator Size: 10 x 2.0 mL Codes: 10445019/RC430 Shelf Life: 24 months	per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevaent grouping. 4. Shelf life evidence/study for the applied product.
21.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 11-05-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944790 dated 08- 05-2020 Tracking ID: S9A- ML1-JR2P	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box	Dimension (Details are under codes) [Cluster for Immuno Chemistry of Cancer Marker] Applied as Cluster. Class-B Model/Codes/Size: 1.Dimension Total Prostate Specific Antigen Flex reagent cartridge Kit Size: 120 Tests Codes: 10444889/RF451 Shelf Life: 18 months Dimension Total/Free	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of Class of the applied as per MDR 2017 along with submission of the fee for the relevaent Class.

		6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Prostate Specific Antigen Calibrator Size: 12 x 2.0 mL Codes: 10445031/RC452 Shelf Life: 24 months 2.Dimension Free Prostate Specific Antigen Flex reagent cartridge Kit Size: 120 Tests Codes: 10444888/RF452 Shelf Life: 12 months Dimension Total/Free Prostate Specific Antigen Calibrator Size: 12 x 2.0 mL Codes: 10445031/RC452 Shelf Life: 24 months	One kit shall be considered in the current application & rest shall be applied through online MDMC portal. 4.Shelf life evidence/study for the applied product.
22.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 06-03-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944783 dated 05-03-2020 Tracking ID: M2L-91X-1EE2	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America	Dimension (Details are under codes) [Cluster for Immuno Chemistry of Cardiac markers for Dimension System] Applied as Cluster. Class-B Model/Codes/Size: CRP Kit: 1.Dimension Cardio Phase high sensitivity CRP Flex reagent cartridge Size: 120 Tests Codes: RF434/ 10444897 Shelf Life: 18 months	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of Class of the applied as per MDR 2017 along with submission of the fee for the relevant Class. One kit shall be considered in the current application & rest shall be applied through

		LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Dimension Revised C-Reactive Protein Calibrator Size: 10x 1.0mL Codes: RC434/ 10445003 Shelf Life: 18 months	online MDMC portal. 4.Shelf life evidence/study for the applied product.
23.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 11-05-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944789 dated 06-05-2020 Tracking ID: 3NQ-M2P-9VZM	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of	Dimension (Details are under codes) Hemoglobin Kit Applied as Cluster. Class-B Model/Codes/Size: 1. Dimension Hemoglobin A I c Kit Size: 120 Tests Codes: DF105A/ 10483822 P/N DF105A Shelf Life: 12 months	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Shelf life evidence/study for the applied product.

		non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non-notarized copy Validity: 15-09-2026		
24.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 30-06-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1942389 dated 08-05-2020 Tracking ID: QRV-NLR-H6RT	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026	Dimension (Details are under codes) [Cluster for Immuno Chemistry of Toxicology for Dimension System] Applied as Cluster. Class-B Model/Codes/Size: 1. Dimension Urine Amphetamine/Methamphetamine Screen Flex reagent cartridge Size: 80 Tests Code: DF91B/ 10444926 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 1	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. - Shelf life evidence/study for the applied product.

		FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Size: 14 ml. Code: 9A529UL/ 10445407 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3 Size: 14 ml. Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 5 Size: 14 ml. Code: 9A609UL/ 10445411 Shelf life: 09 Months. 2. Dimension Urine Barbiturate Screen Flex reagent cartridge Size: 80 Tests Code: DF96A / 10444918 Shelf life: 12 Months Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months.	
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			Emit Calibrator/Control Level 3 Size: 14 ml. Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 4 Size: 14 ml. Code: 9A589UL/ 10445410 Shelf life: 09 Months. Emit Calibrator/Control Level 5 Size: 14 ml. Code: 9A609UL/ 10445411 Shelf life: 09 Months. 3.DIMENSION Urine Benzodiazepines Screen Flex reagent cartridge Size: 80 Tests Code: DF97A / 10444919 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3	
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			Size: 14 ml. Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 4 Size: 14 ml. Code: 9A589UL/ 10445410 Shelf life: 09 Months. Emit Calibrator/Control Level 5 Size: 14 ml. Code: 9A609UL/ 10445411 Shelf life: 09 Months. 4.DIMENSION Urine Cocaine Metabolite Screen Flex reagent cartridge Size: 80 Tests Code: DF92A /10444920 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3 Size: 14 ml. Code: 9A569UL/ 10445409	
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			Shelf life: 09 Months. Emit Calibrator/Control Level 4 Size: 14 ml. Code: 9A589UL/ 10445410 Shelf life: 09 Months Emit Calibrator/Control Level 5 Size: 14 ml. Code: 9A609UL/ 10445411 Shelf life: 09 Months. 5.DIMENSION Urine Methadone Screen Flex reagent cartridge Size: 80 Tests Code: DF90A / 10444922 Shelf life: 12 Months Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3 Size: 14 ml. Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 4	
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			Size: 14 ml. Code: 9A589UL/ 10445410 Shelf life: 09 Months. Emit Calibrator/Control Level 5 Size: 14 ml. Code: 9A609UL/ 10445411 Shelf life: 09 Months. 5.DIMENSION Urine Opiates Screen Flex reagent cartridge Size: 80 Tests Code: DF93A / 10444923 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 1 Size: 14 ml. Code: 9A529UL/ 10445407 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3 Size: 14 ml.	
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			Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 5 Size: 14 ml. Code: 9A609UL/ 10445411 Shelf life: 09 Months. 6.DIMENSION Urine Phencyclidine Screen Flex reagent cartridge Size: 80 Tests Code: DF94A/ 10444924 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3 Size: 14 ml. Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 4 Size: 14 ml. Code: 9A589UL/ 10445410 Shelf life: 09 Months.	
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			7. DIMENSION Salicylate Flex reagent cartridge Size: 120 Tests Code: DF20/ 10444915 Shelf life: 12 Months. DIMENSION Salicylate Calibrator Size: 6 x 2.0 ml. Code: DC38/ 10444992 Shelf life: 12 Months.  8.DIMENSION Acetaminophen Flex reagent cartridge Size: 80 Tests Code:DF88/ 10444916 Shelf life: 12 Months. DIMENSION Drug Calibrator II Size: 10 x 2.0 ml. Code: DC49D/ 10445005 Shelf life: 12 Months. 9.DIMENSION Ethyl alcohol Flex reagent cartridge Size: 120 Tests Code: DF22 / 10459408 Shelf life: 12 Months. DIMENSION Chemistry III Calibrator Size: 6 x 2.0ml. Code: DC130 / 10711580 Shelf life: 12 Months. 10.DIMENSION Urine Cannabinoids Screen Flex reagent cartridge	
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			Size: 80 Tests Code: DF95A/ 10444925 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406 Shelf life: 12 Months. Emit Calibrator/Control Level 2 Size: 14 ml. Code: 9A549UL/ 10445408 Shelf life: 09 Months. Emit Calibrator/Control Level 3 Size: 14 ml. Code: 9A569UL/ 10445409 Shelf life: 09 Months. Emit Calibrator/Control Level 4 Size: 14 ml. Code: 9A589UL/ 10445410 Shelf life: 09 Months. 11.DIMENSION Urine Ecstasy Screen Flex reagent cartridge Size: 80 Tests Code: DF109/ 10444921 Shelf life: 12 Months. Emit Calibrator/Control Level 0 Size: 14 ml. Code: 9A509UL/ 10445406	
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			Shelf life: 12 Months. Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 1 Size: 10 ml. Code: 9R529UL/ 10470441 Shelf life: 12 Months. Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 2 Size: 10 ml. Code: 9R549UL/ 10470442 Shelf life: 12 Months. Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 3 Size: 10 ml. Code: 9R569UL/ 10470443 Shelf life: 12 Months. Emit II Plus 6-AM/Ecstasy Calibrator / Control Level 4 Size: 10 ml. Code: 9R589UL/ 10470444 Shelf life: 12 Months	
25.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 26-01-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2029895 dated 12-01-2021	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA	Immulite (Details are under codes) [Cluster for Immuno Chemistry Anaemia for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1.Immulite 1000 Erythropoietin (EPO) Size: 100 Tests	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee

	Tracking ID: 7U3-AQ7-TBZZ	Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Codes: LKEPN1/10487627 Shelf Life: 12 months 2.Immulite 2000 Erythropoietin (EPO) Size: 200 Tests Codes: L2KEPN2/10487628 Shelf Life: :12 months 3.Immulite 2000 Erythropoietin (EPO) Size: 600 Tests Codes: L2KEPN6/10487629 Shelf Life: 12 months. 4. Immulite EPO Sample Diluent Size: 1x 25mL Codes: LEPZ/10387022 Shelf Life: 36 months. 5. Immulite EPO Control Module Size: 3 x 2mL Codes: LEPCM/10385384 Shelf Life: 36 months. 6. Immulite 1000 Ferritin Size: 100 Tests Codes: LKFE1/10380898 Shelf Life: 12 months. 7. Immulite 2000 Ferritin Size: 200 Tests Codes: L2KFE2/10380908 Shelf Life: 12 months. 8. Immulite 2000 Ferritin Size: 600 Tests Codes: L2KFE6/10380906 Shelf Life: 12 months. 9. Immulite 2000 Multi-Diluent 2 Sample Diluent Size: 1x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months. 10. Immulite 2000 Multi-	submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4. Shelf life evidence/study for the applied product.
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			Diluent 2 Sample Diluent Size: 1x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months. 11.Immulite Ferritin Control Module Size: 2 x 2mL Codes: FECM/10385378 Shelf Life: 24 months. 12.Immulite Ferritin Sample Diluent Size: 1x 25mL Codes: LFEZ/10387025 Shelf Life: 36 months. 13.Immulite 2000 Folic Acid Size: 200 Tests Codes: L2KFO2/10380911 Shelf Life: 12 months. 14.Immulite 2000 Folic Acid Size: 600 Tests Codes: L2KFO6/10380912 Shelf Life: 12 months. 15. Immulite 2000 Vitamin B12/Folic Acid Sample Diluent Size: 1x 25mL Codes: L2FVZ/10387054 Shelf Life: 36 months. 16. Ascorbic Acid Size: - Codes: 10485435 Shelf Life: 06 months.	
26.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 15-02-2021 Fee Details:	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy,	Immulite (Details are under codes) [Cluster for Immuno - Chemistry Bone & Mineral Metabolism for Immulite Immunoassay System] Applied as Cluster.	Deferred for submission of the followings: Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with

	Paid Fee: 25,000/- Challan No. 2029896 dated 12-01-2021 Tracking ID: RD8-72B-3X9W	Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Class-B Model/Codes/Size: 1.IMMULITE 1000 Calcitonin Size: 100 Tests Codes: LKCL1/10381401 Shelf Life: 12 months 2.IMMULITE 2000 Calcitonin Size: 200 Tests Codes: L2KCL2/10381446 Shelf Life: :12 months 3. IMMULITE 2000 Multi-Diluent 2 Sample Diluent Size: 1x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months. 4. IMMULITE 2000 Multi-Diluent 2 Sample Diluent Size: 1x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months. 5. IMMULITE Calcitonin Sample Diluent Size: 1x 25mL Codes: LCLZ/10387019 Shelf Life: 36 months. 6. IMMULITE Calcitonin Control Module Size: 2 x 3mL Codes: LCLCM /10385383 Shelf Life: 36 months. 7.IMMULITE 1000 Osteocalcin Size: 100 Tests Codes: LKON1/10381396 Shelf Life: 12 months. 8.IMMULITE 1000 Osteocalcin Size: 200 Tests Codes:	the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
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			L2KON2/10381477 Shelf Life: 12 months. 9. IMMULITE Osteocalcin Control Module Size: 2x 2mL Codes: LONCM/10385415 Shelf Life: 36 months. 10.IMMULITE 1000 Intact PTH Size: 100 Tests Codes: LKPP1/10381399 Shelf Life: 09 months. 11.IMMULITE 1000 TURBO Intact PTH Size: 50 Tests Codes: LSKPTZ/10381430 Shelf Life: 12 months. 12.IMMULITE 2000 Intact PTH Size: 200 Tests Codes: L2KPP2/10381441 Shelf Life: 09 months. 13.IMMULITE 2000 Intact PTH Size: 600 Tests Codes: L2KPP6/10381442 Shelf Life: 09 months. 14.IMMULITE 2000 Intact PTH Sample Diluent Size: 1x 25mL Codes: L2PHZ/10387060 Shelf Life: 36 months. 15.IMMULITE Intact PTH Sample Diluent Size: 1x 25mL Codes: LPHZ/10283037 Shelf Life: 36 months. 16.IMMULITE Intact PTH Control Module Size: 6 x 2mL Codes: LPHCM/10385354 Shelf Life: 36 months.	
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			17.IMMULITE 1000 Pyrilinks-D Size: 100 Tests Codes: LKPD1/10381389 Shelf Life: 06 months. 18.IMMULITE 2000 Pyrilinks-D Size: 200 Tests Codes: L2KPD2/10381461 Shelf Life: 12 months. 19. IMMULITE Pyrilinks-D Sample Diluent Size: 1x 25mL Codes: LPDZ /10387038 Shelf Life: 24 months. 20. IMMULITE Pyrilinks-D Control Module Size: 1 x 2mL/vial Codes: LPDCM/10385243 Shelf Life: 24 months.	
27.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-06-2021 Fee Details: Paid Fee: 25,000/- Challan No. 280306371 (for Atellica 1500 Reagents.) & 2029877 (copy of fee slip not attached) Tracking ID: L66-MRZ-ZVW5	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024	Immulite (Details are under codes) [Cluster for Immuno-Chemistry Cancer Marker for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1. Immulite / Immulite 1000 BR-MA Size: 100 Tests Codes: LKBR1/10380948 Shelf Life: 12 months 2. Immulite 2000 BR-MA Size: 200 Tests Codes: L2KBR2/10380983 Shelf Life: 12 months 3. Immulite BR-MA Sample Diluent	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of Class of the applied as per MDR 2017 along with submission of the fee for the relevent Class. One kit shall be considered in the current application & rest shall be applied through

		ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Size: 1 x 25mL Codes: LBRZ/10387018 Shelf Life: 36 months 4.Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months 5.Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months 6. Immulite / Immulite 1000 CEA Size: 100 Tests Codes: LKCE1/10380945 Shelf Life: 12 months 7. Immulite 2000 CEA Size: 200 Tests Codes: L2KCE2/10380994 Shelf Life: 12 months 8. Immulite 2000 CEA Size: 600 Tests Codes: L2KCE6/10380995 Shelf Life: 12 months 9.Immulite CEA Sample Diluent Size: 1 x 25mL Codes: LCEZ/10387047 Shelf Life: 36 months 10.Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months 11.Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months 12. Immulite / Immulite 1000 GI-MA	online MDMC portal. 4.Shelf life evidence/study for the applied product.
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			Size: 100 Tests Codes: LKGI1/10380965 Shelf Life: 12 months 13. Immulite 2000 GI-MA Size: 200 Tests Codes: L2KGI2/10380988 Shelf Life: 12 months 14. Immulite GI-MA Sample Diluent Size: 1 x 25mL Codes: LGIZ/10283034 Shelf Life: 36 months 15. Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months 16. Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months 17. Immulite / Immulite 1000 OM-MA Size: 100 Tests Codes: LKOP1/10380969 Shelf Life: 12 months 18. Immulite 2000 OM-MA Size: 200 Tests Codes: L2KOP2/10380972 Shelf Life: 12 months 19. Immulite OM-MA Sample Diluent Size: 1 x 25mL Codes: LOMZ/10387036 Shelf Life: 36 months 20. Immulite 2000 OM-MA Sample Diluent Size: 1 x 25mL Codes: L2OPZ/10387067 Shelf Life: 36 months	
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			21. Immulite 2000 OM-MA Sample Diluent Size: 1 x 25mL Codes: L2OPZ/10387067 Shelf Life: 36 months 22. Immulite / Immulite 1000 PAP Size: 100 Tests Codes: LKPA1/10380953 Shelf Life: 12 months 23. Immulite 2000 PAP Size: 200 Tests Codes: L2KPA2/10380975 Shelf Life: 12 months 24. Immulite PAP Control Module Size: 1 x 2.0mL Codes: PACM/10385588 Shelf Life: 36 months 25. Immulite 2000 Multi-Diluent 1 Sample Diluent Size: 1 x 25mL Codes: L2M1Z/10387057 Shelf Life: 36 months 26. Immulite / Immulite 1000 Free PSA Size: 100 Tests Codes: LKPF1/10380967 Shelf Life: 12 months 27. Immulite 2000 Free PSA Size: 200 Tests Codes: L2KPF2/10380984 Shelf Life: 12 months 28. Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months 29. Immulite 2000 Multi Diluent 2 Sample Diluent Size: 1 x 55mL Codes: L2M2Z4/10387058	
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			Shelf Life: 36 months.	
28.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 17-06-2021 Fee Details: Paid Fee: 25,000/- Challan No. 280306371 (for Atellica 1500 Reagents.) & 2029877 (copy of fee slip attached for some other product) Tracking ID: 6GY-9YG-W3R5	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Immulite (Details are under codes) [Cluster for Immuno-Chemistry Cardiac Marker for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1.Immulite / Immulite 1000 Homocysteine Size: 100 Tests Codes: LKHO1/10381029 Shelf Life: 12 months 2.Immulite 2000 Homocysteine Size: 200 Tests Codes: L2KHO2/10381040 Shelf Life: 12 months 3.Immulite 2000 Homocysteine Sample Diluent Size: 1 x 25mL/vial Codes: L2HOZ /10387055 Shelf Life: 36 months 4.Immulite / Immulite 1000 High Sensitivity CRP Size: 100 Tests Codes: LKCRP1/10286287 Shelf Life: 12 months 5.Immulite 2000 High Sensitivity CRP Size: 200 Tests Codes: L2KCRP2/10381043 Shelf Life: 12 months 6.Immulite C Reactive Protein Control Module Size: 3 x 2mL Codes: LCRCM /10385316 Shelf Life: 12 months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of Class of the applied as per MDR 2017 along with submission of the fee for the releavent Class. One kit shall be considered in the current application & rest shall be applied through online MDMC portal. 4. Shelf life evidence/study for the applied product.

			7.Immulite / Immulite 1000 TURBO D-Dimer Size: 100 Tests Codes: LSKDD1 /10381012 Shelf Life: 12 months 8. Immulite 2000 D-Dimer Size: 200 Tests Codes: L2KDD2/10381041 Shelf Life: 12 months 9.Immulite D-DIMER Control Module Size: 1 x 2.0mL Codes: LDDCM /10385330 Shelf Life: 36 months 10.Immulite / Immulite 1000 Troponin I Size: 100 Tests Codes: LKTI1 /10381026 Shelf Life: 12 months 11.Immulite / Immulite 1000 Turbo Troponin I Size: 100 Tests Codes: LSKTI1 /10381014 Shelf Life: 12 months 12.Immulite Troponin I Sample Diluent Size: 1 x25mL Codes: LTIZ /10386995 Shelf Life: 36 months 13.Immulite 2000 Troponin I Size: 200 Tests Codes: L2KTI2 /10381034 Shelf Life: 12 months 14. Immulite 2000 Multi-Diluent 1 Sample Diluent Size: 1 x 25mL Codes: L2M1Z /10387057 Shelf Life: 36 months 15. Immulite 2000 NT-pro BNP Size: 200 Tests	
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			Codes: L2KNT2 /10381036 Shelf Life: 12 months 16. Immulite NT-Pro BNP Control Module Size: 2 x 3.0mL Codes: LNTCM /10385339 Shelf Life: 36 months 17. Immulite 2000 NT-pro BNP Sample Diluent Size: 1 x 25mL Codes: L2NTZ /10387059 Shelf Life: 36 months	
29.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 26-01-2021 Fee Details: Paid Fee: 25,000/- Challan No. 280306371 (for Atellica 1500 Reagents.) & 1942501 dated 12-01-2021 Tracking ID: LZG-8B8-PE11	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Immulite (Details are under codes) [Cluster for Immuno – Chemistry Haematology Cytokines (lymphokines)/immunomodulatory for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1. Immulite 1000 IL-1 B Size: 100 Tests Codes: LKL11/10381421 Shelf Life: 12 months 2. Immulite Cytokine Control Module Size: 2 x 5mL Codes: LILCM /10385389 Shelf Life: 36 months 3. Immulite 1000 IL2R Size: 100 Tests Codes: LKIP1/10381416 Shelf Life: 12 months. 4. Immulite 2000 IL2R Size: 200 Tests Codes: L2KIP2/ 10381457 Shelf Life: 12 months. 5. Immulite 2000 Multi-	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.

			Diluent 2 Sample Diluent Size: 1 x 25mL Codes: L2M2Z /10283031 Shelf Life: 36 months. 6. Immulite 2000 Multi-Diluent 2 Sample Diluent Size: 1 x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months. 7. Immulite IL2R Sample Diluent Size: 1 x 25mL Codes: LIPZ /10387351 Shelf Life: 24 months. 8. Immulite Cytokine Control Module Size: 1 x 5.0mL Codes: LILCM /10385389 Shelf Life: 36 months. 9. Immulite 1000 IL-6 Size: 100 Tests Codes: LK6P1/10381411 Shelf Life: 12 months. 10. Immulite 2000 IL-6 Size: 200 Tests Codes: L2K6P2/10381452 Shelf Life: 12 months. 11. Immulite 2000 Multi-Diluent 2 Sample Diluent Size: 1 x 25mL Codes L2M2Z/10283031 Shelf Life: 36 months. 12. Immulite 2000 Multi-Diluent 2 Sample Diluent Size: 1 x 55mL Codes: L2M2Z4/10387058 Shelf Life: 36 months. 13. Immulite Cytokine Control Module Size: 2 x 5.0mL Codes: LILCM/10385389 Shelf Life: 36 months.	
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			14. Immulite 1000 IL-8 Size: 100 Tests Codes: LK8P1/10381407 Shelf Life: 12 months. 15. Immulite IL-8 Sample Diluent Size: 1 x 25mL Codes: L8PZ/10387010 Shelf Life: 36 months. 16. Immulite Cytokine Control Module Size: 2 x 5.0mL Codes: LILCM/10385389 Shelf Life: 36 months. 17. Immulite 1000 IL-10 Size: 100 Tests Codes: LKXP1/10381383 Shelf Life: 12 months. 18. Immulite IL-8 Sample Diluent Size: 1 x 25mL Codes: L8PZ/10387010 Shelf Life: 36 months. 19. Immulite IL-10 Control Module Size: 1 x 4.0mL Codes: LXPCM/10385248 Shelf Life: 36 months. 20. Immulite 1000 TNF-alfa Size: 100 Tests Codes: LKNF1/10381417 Shelf Life: 06 months. 21. Immulite TNF-alfa Sample Diluent Size: 1 x 25mL Codes: LNFZ/10387035 Shelf Life: 24 months. 22. Immulite Cytokine Control Module Size: 2 x 5mL Codes: LILCM/10385389	
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			Shelf Life: 36 months.	
30.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 15-02-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2029897 dated 12-01-2021 Tracking ID: TUQ-L3T-1NAP	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Immulite (Details are under codes) [Cluster for Immuno Chemistry Diabetic Assays for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1. Immulite / Immulite 1000 C-Peptide Size: 100 Tests Codes: LKPEP1/10381397 Shelf Life: 06 months 2. Immulite 2000 C-Peptide Size: 200 Tests Codes: L2KPEP2/10381450 Shelf Life: 06 months 3. Immulite C-Peptide Sample Diluent Size: 1 x 25mL Codes: LPEZ/10387039 Shelf Life: 36 months. 4. Immulite 2000 C-Peptide Sample Diluent Size: 1 x 25mL Codes: L2PEZ/10387068 Shelf Life: 36 months. 5. Immulite C-Peptide Control Module Size: 3 x 2mL Codes: PECM/10385589 Shelf Life: 36 months. 6. Immulite / Immulite 1000 Insulin Size: 100 Tests Codes: LKIN1/10381429 Shelf Life: 12 months. 7. Immulite 2000 Insulin	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4. Shelf life evidence/study for the applied product.

			Size: 200 Tests Codes: L2KIN2/10381455 Shelf Life: 12 months. 8. Immulite 2000 Insulin Size: 600 Tests Codes: L2KIN6/10381456 Shelf Life: 12 months. 9. Immulite 2000 Insulin Sample Diluent Size: 1 x 25mL Codes: L2INZ/10387066 Shelf Life: 36 months. 10. Immulite Insulin Control Module Size: 02 vials Codes: LINCM /10286614 Shelf Life: 36 months. 11. Immulite Insulin Sample Diluent Size: 1 x 25mL Codes: LINZ/10387034 Shelf Life: 36 months. 12. Immulite / Immulite 1000 Albumin Size: 100 Tests Codes: LKHA1/10381385 Shelf Life: 12 months. 13. Immulite 2000 Albumin Size: 200 Tests Codes: L2KHA2/10381453 Shelf Life: 12 months. 14. Immulite Albumin Control Module Size: 1 x 2.0mL Codes: LHACM/10385388 Shelf Life: 36 months. 15. Immulite Albumin Sample Diluent Size: 1x 25mL Codes: LHAZ/10387031 Shelf Life: 36 months. 16. Immulite 2000 Multi-	
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			Diluent 2 Sample Size: 1x 25mL Codes: L2M2Z/10283031 Shelf Life: 36 months. 17. Immulite 2000 Multi-Diluent 2 Sample Size: 1x 50mL Codes: L2M2Z4/10387058 Shelf Life: 36 months.	
31.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 26-01-2021 Fee Details: Paid Fee: 25,000/- 1942502 dated 12-01-2021 Tracking ID: 5L5-9ZW-8WMW	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non-notarized copy Validity: 15-09-2026	Immulite (Details are under codes) [Cluster Immuno – Chemistry Fertility/Pregnancy/ Hormones/ Proteins for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1.IMMULITE 1000 Androstenedione Size: 100 Tests Codes: LKAO1/10381158 Shelf Life: 12 months 2.IMMULITE 2000 Androstenedione Size: 200 Tests Codes: L2KAO2/10381188 Shelf Life: 12 months 3.IMMULITE 1000 DHEA-SO4 Size: 100 Tests Codes: LKDS1/10381130 Shelf Life: 12 months. 4.IMMULITE 2000 DHEA-SO4 Size: 200 Tests Codes: L2KDS2/10381193 Shelf Life: 12 months. 5. IMMULITE DHEA-SO4 Sample Diluent	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.

			Size: 1 x 25mL Codes: LDSZ/10387020 Shelf Life: 36 months. 6.IMMULITE 2000 Multi-Diluent 1 Size: 1 x 25mL Codes: L2M1Z/10387057 Shelf Life: 36 months. 7.IMMULITE 1000 Estradiol Size: 100 Tests Codes: LKE21/10381132 Shelf Life: 12 months. 8.IMMULITE 2000 Estradiol Size: 200 Tests Codes: L2KE22/10381178 Shelf Life: 12 months. 9.IMMULITE 2000 Estradiol Size: 600 Tests Codes: L2KE26/ 10381177 Shelf Life: 12 months. 10.IMMULITE 2000 Estradiol Sample Diluent Size: 1 x 25mL Codes: L2E2Z/10387063 Shelf Life: 36 months. 11.IMMULITE Estradiol Sample Diluent Size: 1 x 25mL Codes: LE2Z/ 10387021 Shelf Life: 36 months. 12.IMMULITE Estradiol Control Module Size: 1 x 2mL Codes: E2TC1/10389765 Shelf Life: 24 months. 13. IMMULITE 1000 FSH Size: 100 Tests Codes: LKFS1/10381153 Shelf Life: 12 months. 14. IMMULITE 2000	
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			FSH Size: 200 Tests Codes: L2KFS2/10381201 Shelf Life: 12 months. 15. IMMULITE 2000 FSH Size: 600 Tests Codes: L2KFS6/10381180 Shelf Life: 12 months 16. IMMULITE 2000 FSH Sample Diluent Size: 1 x 25mL Codes: L2FSZ/10387064 Shelf Life: 36 months 17. IMMULITE FSH Sample Diluent Size: 1 x 25mL Codes: LFSZ/10387026 Shelf Life: 36 months 18. IMMULITE 1000 LH Size: 100 Tests Codes: LKLH1/10381141 Shelf Life: 12 months 19. IMMULITE 2000 LH Size: 200 Tests Codes: L2KLH2/10381211 Shelf Life: 12 months 20. IMMULITE 2000 LH Size: 600 Tests Codes: L2KLH6/10381212 Shelf Life: 12 months 21. IMMULITE 1000 Progesterone Size: 100 Tests Codes: LKPW1/10381128 Shelf Life: 12 months 22. IMMULITE 2000 Progesterone Size: 200 Tests Codes: L2KPW2/10381181 Shelf Life: 12 months 23. IMMULITE 2000 Progesterone	
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			Size: 600 Tests Codes:L2KPW6/10381170 Shelf Life: 12 months 24.IMMULITE 2000 Multi-Diluent 1 Size: 1 x 25mL Codes: L2M1Z/10387057 Shelf Life: 36 months 25.IMMULITE Progesterone Sample Diluent Size:1 x 25mL Codes: LPWZ/10388207 Shelf Life: 36 months 26.IMMULITE 1000 Prolactin Size: 100 Tests Codes: LKPR1/10381145 Shelf Life: 12 months 27.IMMULITE 2000 Prolactin Size: 200 Tests Codes: L2KPR2/10381200 Shelf Life: 12 months 28.IMMULITE 2000 Prolactin Size: 600 Tests Codes: L2KPR6/10381199 Shelf Life: 12 months 29.IMMULITE Prolactin Sample Diluent Size: 1 x 25mL Codes: LPRZ/10387040 Shelf Life: 36 months 30.IMMULITE 2000 Prolactin Sample Diluent Size: 1 x 25mL Codes: L2PRZ/10387069 Shelf Life: 36 months 31.IMMULITE 1000 SHBG Size: 100 Tests Codes: LKSH1/10381138	
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			Shelf Life: 12 months 32.IMMULITE 2000 SHBG Size: 200 Tests Codes: L2KSH2/10381198 Shelf Life: 12 months 33.IMMULITE 1000 SHBG Sample Diluent Module Size: 1 x 25mL Codes:L1KSHW1/10385366 Shelf Life: 36 months 34.IMMULITE SHBG Control Module Size: 1 x 2.0mL Codes: LSHCM/10285226 Shelf Life: 36 months 35. IMMULITE 1000 Total Testosterone Size: 100 Tests Codes: LKTW1/10381156 Shelf Life: 09 months 36. IMMULITE 2000 Total Testosterone Size: 200 Tests Codes: L2KTW2/10381190 Shelf Life: 09 months 37. IMMULITE 2000 Total Testosterone Size: 600 Tests Codes: L2KTW6/10381191 Shelf Life: 09 months 38.IMMULITE 2000 Multi-Diluent 1. Size: 1 x 25mL Codes: L2M1Z/10387057 Shelf Life: 36 months	
32.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037)	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave.	Immulite (Details are under codes) [Cluster Immuno – Chemistry Non-	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of

	Date of R&I 26-01-2021 Fee Details: Paid Fee: 25,000/- 1942503 dated 12-01-2021 Tracking ID: R6N-UVT-L2D8	Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Immunosuppressive Therapeutic Drug Monitoring for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1.Immulite 1000 Carbamazepine Size: 100 Tests Codes: LKCB1/10381505 Shelf Life: 12 months 2.Immulite 2000 Carbamazepine Size: 200 Tests Codes:L2KCB2/10381550 Shelf Life: 12 months 3. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months. 4.Immulite 1000 Digitoxin Size: 100 Tests Codes: LKDG1/10381508 Shelf Life: 12 months. 5.Immulite 2000 Digitoxin Size: 200 Tests Codes:L2KDG2/10381538 Shelf Life: 12 months. 6. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months. 7. Immulite 1000 Digoxin Size: 100 Tests Codes: LKDI1/10381517 Shelf Life: 12 months. 8. Immulite 2000 Digoxin	origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
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			Size: 200 Tests Codes: L2KDI2/10381529 Shelf Life: 12 months. 9. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months. 10. Immulite 1000 Phenobarbital Size: 100 Tests Codes: LKPB1/10381512 Shelf Life: 12 months. 11. Immulite 2000 Phenobarbital Size: 200 Tests Codes: L2KPB2/10381542 Shelf Life: 12 months. 12. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months. 13. Immulite 1000 Phenytoin Size: 100 Tests Codes: LKPN1/10381510 Shelf Life: 12 months. 14. Immulite 2000 Phenytoin Size: 200 Tests Codes: L2KPN2/10381548 Shelf Life: 12 months. 15. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months 16. Immulite 1000 Theophylline Size: 100 Tests Codes: LKTN1/10381503 Shelf Life: 12 months	
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			17.Immulite 2000 Theophylline Size: 200 Tests Codes:L2KTN2/10381539 Shelf Life: 12 months 18. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months 19.Immulite 1000 Valproic Acid. Size: 100 Tests Codes: LKVA1/10381509 Shelf Life: 12 months 20.Immulite 2000 Valproic Acid. Size: 200 Tests Codes:L2KVA2/10381544 Shelf Life: 12 months 21. Immulite Serum Drug Control Module Size: 2 x 5mL Codes: SDCM/10385397 Shelf Life: 36 months	
33.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 26-01-2021 Fee Details: Paid Fee: 25,000/- 2029894 dated 12-01-2021 Tracking ID: HAG-MJT-HYJ3	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of	Immulite (Details are under codes) [Cluster for Immuno-Chemistry Renal Metabolism Assays for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1. Immulite 1000 Cortisol Size: 100 Tests Codes: LKCO1/10381388 Shelf Life: 06 months 2. Immulite 2000 Cortisol Size: 200 Tests	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like

		non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Codes: L2KCO2/10381476 Shelf Life: :06 months 3. Immulite 2000 Cortisol Size: 600 Tests Codes: L2KCO6/10381480 Shelf Life: 06 months. 4. Immulite 2000 Multi-Diluent 1 Sample Diluent Size: 1x 25mL Codes: L2M1Z/10387057 Shelf Life: 36 months. 5.Immulite Cortisol Sample Diluent Size: 1x 25mL Codes: LCOZ/10386981 Shelf Life: 36 months.	catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
34.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 17-02-2021 Fee Details: Paid Fee: 25,000/- 1942505 dated 12-01-2021 Tracking ID: YML-T7Z-19RN	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Immulite (Details are under codes) [Cluster for Immuno Chemistry Thyroid Function Marker for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1. Immulite 1000 Free T3 Size: 100 Tests Codes: LKF31/10381626 Shelf Life: 06 months 2. Immulite 2000 Free T3 Size: 200 Tests Codes: L2KF32/10381675 Shelf Life: 06 months 3. Immulite 2000 Free T3 Size: 600 Tests Codes: L2KF36/10381682 Shelf Life: 06 months. 4. Immulite 1000 Total T3	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. - Shelf life evidence/study for the applied product.

		EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Size: 100 Tests Codes: LKT31/10381630 Shelf Life: 12 months. 5. Immulite 2000 Total T3 Size: 200 Tests Codes: L2KT32/10381654 Shelf Life: 12 months. 6. Immulite 2000 Total T3 Size: 600 Tests Codes: L2KT36/10381657 Shelf Life: 12 months. 7. Immulite Total T3 Sample Diluent Size: 1x 25mL Codes: LT3Z/10387578 Shelf Life: 36 months. 8. Immulite 1000 Free T4 Size: 100 Tests Codes: LKFT41/10381622 Shelf Life: 12 months. 9. Immulite 2000 Free T4 Size: 600 Tests Codes: L2KFT46/10381677 Shelf Life: 12 months. 10. Immulite 2000 Free T4 Size: 200 Tests Codes: L2KFT42/10381678 Shelf Life: 12 months. 11. Immulite 1000 Total T4 Size: 100 Tests Codes: LKT41/10381633 Shelf Life: 12 months. 12. Immulite 1000 Total T4 Size: 500 Tests Codes: LKT45/10381635 Shelf Life: 12 months. 13. Immulite 2000 Total	
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			T4 Size: 200 Tests Codes: L2KT42/10381685 Shelf Life: 12 months. 14. Immulite 2000 Total T4 Size: 600 Tests Codes: L2KT46/10381664 Shelf Life: 12 months. 15. Immulite Total T4 Sample Diluent Size: 1x 25mL Codes: LT4Z/10387587 Shelf Life: 36 months. 16. Immulite 2000 Multi-Diluent 1 Size: 1x 25mL Codes: L2M1Z/10387057 Shelf Life: 36 months. 17. Immulite 1000 TBG Size: 100 Tests Codes: LKTB1/10381643 Shelf Life: 12 months. 18. Immulite 2000 TBG Size: 200 Tests Codes: L2KTB2/10381660 Shelf Life: 12 months. 19. Immulite 2000 TBG Sample Diluent Size: 1x 25mL Codes: L2TBZ/10387072 Shelf Life: 36 months. 20. Immulite TBG Control Module Size: 1x 2mL Codes: LTBCM/10385244 Shelf Life: 24 months. 21. Immulite 1000 Thyroglobulin Size: 100 Tests Codes: LKTY1/10381644 Shelf Life: 12 months. 22. Immulite 2000	
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			Thyroglobulin Size: 200 Tests Codes: L2KTY2/10381648 Shelf Life: 12 months 23.Immulite Thyroglobulin Sample Diluent Size: 1x 25mL Codes: LTYZ/10387046 Shelf Life: 36 months 24.Immulite Thyroglobulin Recovery Sample Size: 2 x 1mL Codes: LTYRM/10381639 Shelf Life:06 months 25. Immulite 1000 Anti- TG Size: 100 Tests Codes: LKTG1/10381641 Shelf Life:06 months 26. Immulite 2000 Anti- TG Ab Size: 200 Tests Codes: L2KTG2/10381659 Shelf Life:12 months 27. Immulite 2000 Anti- TG Ab Size: 600 Tests Codes: L2KTG6/10381655 Shelf Life:12 months 28.Immulite Thyroid Autoantibody Control Module Size: 1x 5.0mL Codes: LAACM/10385381 Shelf Life:36 months 29. Immulite 1000 Anti- TPO Ab Size: 100 Tests Codes: LKTO1/10381618 Shelf Life:12 months 30. Immulite 2000 Anti- TPO Ab	
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			Size: 200 Tests Codes: L2KTO2/10381650 Shelf Life:12 months 31. Immulite 2000 Anti-TPO Ab Size: 600 Tests Codes: L2KTO6/10381649 Shelf Life:12 months 32.Immulite Thyroid Autoantibody Control Module Size: 1x 5.0mL Codes: LAACM/10385381 Shelf Life:36 months 33. Immulite 1000 Thyroid Uptake Size: 100 Tests Codes: LKTU1/10381619 Shelf Life:12 months 34. Immulite 2000 Thyroid Uptake Size: 200 Tests Codes: L2KTU2/10381669 Shelf Life:12 months 35. Immulite 1000 Rapid TSH Size: 100 Tests Codes: LKRT1/10381637 Shelf Life:12 months 36. Immulite 1000 Rapid TSH Size: 500 Tests Codes: LKRT5/10381628 Shelf Life:12 months 37. Immulite 2000 Rapid TSH Size: 200 Tests Codes: L2KRT2/10381651 Shelf Life:12 months 38. Immulite 2000 Rapid TSH Size: 600 Tests Codes: L2KRT6/10381652	
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			Shelf Life:12 months 39. Immulite 2000 Third Generation TSH Sample Diluent Size: 1x 25mL Codes: L2TSZ/10387061 Shelf Life:36 months 40. Immulite 1000 Third Generation TSH Size: 100 Tests Codes: LKTS1/10381620 Shelf Life:12 months 41. Immulite 1000 Third Generation TSH Size: 500 Tests Codes: LKTS5/10381627 Shelf Life:12 months 42. Immulite 2000 Third Generation TSH Size: 200 Tests Codes: L2KTS2/10381665 Shelf Life:12 months 43. Immulite 2000 Third Generation TSH Size: 600 Tests Codes: L2KTS6/10381667 Shelf Life:12 months 44. Immulite 2000 Third Generation TSH Sample Diluent Size: 1x 25mL Codes: L2TSZ/10387061 Shelf Life:36 months 45. Immulite Third Generation TSH Control Module Size: 1x 2.0mL Codes: LTGCM/10385395 Shelf Life:36 months 46. Immulite Rapid TSH Sample Diluent Size: 1x 25mL Codes: LRTZ/10387486 Shelf Life:36 months	
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			47. Immulite 2000 TSI Size: 200 Tests Codes: L2KSI2/10713448 Shelf Life:12 months 48. Immulite 2000 Multi-Diluent 2 Size: 1x 25mL Codes: L2M2Z/10283031 Shelf Life:36 months 48. Immulite 2000 Multi-Diluent 2 Size: 1x 55mL Codes: L2M2Z4/10387058 Shelf Life:36 months	
35.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 15-02-2021 Fee Details: Paid Fee: 25,000/- 1942504 dated 12-01-2021 Tracking ID: DDX-JNW-WRGM	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 11-09-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy	Immulite (Details are under codes) [Cluster for Immuno Chemistry Vitamins for Immulite Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 1. Immulite / Immulite 1000 Vitamin B12 Size: 100 Tests Codes: LKVB1/10380900 Shelf Life: 12 months 2.Immulite 2000 Vitamin B12 Size: 200 Tests Codes: L2KVB2/10380914 Shelf Life: 12 months 3. Immulite 2000 Vitamin B12 Size: 600 Tests Codes: L2KVB6/10380913 Shelf Life: 12 months. 4.Immulite 2000 Vitamin B12/Folic Acid Sample Diluent	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.

		Validity: 15-09-2026	Size: 1 x 25mL Codes: L2FVZ/10387054 Shelf Life: 36 months. 5.Immulite Vitamin B12 Sample Diluent Size: 1 x 25mL Codes: LVBZ/10386999 Shelf Life: 36 months	
36.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-04-2021 Fee Details: Paid Fee: 25,000/- 554503446804 dated 30-06-2021 for cluster of other hematology test Advia 360 reagent Tracking ID: SQL- B9X-ZL35	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site for Serial No. 1 to 5 as per FSC: Siemens Healthcare Diagnostics Manufacturing Ltd. Diatron MI Plc Tablas Str. 39 Budapest, Hungary H-1097. Manufacturing Site for Serial No. 6 to 7 as per FSC: R&D Systems, Inc. 614 McKinley Place, NE Minneapolis, MN, 55413, United States of America. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC-I (S#1-5) Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Issuance: 04-06-2024. Validity: Not mentioned FSC-II (S#6-7) Type: Scan copy of non-notarized copy Issued By: HPRA,	ADVIA (Details are under codes) [Cluster for Hematology Tests of Advia 360 Hematology reagents.] Applied as Cluster. ♦ Class-B Model/Codes/Size: 1. ADVIA 360/560 Dil Codes: 11170845 Shelf Life: 36 months 2. ADVIA 360 Lyse 3P Diff Codes: 11170848 Shelf Life: 48 months 3. ADVIA 360 Cleaner Codes: 11170849 Shelf Life: 48 months 4. ADVIA 360/560 Hypoclean Codes: 11170850 Shelf Life: 24 months 5.ADVIA 360/560 Hypoclean CC Codes: 11170851 Shelf Life: 18 months 6.ADVIA 360/560 Calibrator Codes: 11170852 Shelf Life: 09 months 7. ADVIA 360 Control Set Codes: 11170853 Shelf Life: 09 months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4.Shelf life evidence/study for the applied product.

		Ireland Issuance: 08-12-2022. Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026		
37.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-04-2021 Fee Details: Paid Fee: 25,000/- 8717860629dated 30-06-2021 for cluster of other hematology test Advia 560 reagent Tracking ID: 2G8-6B6-2ZTX	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site for Serial No. 1 to 5 as per FSC: Siemens Healthcare Diagnostics Manufacturing Ltd. Diatron MI Plc Tablas Str. 39 Budapest, Hungary H-1097. Manufacturing Site for Serial No. 6 to 7 as per FSC: R&D Systems, Inc. 614 McKinley Place, NE Minneapolis, MN, 55413, United States of America. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC-I (S#1-5) Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Issuance: 04-06-2024. Validity: Not	ADVIA (Details are under codes) [Cluster of Hematology Tests of Advia 560 Hematology reagents.] Applied as Cluster. Class-B Model/Codes/Size: 1. ADVIA 360/560 Dil Codes: 11170845 Shelf Life: 36 months 2. ADVIA 560 Lyse Codes: 11170846 Shelf Life: 48 months 3. ADVIA 560 5P Diff Codes: 11170847 Shelf Life: 48 months 4. ADVIA 360/560 Hypoclean Codes: 11170850 Shelf Life: 24 months 5. ADVIA 360/560 Hypoclean CC Codes: 11170851 Shelf Life: 18 months 6. ADVIA 360/560 Calibrator Codes: 11170852 Shelf Life: 09 months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevent grouping. 4. Shelf life evidence/study for the applied product.

		mentioned FSC-II (S#6-7) Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Issuance: 08-12-2022. Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	7. ADVIA 360 Control Set Codes: 11170853 Shelf Life: 09 months	
38.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-04-2021 Fee Details: Paid Fee: 25,000/- 21724115909 dated 30-06-2021 for cluster of other hematology test Advia 2120i reagent Tracking ID: 3Y2- TZ1-J4A8	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland. Manufacturing Site as per FSC: Streck Laboratories, 7002 South 109 th Street, Omaha, NE 68128, United States of America. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 16-08-2024	ADVIA (Details are under codes) [Cluster of hematology Tests of Advia 2120i Hematology reagents] Applied as Cluster. Class-B Model/Codes/Size: 1. Advia 120 / 2120 / 2120i CN-Free CBC TIMEPAC Codes: 10341169/ T00301-3626-52 Shelf Life: 14 months 2. Advia 120 / 2120 / 2120i DIFF TIMEPAC Codes: 10312270/ T01-3621-52 Shelf Life: 12 months 3. Auto Retic Codes: 10336651/ T01-3622-51 Shelf Life: 48 months 4. Advia 120 / 2120 / 2120i Perox Sheath Codes: 10312275/	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.

		ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	T01-3633-54 Shelf Life: 24 months 5. EZ-Kleen Codes: 10312273/ T01-3624-54 Shelf Life: 18 months 6. Advia 120 / 2120 / 2120i Sheath/Rinse Codes: 10312272/ T01-3623-01 Shelf Life: 09 months 7. Avia 120 TEST point Control Low. Codes: 10312287/ T03-3686-54 Shelf Life: 09 months 8. Advia 120 TEST point Control Normal. Codes: 10312289/ T03-3687 -54 Shelf Life: 09 months 9. Advia 120 TEST point Control High. Codes: 10312291/ T03-3688-54 Shelf Life: 09 months 10. Advia 120 / 2120 / 2120i Opti point. Codes: 10312283/ T03-3682-54 Shelf Life: 09 months 11. Advia 120 / 2120 / 2120i Setpoint Calibrator. Codes: 10312285/ T03-3685-52 Shelf Life: 09 months. Remaining codes along with their description are attached below	
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39.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-04-2021 Fee Details: Paid Fee: 25,000/- 241751437988 dated 30-06-2021 for Hematek Reagents. Tracking ID: DZL- RQW-8T1L	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Manufacturing Ltd. (Richard-Allan Scientific Co.) (A Subsidiary of thermos Fisher Scientific Inc.) 4481 Campus Drive Kalamazoo, MI,49008, USA. Manufacturing Site as per FSC: Reactifs RAL, S.A., Site Montesquieu 33651, Martillac, CEDEX, France. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 16-08-2024 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	ADVIA (Details are under codes) [Cluster for Hematek 3000 Autoslide Stainer with its consumables] Applied as Cluster. Class-B Model/Codes/Size: Hematek Stain Pak- Modified Wright's Stain Code: 10310965 Remaining codes are attached below	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.
40.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037)	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY	Dimension EXL (Details are under codes) [Cluster Dimension EXL 200 reagents]	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference

	Date of R&I 07-07-2021 Fee Details: Paid Fee: 25,000/- 04185995010 dated 30-06-2021 for Dimension Exl 200 Reagents.. Tracking ID: VR1- NAY-V35X	10591, USA Legal Manufacturer & Manufacturing Site as per FSC: Siemens Healthcare Diagnostics Manufacturing Ltd Address: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: 700 GBC Drive Newark DE 19702 Glasgow, Delaware U.S. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC-I Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Applied as Cluster. Class-B Model/Codes/Size: 1. 10481507 2. 10445042 3. 10445039 4. 10445041 5. 10445040 6. 10444887 7. 10444870 8. 10445043 9. <u>10445052</u> 10. 10445036 11. <u>10445035</u> 12. <u>10445038</u> 13. <u>10445044</u> 14. <u>10444875</u> Detail Codes along with shelf life are attached below.	Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.
41.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 07-07-2021 Fee Details: Paid Fee: 25,000/- 1261676568 for EPOC Reagents. Tracking ID: 944-	Legal Manufacturer as per Form-7A: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Manufacturing Ltd Address: Eurotrol B.V, Keplerlaan 20 6716BS Ede Netherlands.	Eurotrol reagents blood gas analyzer (Details are under codes) [Cluster for Eurotrol reagents blood gas analyzer] Applied as Cluster. Class-B Model/Codes/Size: 1. 10736354 2. 10736355 3. 10736356	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee

	N1G-4HPQ	Legal Manufacturer & Manufacturing Site as per FSC: Eurotrol B.V, Keplerlaan 20 6716BS Ede Netherlands. LOA (Siemens Healthcare) Type: Scan copy of non-notarized copy. Validity: 17-01-2026 LOA (Eurotrol Netherlands.) Type: Scan copy of non-notarized copy. Validity: 07-05-2022 FSC-I Type: Scan copy of non-notarized copy Issued By: Netherlands Validity: 03-03-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	4. 10736357 5. 10736358 6. 10736359 7. 10736361 8. 10736360 9. 10736510 10. 10736511 11. 10736512 12. 10736513 13. 10736514 14. 10736515 15. 10736382 Detail Codes along with shelf life are attached below.	submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4. Shelf life evidence/study for the applied product.
42.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 11-05-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1942375 dated 08-05-2020 Tracking ID: Z9G-434-6VBG	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of	ADVIA [Cluster of Immuno-Chemistry Bone & Mineral Metabolism for Advia Centaur System] Applied as Cluster. Class-B Model/Codes/Size: 1. ADVIA Centaur Intact PTH Size: 500 Tests Codes: 10699155 Shelf Life: 14 months 2. ADVIA Centaur Intact	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the

		non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	PTH Size: 100 Tests Codes: 10699154 Shelf Life: 14 months 3. ADVIA Centaur Intact PTH 1,2,3 Quality Control Material Size: 2 x 1ml (control 1, 2 & 3) Codes: 10699156 Shelf Life: 26 months. 4. ADVIA Centaur Multi-Diluent 13 Size: 2 x 10 ml Codes: 10492364 Shelf Life: 26 months.	applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.
43.	M/s. Hooraa Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 26-06-2021 Fee Details: Paid Fee: 25,000/- Challan No. 496152088886 for Cluster of liver function for Advia Centaur. Tracking ID: YXR-Y4S-M1EJ	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Legal Manufacturer & Manufacturing Site as per FSC: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA Ireland Validity: 25-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	ADVIA [Cluster of immune chemistry liver function for Advia Centaur System] Applied as Cluster. Class-B Model/Codes/Size: ADVIA Centaur® HA assay Code: 10493157 Shelf Life: 27 months ADVIA Centaur ELF Calibrator Code: 10492344 Shelf Life: 28 months ADVIA Centaur ELF Quality Control Material Code: 10492342 Shelf Life: 27 months ADVIA Centaur Multi-Diluent 13 Code: 10492364 Shelf Life: 09 months ADVIA Centaur PIINP Code: 10492440 Shelf	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. - Shelf life evidence/study for the applied product.

			Life: 27 months ADVIA Centaur ELF Calibrator Code: 10492344 Shelf Life: 28 months ADVIA Centaur ELF Quality Control Material Code: 10492342 Shelf Life: 27 months ADVIA Centaur Multi-Diluent 13 Code: 10492364 Shelf Life: 09 months ADVIA Centaur TIMP-1 Code: 10492065 Shelf Life: 26 months ADVIA Centaur ELF Calibrator Code: 10492344 Shelf Life: 28 months ADVIA Centaur ELF Quality Control Material Code: 10492342 Shelf Life: 27 months ADVIA Centaur Multi-Diluent 10 Code: 10310280 Shelf Life: 11 months	
44.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 17-06-2021 Fee Details: Paid Fee: 25,000/- Challan No. 2029880 for Chemistry	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA.	ADVIA [Cluster of Immuno - Chemistry Endocrine Hormone & Peptides for Advia Centaur System] Applied as Cluster. Class-B Model/Codes/Size: Advia Centaur Pregnancy-Associated Plasma Protein-A (PAPP-A)	Deferred for submission of the followings: Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC.

	Rheumatoid Inf Disease. Tracking ID: PQ2-BT9-HLJU	LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA Ireland Validity: 25-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	CODE: 10995000 Shelf Life 09 months Advia Centaur Pregnancy-Associated Plasma Protein-A (PAPP-A) CODE: 10995001 Shelf Life 09 months Advia Centaur Multi-Diluent 13 CODE: 10492364 Shelf Life 24 months Advia Centaur SHBG CODE: 10997191 Shelf Life 18 months Advia Centaur SHBG Calibrator CODE: 10997192 Shelf Life 12 months Advia Centaur Multi-Diluent 1 CODE: 10309941 Shelf Life 12 months Advia Centaur Multi-Diluent 1 CODE: 10309942 Shelf Life 12 months Advia Centaur DHEA-SO4 CODE: 10282227 Shelf Life 12 months Advia Centaur Multi-Diluent 1 CODE: 10309942 Shelf Life 12 months Advia Centaur Multi-Diluent 1 CODE: 10309941 Shelf Life 12 months Advia Centaur Multi-Diluent 1 CODE: 10311571 Shelf Life 12 months	2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
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45.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-06-2021 Fee Details: Paid Fee: 25,000/- Challan No. 8506377719 for Cluster of Complement Component for Dimension. Tracking ID: 2L3-5B9-NRWV	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Siemens Healthcare Diagnostics Inc. 700 GBC Drive Newark DE 19702 Glasgow, Delaware, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA, Ireland Validity: 27-05-2025 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Dimension (Details are under codes) [Cluster for Immuno Chemistry Complement Components for Dimension System] Applied as Cluster. Class-B Model/Codes/Size: Dimension Complement C3 Flex reagent cartridge Code: 10444980 Shelf Life: 12 Months Size: 120 Tests Dimension Special Protein Calibrator Code: 10445028 Shelf Life: 12 Months Size: 10 x 2.0 mL Dimension Complement C4 Flex reagent cartridge Code: 10444981 Shelf Life: 12 Months Size: 120 Tests Dimension Special Protein Calibrator Code: 10445028 Shelf Life: 12 Months Size: 10 x 2.0 mL	Deferred for submission of the followings: - Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. - Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. - Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevent grouping. - Shelf life evidence/study for the applied product.
46.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 04-09-2020 Fee Details: Paid Fee: 25,000/- Challan No. 1944816	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC	Atellica (Details are under codes) [Cluster for Immuno Chemistry of Cardiac Markers] Applied as Cluster. Class-B Model/Codes/Size: Model/Codes/Size:	Deferred for submission of the followings: Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be

	dated 17-07-2020 Tracking ID: Y7Q-BZN-URSV	Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Atellica CH High Sensitivity C-Reactive Protein Code: 11097633 Shelf Life: 15 months Size: 740 Tests Atellica CH High Sensitivity C-Reactive Protein Calibrator Code: 11099412 Shelf Life: 18 months Size: 1 x 1.0mL Atellica CH Creatine Kinase Code: 11097640 Shelf Life: 14 months Size: 996 Tests Atellica CH ENZ 3 Calibrator Code: 11099319 Shelf Life: 12 months Size: 6 x 2.0mL	issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
47.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 04-09-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029868 dated 02-09-2020 Tracking ID: MZ4-ZLT-23Q4	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA-UK Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Atellica (Details are under codes) [Cluster for Immuno Chemistry of Cardiac Markers] Applied as Cluster. Class-B Model/Codes/Size: Model/Codes/Size: 1.Atellica IM Homocysteine (HCY) Code: 10995606 Shelf Life: 12 months Size: 100 Tests. Atellica IM Homocysteine (HCY) Code: 10995607	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of Class of the applied as per MDR 2017 along with submission of the fee for the releavent Class. One kit shall be considered

		EC Certificate: Type: Scan copy of non- notarized copy Validity: 15-09-2026	Shelf Life: 12 months Size: 500 Tests Atellica IM Homocysteine Calibrator Code: 10995498 Shelf Life: 12 months Size: 2 x 2.0 mL. Atellica IM Homocysteine Diluent (HCY DIL) Code: 10995608 Shelf Life: 11 months Size: 2 x10.0mL	in the current application & rest shall be applied through online MDMC portal. 4.Shelf life evidence/study for the applied product.
48.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 28-01-2021 Fee Details: Paid Fee: 25,000/- Challan No. 388341649 Tracking ID: 1JP-ZED-ZWNA	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America Manufacturer (Legal & Site as per FSC) Siemens Healthcare Diagnostics Inc., 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE 19714, United States of America LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026	Dimension (Details are under codes) [Cluster of Immuno-Chemistry Rheumatoid inflammatory diseases markers for Dimension System] Applied as Cluster. Class-B Model/Codes/Size: Dimension C-Reactive Protein Flex reagent cartridge Code:10444894 Shelf Life: 12 Months Size: 120 Tests Dimension C-Reactive Protein Calibrator Code:10444988 Shelf Life: 12 Months Size: 10x 1.0mL Dimension C-Reactive Protein Extended Range Flex reagent cartridge Code:10444903 Shelf Life: 13 Months	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.

		FSC Type: Scan copy of non-notarized copy Issued by: HPRA, Ireland Date of Issuance: 06-06-2024 Validity: Not mentioned ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2027 EC Certificate: Type: Scan copy of non-notarized copy Validity: 15-09-2026	Size: 120 Tests Dimension Revised C-Reactive Protein Calibrator Code: 10445026 Shelf Life: 13 Months Size: 10x 1.0mL	
49.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029864 dated 02-09-2020. Tracking ID: RXQ-WBU-D345	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA Validity: 31-12-2020 ISO 13485: Type: Scan copy of non-notarized copy Validity: 31-12-2027	ADVIA [Cluster of Immuno Chemistry Thyroid Function Marker for Atellica Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: Atellica IM Total Triiodothyronine (T3) 10995678 11 months 600 Tests Atellica IM Total Triiodothyronine (T3) 10995679 11 months Atellica IM Calibrator A (CAL A) 10995500 16 months 2 x 5.0 mL Atellica IM Calibrator A (CAL A)	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. 4. Shelf life evidence/study for the applied product.

			10995501 16 months 6 x 5.0 mL Atellica IM Total Triiodothyronine Diluent (T3 DIL) 10995680 09 months 10.0 mL/vial Atellica IM Total Thyroxine (T4) 10995684 16 months 150 Tests Atellica IM Total Thyroxine (T4) 10995685 09 months 750 Tests Atellica IM Total Thyroxine Diluent (T4 DIL) 10995686 15 months 10.0mL/vial Atellica IM Free Triiodothyronine (FT3) 10995584 12 months 300 Tests Atellica IM Free Triiodothyronine (FT3) 10995585 12 months 60 Tests Atellica IM Free Thyroxine (FT4) 10995588 12 months 250 Tests Atellica IM Free Thyroxine (FT4) 10995589 12 months 50 Tests	
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			Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) 10995703 12 months 110 Tests Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) 10995704 12 months 550 Tests Atellica IM Multi-Diluent 15 11200798 12 months 2x25.0mL/pack Atellica IM Thyroid Uptake (TUp) 10995711 04 months 250 Tests Atellica IM Thyroid Uptake (TUp) 10995712 04 months 50 Tests Atellica IM Anti-Thyroglobulin (aTG) 10995461 12 months 100 Tests Atellica IM Anti-Thyroglobulin (aTG) 10995462 12 months 500 Tests Atellica IM Calibrator 1 10995493 16 months 2 x 1.0 mL Atellica IM Anti-Thyroglobulin Quality Control (aTG QC)	
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			10995465 16 months 3 x 2.0 mL Atellica IM Anti-Thyroglobulin Diluent (aTG DIL) 10995463 16 months 2x5.0mL/ pack Atellica IM Anti-Thyroid Peroxidase (aTPO) 10995466 16 months 100 Tests Atellica IM Anti-Thyroid Peroxidase (aTPO) 10995467 16 months 500 Tests Atellica IM Calibrator O (CAL O) 10995516 16 months 2 x 1.0 mL Atellica IM Anti-Thyroid Peroxidase Quality Control (aTPO QC) 10995470 16 months 3 x 2.0 mL Atellica IM Anti-Thyroid Peroxidase Diluent (aTPO DIL) 10995468 16 months 2x5.0mL/pack	
50.	M/s. Hoorah Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc.	Atellica [Immuno Chemistry Allergy for Atellica Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size:	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall

	Fee Details: Paid Fee: 25,000/- Challan No. 2029870 dated 02-09-2020. Tracking ID: JW4-XL5-62AA	333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Atellica IM Total IgE (tIgE) Code: 10995614 12 months Atellica IM Total IgE (tIgE) Code: 10995615 12 months Atellica IM Calibrator 80 (CAL 80) Code: 10995497 16 months Atellica IM Total IgE Diluent (tIgE OIL) Code: 10995616 20 months	be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevent grouping. 4.Shelf life evidence/study for the applied product.
51.	M/s. Hoora Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029886 dated 28-09-2020. Tracking ID: PYG-4V5-ZHDM	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Atellica [Immuno Chemistry Non-Immunosuppressive therapeutic drug monitoring for Atellica Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: Atellica IM Digitoxin (Dgtn) Code: 10995553 12 months Atellica IM Digitoxin (Dgtn) Code: 10995554 12 months Atellica IM Calibrator Z (CAL Z) Code: 10995521 19 months Atellica IM Multi-Diluent 5 Code: 10995647 12 months Atellica IM Digoxin (Dig) Code: 10995557	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevent grouping. 4.Shelf life evidence/study for the applied product.

			12 months Atellica IM Digoxin (Dig) Code: 10995558 12 months Atellica IM CAL B Code: 10995503 16 months Atellica IM CAL B Code: 10995504 16 months	
52.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037) Date of R&I 14-12-2020 Fee Details: Paid Fee: 25,000/- Challan No. 2029865 dated 28- 09-2020. Tracking ID: Y6S- 1AQ-34BM	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as per Form-7A: Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA, 02032, USA. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA Validity: 31-12-2020 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Atellica [Fertility/pregnancy hormones/ proteins for Atellica Immunoassay System] Applied as Cluster. Class-B Model/Codes/Size: 10995580, 10995581, 10995503, 10995504 10995637, 10995638 10995639, 10995634, 10995635, 10995655, 10995656, 10995659, 10995660, 10995512, 10995513, 10995645, 10995707, 10995708 10995689, 10995690, 10995691, 10995692, 10995693, 10995561, 10995562, 10995495, 10995496, 10995563 Codes details along with shelf life are given below.	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2. Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3. Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the relevant grouping. Shelf life evidence/study for the applied product.
53.	M/s. Hoor Pharma (Pvt.) Ltd. Karachi (ELI-00037)	Legal Manufacturer: Siemens Healthcare Diagnostics Inc. 511, Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site as	Rapid lab 348EX consumables. Applied as Cluster. Class-B	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority

	Date of R&I 28-04-2021 Fee Details: Paid Fee: 25,000/- Challan No. 12675962902 Tracking ID: WU3-PG7-5RVQ	per Form-7A: Siemens Healthcare Diagnostics Manufacturing Ltd Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ U.K. LOA Type: Scan copy of non-notarized copy. Validity: 17-01-2026 FSC Type: Scan copy of non-notarized copy Issued By: HPRA of Ireland. Issuance Date: 17-05- 2023. Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-12-2027	Model/Codes/Size:	wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. The manufacturer shall be issued as per FSC. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. 4.Shelf life evidence/study for the applied product.
54.	M/s Combined Engineers ELI-00377 R&I Details 03/03/2023 Fee of Rs. 25000/- Fee Challan No. 1788055546	M/s Foshan JoinChamp Medical Device Co. Ltd. No. 1 Keyang Road, Nanzhuang Town, 528000, Foshan City, Guangdong, P.R.ina. LOA Type: Scan copy of notarized copy. Validity: 31-12-2026 FSC Type: Scan copy of non-notarized copy Issued By: MHRA UK Validity: 30-06-2029 FSC Type: Scan copy of non-notarized copy Issued By: China	ZC series Integral dental unit Integral dental unit Class B Applied as Family. Shelf life: life expectancy 10 years Codes/Sizes (if any) (configuration) ZC-A200 ZC-A300 ZC-A400 ZC-A500 ZC-E300 ZC-9200A ZC-S300 ZC-S400 ZC-S500 ZC-S530 ZC-S600	Deferred for submission of the followings: 1. Valid notarized LOA of the applied product issued by the legal manufacturer. 2.Justification of grouping as per MDR 2017 with documentary evidence like catalog etc. along with submission of the fee for the releavent grouping. If the product is a system one system shall be considered in the current application. 3.Shelf life evidence/study for the applied product.

		Validity: 31-05-2026 ISO 13485: Type: Scan copy of non- notarized copy Validity: 30-09-2026 EC Certificate: Type: Scan copy of non- notarized copy Validity: 26-05-2024	ZC-S700 ZC-S730 ZC-S800	
55.	JF International Karachi, ELI-00246 R&I Details Not attached Fee of Rs. 25000/- Fee Challan No. 5294562996	Medical ECONET GmbH, Im Erlengrund 20 46149 Oberhausen Germany LOA Type: Scan copy of notarized copy. Date of issuance: 11-06-2021 Validity: 11-06-2026 FSC Type: Scan copy of notarized copy Issued By: Germany Issuance Date: 22-10-2021 Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 15-02-2024 EC Certificate: Type: Scan copy of non- notarized copy Validity: 04-12-2023	Medical ECONET Electrocardiograph Class B Applied as . Shelf life: not mentioned Model: Cardio M Pro	Deferred for submission of the followings: 1.R&I receiving along with verifiable copy of fee slip for applied product. 2. Copy of the Form-7A duly signed along with all the relavent annexures. 3.Shelf life evidence/study for the applied product. Furthermore, the board also decided to issue “Personal Hearing notice that will be issued to both of the company i.e. M/s Hi-Mod Technologies, Lahore & JF International Karachi to provide/prove the Authorization from the legal manufactory for the product Medical Econet (ECG)- Cardio M Pro.”
56.	Cortex Core (SMC-PVT) Ltd, Karachi. ELI-00905 R&I Details 01-02-2024.	Legal Manufacturer (as per FSC-UK): Hangzhou Singclean Medical Products Co., Ltd., No.125 (E), 10th Street, Hangzhou Economic and Technological	Singjoint 20MG/ML Medical Sodium Hyaluronate Gel for Bone Joint Class D	Approved

	Fee of Rs. 50,000/- Fee Challan No. 4678197997	Development Zone, Zhejiang Province, 310018, China. Manufacturing Site (as per FSC-UK): Hangzhou Singclean Medical Products Co., Ltd., No. 125(E), 10th street, Hangzhou Qiantang New Area, Hangzhou, Zhejiang, 310018, China. Distribution agreement: Type: Scan copy of notarized copy. Date of issuance: 16- 03-2023 Validity: 15-03-2025 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: MHRA, UK Validity: 13-07-2028 ISO 13485: Type: Scan copy of non- notarized copy Validity: 31-08-2026	Applied as Single. Shelf life: 2 years Model: 3mL Pre-filled Syringe (2%)	
57.	M/s Muller & Phipps, Uzma Court, Main Clifton Road Karachi ELI-00030 R&I Details 19-08-2020.	Legal Manufacturer (as per Form-7A): ConvaTec Limited First Avenue Deeside Industrial Park Deeside, Flintshire, CH5 2NU, UK.	Stomahesive Protective Powder Class A Applied as Single. Shelf life: 3 years	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer &

	Fee of Rs. 5,000/- Fee Challan No. 0829160 dated 06-08-2020	Manufacturing Site (as per Form-7A): PharmaPac (UK) Ltd. Unit 22, Valley Road Business Park, Bidston, Wirral, CH41 7EL.UK. Manufacturer Name as per FSC (UK): ConvaTec Limited Letter of Authorization: Type: Scan copy of notarized copy. Date of issuance: 29-07-2024 Validity: 28-01-2026 FSC Type: Scan copy of notarized copy Issued By: MHRA, UK Date of Issuance: 14-05-2015 Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 03-01-2026	Code/sizes: 025510	manufacturing sites shall be mentioned along with the applied product along with required codes. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product. 3.Justification/ Clarification is required if the applied product is medical device as per MDR 2017 with documentary evidence like catalog, etc. 4.Justification class of the product as per MDR 2017 & releavent fee if applicable. 5.Shelf life evidence/study for the applied product.
58.	M/s Muller & Phipps, Uzma Court, Main Clifton Road Karachi ELI-00030 R&I Details 19-06-2020. Fee of Rs. 5,000/- Fee Challan No. 0808822 dated 13-06-2020	Legal Manufacturer (as per Form-7A): ConvaTec Limited First Avenue Deeside Industrial Park Deeside, Flintshire, CH5 2NU, UK. Manufacturing Site (as per Form-7A): ConvaTec Dominican Re-Public, Inc. Carretera Sanchez, Km. 18.5, Parque Industrial Itabo, S.A.	ConvaTec- Straight Tail Closures Tail Closure Class A Applied as Single. Shelf life: 5 years Code/sizes: 175635	Deferred for submission of the followings: 1. Valid Legalized Free Sale Certificate of country of origin or any Reference Regulatory Authority wherein all the legal manufacturer & manufacturing sites shall be mentioned along with the applied product along with required codes. 2.Verifiable evidence of fee submission or original pink slip of the fee receipt for the applied product.

		Dominican Republic. Manufacturer Name as per FSC (UK): ConvaTec Limited Letter of Authorization: Type: Scan copy of notarized copy. Date of issuance: 29-07-2024 Validity: 28-01-2026 FSC Type: Scan copy of notarized copy Issued By: MHRA, UK Date of Issuance: 14-05-2015 Validity: Not mentioned ISO 13485: Type: Scan copy of non- notarized copy Validity: 03-01-2026		3. Justification/ Clarification is required that the product name is Surfit Active Life Tail Closure in FSC & DOC while applied as ConvaTec-Straight Tail Closures as per attached Form-6A. 4. Shelf life evidence/study for the applied product.
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Item No. II(B): REGISTRATION / ENLISTMENT OF MEDICAL DEVICE FOR IMPORT / LOCAL PRODUCTS.

Evaluator: Rana Ahsan Ul Haq Attar (Deputy Director)

DEFERRED CASES AGENDA

DEFERRED CASES IMPORT

S#	Importer Name	Manufacturer Details	Name of MD / Class / Codes / Shelf life / etc.	Decision
1.	Coral Pharmaceuticals, A-85 SMCHS, Karachi (ELI-00065) Evaluator: AD-VI R&I Date 06-01-2026	Legal Manufacturer: Dynek Pty Ltd. 9 Circuit Drive, Hendon, SA 5014 Australia FSC: Australia Issued: 27-8-2018	BIOVEK Suture. (Polyglycolic Acid) Class: D Shelf Life: 03-Years 044805 / 21-11-2021	Deferred for submission of legalized/apostilled FSC highlighting the cades/sizes alongwith Product Catalogue

2.	Claris Medical, Flat No. 001, Ground Floor, Rayyan Heights, Gangal East Service Road, Islamabad Expressway, Islamabad ELI-00269 Date of R&I 25-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 2779821195	Legal Manufacturer: De Soutter Medical Limited, Halton Brook Business Park, Weston Road, Aston Clinton, Bucks, HP22 5WF United Kingdom LOA Validity: 08-04-2027 FSC: UK Validity: 30-06-2029 ISO Validity: 11-08-2026 EU QA Certificate Validity: 10-05-2028	De Soutter Medical SternuDrive Sternum Saw Class-B Shelf life:5 years Models/ Specification; As per FSC	Approved CARDIO SAW (Sternum Saw) DPC-470.
3.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 31.07.2023 Fee: 5,000/- Slip #7130204351 This evaluation is based on the on-line data submitted through E-App. Tracking ID: XL4-4SJ-JURJ	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	Brand Name: Powerhaler Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D05 Shelf Life: 36 months	Approved.
4.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 17.03.2022 Fee: 5,000/- Slip #83059332595 This evaluation is based on the on-line	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese	Brand Name: ROTAFLO Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D07 Shelf Life: 36 months	Approved.

	data submitted through E-App. Tracking ID: R4V-NYZ-J4QM	with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL		
5.	Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore ELI-00646 R&I Date: 10.05.2022 Fee: 5,000/- Slip #7396113710 This evaluation is based on the on-line data submitted through E-App. Tracking ID: MX9-8G7-QJ5W	Manufacturer: Mis Taian Dalu Medical Instrument Co. Ltd. West part of Yitianmen street, Hi- Tech Zone Taian, Shandong, China LOA Type: scanned copy Notarization in Chinese with English translation. Validity: 5 years from 15.02.2022 FSC Type: scanned copy Issued by: NIL Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 21.10.2027 CE certificate / EU QMS certificate (MDR) Type: NIL Notarization: NIL Validity: NIL	Brand Name: REVOLIZER Generic Name: Dry Powder Inhaler Applied as: Single Class: A Models/Code/sizes (as per FSC & application: DL-D07 Shelf Life: 36 months	Approved.
6.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail	Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK.	Brand name: Anti-A Monoclonal Generic Name: Blood Grouping Reagent Kit Applied as: Kit	Approved.

	16-06-2025 Fee: 62,000/- Slip: 031845124	• LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned • FSC Not submitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025	Class: C Model/Codes/Sizes: BG-A10 (as per DOC) Shelf life: Not mentioned	
7.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail 16-06-2025 Fee: 62,000/- Slip: 416173331	Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK. • LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned • FSC Not submitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025	Brand name: Anti-D Monoclonal (IgG + IgM) Generic Name: Blood Grouping Reagent Kit Applied as: Kit Class: C Model/Codes/Sizes: BG-D10 (as per DOC) Shelf life: Not mentioned	Approved.
8.	M/s. A.M. Sales &	Name of	Brand name:	Rejected as the product is

	Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail 16-06-2025 Fee: 62,000/- Slip: 70654835	Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK. • LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned • FSC Not aubmitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025	ABOD Blood Grouping Kit Generic Name: Blood Grouping Reagent Kit Applied as: Kit Class: C Model/Codes/Sizes: BG-ABOD10 (as per DOC) Shelf life: Not mentioned	not mentioned in the FSC.
9.	M/s. A.M. Sales & Services, A.M house 82-L, Block-02, PECHS, Karachi. (ELI- 00244) R&I detail 16-06-2025 Fee: 62,000/- Slip: 3695108471	Name of Manufacturer: M/s Rapid Labs Ltd., Unit 2& 2a Hall Farm, Church Road, Little Bentley, Colchester, Essex, CO7 8SD., UK. • LOA Type: Original Notarization: Notarize Issue Date: 23-04-2025 Validity: Not mentioned • FSC Not aubmitted. • ISO Certificate Type: Original Notarization: Notarized Validity: 15-10-2027	Brand name: Anti-B Monoclonal Generic Name: Blood Grouping Reagent Kit Applied as: Kit Class: C Model/Codes/Sizes: BG-B10 (as per DOC) Shelf life: Not mentioned	Approved.

		• CE Certificate Type: Original Notarization: Notarized Validity: 27-05-2025		
10.	M/s Intek Corporation Office # 30, AL Amin Plaza, the Mall, Rawalpindi. ELI-00034 943-P Evaluator AD-III R&I Date 13-11-2025.	<u>Legal Manufacturer:</u> TERUMO CORPORATION 44-1, 2-Chome, Hatagaya, Shibuya-Ku, Tokyo 151-0072 JAPAN <u>Manufacturing Sites</u> TERUMO CORPORATION ASHITAKA FACTORY Address: 150, Maimaigi-Cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan. TERUMO VIETNAM CO., LTD. Lot 44a-44b-44c Quang Minh Industrial Zone, Me Linh District, Hanoi CITY, VIETNAM FSC Japan issuance 18-02-2020	Radifocus Guide Wire M (Catheter Guide Wire) Class-D Shelf life: 3 years Codes as per FSC	Approved.
11.	M/s. Varitron, First Floor 60-D, F.C.C. Zahoor Elahi Road, Gulberg-IV, Lahore. (ELI- 00510) R&I detail 24-06-2025 Fee: 240,000/- Slip: 9646735025 R&I Date 09-10-2025.	<u>Legal Manufacturer:</u> Blue Belt Technologies, Inc., 2875 Railroad Street, Pittsburgh, PA USA 15222. <u>Manufacturing Sites:</u> 1. Smith & Nephew Inc., Endoscopy, 76 S. Meridian Ave., Oklahoma City, OK USA 73107. 2. Smith & Nephew Inc., Endoscopy, 120 Forbes Blvd., Suite 150/130 Forbes Blvd., Mansfield, MA USA 02048. • LOA Type: Copy of Notarized Notarization: Notarized Issue Date: 03-04-2025 Validity: Not mentioned • FSC Type: Original Issued By: US FDA Legalization: Apostilled Validity: 18-11-2026 • ISO Certificate Type: Copy Notarization: Not	<u>Brand name:</u> CORI Real Intelligence Surgical System <u>Generic Name:</u> Ophthalmic Viscosurgical Device <u>Applied as:</u> System <u>Class:</u> B <u>Model/Codes/Sizes (as per FSC & Application):</u> i. ROB10024-Real Intelligence CORI ii. ROB10025-Real Intelligence Tracking Camera iii. ROB10027-Real Intelligence Tablet iv. ROB10001-Real Intelligence Robotics Instruments v. ROB10026-Real Intelligence Foot Pedal vi. ROB10013-Real Intelligence Robotics Drill	Deferred for the following: 1. Notarized original LOA issued by the legal manufacturer (as per FSC) required. The manufacturing site of the last two codes not mentioned in the application. 3. AN FSC in which complete system is mentioned require. 4. Product catalogue required. 5. Shelf life studies required.

		Notarized Validity: 08-08-2026	vii. ROB10014-Real Intelligence Robotics Drill Tracker viii. ROB10010-Real Intelligence Robotics Bone Pins 4.0mm x 127mm ix. ROB10011-Real Intelligence Robotics Bone Pins 4.0mm x 152mm x. ROB00032-Navio Bone Pin 3.5mm x 127mm xi. ROB10002-Real Intelligence Robotics Cart Column. xii. ROB10003-Real Intelligence 24" Touch Screen. xiii. ROB10031-Real Intelligence Tubing Set. xiv. ROB10024S-Real Intelligence CORI. xv. ROB10025S-Real Intelligence Tracking Camera. xvi. ROB10027S-Real Intelligence Tablet. xvii. ROB10013S-Real Intelligence Robotic Drill. xviii. ROB10003S-Real Intelligence 24" Touch Screen. xix. ROB10028-Real Intelligence Transportation Case. xx. ROB10015-Real Intelligence Robotics Drill Attachment. xxi. ROB10017-Real Intelligence Point Probe. xxii. ROB10086-Real Intelligence Plane Visualizer. xxiii. ROB10020-Real Intelligence Tracker Clamp. xxiv. ROB10018-Real Intelligence Femur Tracker. xxv. ROB10019-Real Intelligence Tibbia Tracker. xxvi. ROB10021-Real Intelligence Drill Guide. xxvii. ROB10022-Real Intelligence Check Point Tool.	
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			xxviii. ROB10012-Real Intelligence Check Point Pins Qty:4. xxix. ROB10023-Real Intelligence Z-Retractor. xxx. ROB10050-Real Intelligence Robotics Instrument Tray. xxxi. ROB10016-Real Intelligence Robotics Drill Guard. xxxii. ROB10000-CORI Starter Kit. xxxiii. ROB10051-Real Intelligence Robotics Pin Caddy. xxxiv. ROB10052-Real Intelligence Robotics Pin Caddy Lid. xxxv. ROB10053-JOURNEY II Uni Robotics Finishing Insert(F). xxxvi. ROB10054-Universal Insert Lid(F) xxvii. ROB10055-Real Intelligence Shipping Inser(A). xxviii. ROB10056-Real Intelligence Shipping Inser(B). xxxix. ROB10057-Real Intelligence Shipping Inser(C). xl. ROB10058-Real Intelligence Shipping Inser(F). xli. ROB10087-Universal Base Tray Lid. xlii. ROB100022-Real Intelligence Robotics Cart Base 220. xliii. ROB10014S-Real Intelligence Robotic Drill Tracker. xliv. ROB10015S-Real Intelligence Robotic Drill Attachement. xlv. ROB10400-Real Intelligence Implant Database V2.88. xlvi. ROB00025-TKA Left Tibbia Twin Peg Cut Guide. xlvii. ROB00026-KA Right Tibbia Twin Peg Cut Guide	
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			xlviii. ROB00060-TKA Distal FMR Punches-38mm xlix. ROB00061-TKA Distal FMR Punches-45mm l. ROB10300-Welcome Box 1 li. PFSDV0016-Navio Flat Markers (Case of 18) lii. ROB10033-Real Intelligence 6mm Bullet Bur. liii. ROB10035-Real Intelligence 5mm Cylindrical Bur. liv. ROB10036-Real Intelligence 6mm Cylindrical Bur. lv. ROB10034-Real Intelligence 6mm Chip Breaker Bullet Bur. Service life: Not mentioned	
12.	M/s. Biocare Pharma, B-175, Block H, North Nazimabad, Aziz Bhatti Road, Karachi. (ELI- 00634) R&I detail 09-05-2025 Fee: 6,000/- Slip: 20228851163 Dated: 07-05-2025	Name of Manufacturer: M/s. Pergo Medikal ve Ilac Sanayi A.S., Buca Osb Mh 2/20 Sk, No 9 BUCA IZMiR, Turkey. • LOA Not Submitted • FSC Type: Copy of apostilled Issued By: M&MD Agency Legalization: Apostilled Validity: 25-01-2026 • ISO Certificate Type: Copy of notarized Notarization: Notarized Validity: 23-05-2027	Brand name: Pergo Disposable Suction Liner System Generic Name: Surgical Waste Liner System Class: A Codes/Sizes: Not mentioned in application Applied as: Single Shelf life: 5 Years	Approved.
13.	Biocare Pharma, B-175, Block H, North Nazimabad, Aziz Bhatti Road, Karachi (ELI-00634)	Hefei Jingpu Sensor Technology Co., Ltd, Floor 2-4, No. 2 Keyna Building, Jinhui Photoelectric Industrial	Brand Name: Medical Temperature Sensor	Approved

	Date of R&I 18-04-2025 Fee Details: Paid Fee: 6030/- Fee Challan No: 47520053284	Park, Intersection of Pahie Avenue, and Jixin Road, Economic Development Zone, Fexi County, Hefei, China LOA Validity: Issue date: 14-03-2027 (Copy) FSC: China Validity: 13-08-2025 (Copy) ISO13485: nil EC validity: 25-09-2028 (Copy)	Class: A Shelf Life : 5 Years Applied as: Single Models/ Specification	
14.	Name M/s Biocare Pharma, Address of Importer B-175, Block H, North Nizamabad, Aziz Bhatti Road, Karachi ELI-00634 Date of R& I 04 SEPTEMBER 2024 Fee Rs. 5,030/ through slip no. 911077981,	M/s Shandong Hapool Medical Technology Co., Ltd No111, Changuo Road, High- Tech zone, Zibo city, Shandong Province China FSC: China Chamber of commerce for Import and Expert of Medicine and Healthcare products Valid Till December 27, 2025 FREE SALE CERTIFICATE OF REFERNCE AUTHOURITY: Issuance authority: Medicine and Healthcare Products Regulatory agency of UK: mhra.gov.pk Certificate number: 2024052402364466/1 CFS Expiry Date: 30/06/2029 Marketing Authorization Letter:	Hapool Heparin Cap/ IV Stopper Shelf Life: 3 Years	Approved in class B.

		NOTARIZED LOA valid till 24-03-2027 Full Quality Assurance Certificate Or Equivalent: Issued By: Identified No 0197: TUV Rhineland LGA Products GmbH Validity Up To: 2027-Dec-31		
15.	Royal Medical, Office No. 26th, 3rd United Trade Center Plot No. 5 Block 6, Gulshan-e-Iqbal, Karachi ELI-00691 Date of R&I 22-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 086749938764 R&I Date 18-09-2025	<u>Legal Manufacturer:</u> Shenzhen Antmed Co., Ltd., 18 Jinhui Ave, Pingshan New District, Shenzhen 518122, China Other manufacturing site: NO. 3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Validity: 16-02-2030 FSC: China Validity: 26-10-2025 ISO Validity: 30-10-2026 EU QA Certificate Validity: 05-02-2029	Antmed Inflation Device Class-B Shelf life: 5 Years Models/ Specification; ID-1000 ID-1001 ID-3000 ID-3001	Deferred for the following: 1. The device mentioned in CE certificate is Cardiac Angiography Devices. 2. Clarification that Cardiac Angiographic Device is of class A. 3. Fee for the family required. 4. After fulfilment of shortcomings, the personal hearing will be given to both parties. i.e. Royal Medical, and Ahmad care International.
16.	Royal Medical, Office No. 26th, 3rd United Trade Center Plot No. 5 Block 6, Gulshan-e-Iqbal, Karachi ELI-00691 Date of R&I 22-04-2025 Fee Details: Paid Fee: 31000/- Fee Challan No: 501445524411 R&I Date 18-09-2025	<u>Legal Manufacturer:</u> Shenzhen Antmed Co., Ltd., 18 Jinhui Ave, Pingshan New District, Shenzhen 518122, China Other manufacturing site: NO. 3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Validity: 16-02-2030 FSC: China Validity: 26-10-2025 ISO Validity: 30-10-2026 EU QA Certificate Validity: 05-02-2029	Antmed Maniflod Class-B Shelf life: 3 Years Models/ Specification; MD-M-1 MD-M-2 MD-M-3 MD-M-4 MD-L-1 MD-L-2	Deferred for the following: 1. The device mentioned in CE certificate is Extensions has been mentioned instead of manifold. 2. Fee for the family required. 3. After fulfilment of shortcomings, the personal hearing will be given to both parties. i.e. Royal Medical, and Ahmad care International.
17.	Royal Medical, Office No. 26th, 3rd Floor United Trader Centre Plot	Shenzhen Antmed Co., Ltd., 18 Jinhui Ave., Pingshan New District,	Antmed Disposable Pressure Transducer	Approved.

	No. 5, Block-6, Gulshan-e-Iqbal, Karachi (ELI-00691) Date of R&I 22-04-2025 Fee Details: Paid Fee: 62030/- Fee Challan No: 27370964 R&I Date 18-09-2025	Shenzhen 518122, China Other Manufacturing Site: No. 3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Validity: 16-02-2030 (Notarized) FSC (china) Valid till: 26-10-2025 (Apostille) ISO Validity: 30-10-2026 (Notarized) EU QMS certificate 05-02-2029 (Notarized)	Class C Shelf Life: 5 years Applied as: Single Models/ Specification: PT-01, PT-012, PT-013, PT-02, PT-022, PT-023, PT-03, PT-032, PT-033,	
18.	Muslim Scientific Corporation, 3 Syed Moj Darya Road 3rd Floor of Building <u>Warehouse Address:</u> House # 57 PAF Colony Zarar Shaheed Road, Lahore ELI: 00431 3036-P 13-06-2022	<u>Legal Manufacturer:</u> Taidoc Technology Corporation 127, Wugong 2nd Road, Wugu District, New Taipei City, Taiwan 248	CC TD-4116 (CC Advance Glucometer+ strips) Class-C Shelf life: AS per stability study	Approved.
19.	M/s Rafi Sultan Enterprises, Plot No. 19-1-A, Office No. M-1, Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi ELI-00232 Date of R&I 28-04-2025 Fee Details: Paid Fee: 25,000/- Fee Challan No: 7846570615 and 7058095981 Dated: 21-04-2025 R&I Date 19-09-2025	M/s. Wenzhou Bokang Instruments, Co., Ltd., No. 1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province, China LOA Validity: 16-03-2028 FSC: China Validity: 16-12-2026 FSC: Germany Issue date:26-05-2021 ISO Validity: 01-04-2026	Brand name: Bokang Stethoscope Generic: Non Invasive Stethoscope Class-A Family. Shelf life: N/a Models/ Specification: BK3003 BK3013	Deferred for the clarification that: 1. Manufacturer as per FSC (Germany) is Wenzhou Bokang Instrument Co., Ltd. No.1500 Haining Road, Haibin, Longwan 355024 Wenzhou, P. R. China. 2. Documentary evidence for the shelf life.
20.	M/s Rafi Sultan Enterprises, Plot No. 19-	M/s. Wenzhou Bokang Instruments, Co., Ltd., No.	Brand name:	Deferred for the clarification that:

	1-A, Office No. M-1, Mezzanine Floor, Business Centre, PECHS Block 6, Shahrah-e-Faisal, Karachi ELI-00232 Date of R&I 28-04-2025 Fee Details: Paid Fee: 25,000/- Fee Challan No: 98788267 and 22306425 Dated: 21-04-2025 R&I Date 19-09-2025	1099 Kunbei Road, Lingkun Street, Wenzhou Marine Economic Development Demonstration Zone, Wenzhou 325026, Zhejiang Province, China LOA Validity: 16-03-2028 FSC: China Validity: 16-12-2026 FSC: Germany Issue date:26-05-2021 ISO Validity: 01-04-2026	Bokang Aneroid Sphygmomanometer Generic: Non Invasive Sphygmomanometer Class-A Family. Shelf life: Service life 3 Years Models/ Specification: BK2001, BK2002, BK2003, BK2004, BK2005, BK2006, BK2007, BK2008, BK2009, BK2010, BK2011, BK2012, BK2013, , BK2015, BK2066, BK2001-3001, BK2003, BK2009	1. Manufacturer as per FSC (Germany) is Wenzhou Bokang Instrument Co., Ltd. No.1500 Haining Road, Haibin, Longwan 355024 Wenzhou, P. R. China. 2. Documentary evidence for the shelf life. 3. DOC not submitted.
21.	M/s Saru International, B-194/1 Block-12, Gulistan-e-Johar Karachi. (ELI- 00316) Date of R&I 03-07-2025 Fee Details: Paid Fee: 25,000/- Challan No. 0832664 for Cliniwax dated 08-01-2019	Yucel Medikal Ve Tekstül Urunlerd Sanayd Tdc.LTD.STD Ornek Mah. 1612 Sok. Evren San. Sit. 2. Kısım 24.Blok No:19 34850 Esenyurt-Istanbul-Turkey. LOA Type: Scan copy of non-notarized copy. Validity: 15-05-2027 FSC Type: Scan copy of non-notarized copy Issued By: Turkey Validity: 18-03-2027 • ISO 13485: Type: Scan copy of non- notarized copy Validity: 18-10-2025 • CE (FQA): Type: Scan copy of non- notarized copy Validity: 26-05-2024	BONEWAX (Sterile Haemostatic BONEWAX) Applied as Single: Class-B Shelf life: 5 Years Codes/Model/Sizes BW-110 (as per From-7A) BW24 (as per Fsc)	Approved.
22.	Aston Medical Pakistan 4-A 4th Floor 38c Bukhari Commercial,	Semikal Teknoloji Sanayi VE Ticaret Anonim Sirketi, AOSB 3, Kisim 25,	Sectalon Intra-Articular Gel Sodium Hyaluronate 30mg/2ml,	Approved following Devices: 1. Sectalon Intra-

	Lane 8, Phase 6, Dha, Karachi (ELI-00797) Date of R&I 30-04-2025 Fee Details: Paid Fee: 62030/- Fee Challan No: 135864189	Cad. No: 14/11, Dosemealti, Antalya/Turkiye LOA Validity: 25-03-2033 (notarized) FSC Valid till: 30-01-2028 (notarized) ISO Validity: 17-03-2026 (notarized) EC (FQA) certificate 27-05-2024 (notarized) Design Examination Certificate valid up to 27-05-2024 (notarized)	Sodium Hyaluronate 40mg/2ml, Sodium Hyaluronate 60mg/2.5ml, Sodium Hyaluronate 75mg/3ml, Sodium Hyaluronate 90mg/3ml, Sodium Hyaluronate Cross Linked % 2.4/2.5ml, Sodium Hyaluronate Cross Linked % 2.5/3ml, Sodium Hyaluronate Cross Linked % 3/3.0ml Class C Shelf Life: 5 years Applied as: Single Models/ Specification; as above	Articular Gel (Sodium Hyaluronate 60mg/2.5ml) Code AG007 2. Sectalon Intra-Articular Gel (Sodium Hyaluronate Cross Linked % 3/3.0ml) Code AG108. 3. Sectalon Intra-Articular Gel (Sodium Hyaluronate Cross Linked % 2.4/2.5ml) Code AG106. 4. Sectalon Intra-Articular Gel (Sodium Hyaluronate 90mg/3ml) Code AG009. 5. Sectalon Intra-Articular Gel (Sodium Hyaluronate Cross Linked % 2.5/3ml) Code AG107. 6. Sectalon Intra-Articular Gel (Sodium Hyaluronate 75mg/3ml) Code AG 008.
23.	Ophtahalmio-Tec, Shahrah-e-Liaqaut Haji Fazal Ellahi Building Opp. Women College Karachi (ELI-00310) Dossier#4892-7A Date:07-07-22 Submitted Fee: 50,000/-PKR Challan No.: 96177471743 Evaluator: DD-II	Legal Manufacturer: Ophtahalmic Solution inc. 820 Corridor Park Blvd. Knoxville, TN 37932, USA FSC: Not provided	MIRADO Hydrophobic acrylic foldable intra ocular lens Codes & Sizes: FSC: Not provided Class-C Shelf Life: 05 years	Rejected for the followings. 1. original documents not submitted. 2. LOA valid till 13.06.2025. 3. the device MIRADO Hydrophobic acrylic foldable intra ocular lens not mentioned in FSC. 4. copy of CFG is valid till 21.10.2023. 5. copy of the EC Certificate (FQA) valid till 26.05.2024.
24.	M/s. Muller & Phips Pakistan (Pvt.) Limited, Uzma Court,	Name of Manufacturer: M/s. Viking Lab Oy,	Brand name: Biofrost Relief	Deferred for the submission of the following: 1. the fee for the family.

	Mian Clifton Road, Karachi. (ELI- 00030) R&I detail 05-05-2025 Fee: 6,000/- Slip: 336286781212	Vanha Vaasantie 8 C FI-33470 Ylojarvi, Finland. • LOA Type: Original Notarization: Notarized Validity: 25-06-2029 • FSC Type: Copy Issued By: Finnish Medicine Agency Legalization: Not Legalized Issue Date: 19-06-2024 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 18-06-2027	Generic Name: Cold therapy gel for muscle & joint pain. Class: A Codes/Sizes: BF-1005-3ml (Sachet) BF-1003-75ml (Roll On) BF-1009-100ml (Tube) Applied as: Single Shelf life: 3 Years	2. formulation of the product. 3. product catalogue required.
25.	M/s. Muller & Phips Pakistan (Pvt.) Limited, Uzma Court, Mian Clifton Road, Karachi. (ELI- 00030) R&I detail 13-05-2025 Fee: 6,000/- Slip: 0002498617	Name of Manufacturer: M/s. Viking Lab Oy, Vanha Vaasantie 8 C FI-33470 Ylojarvi, Finland. • LOA Type: Original Notarization: Notarized Validity: 25-06-2029 • FSC Type: Copy Issued By: Finnish Medicine Agency Legalization: Not Legalized Issue Date: 19-06-2024 Validity: Not mentioned • ISO Certificate Type: Original Notarization: Notarized Validity: 18-06-2027	Brand name: Biofrost Active Generic Name: Cold-Heat Gel for muscle & joint pain. Class: A Codes/Sizes: BF-2003-3ml (Sachet) BF-2002-75ml (Roll On) BF-2005-100ml (Tube) Applied as: Single Shelf life: 3 Years	Deferred for the submission of the following: 1. the fee for the family. 2. formulation of the product. 3. product catalogue required.

26.	RMK Bio Private Ltd, 83A, BIII, Gulberg III, MM Alam Road, Near Hussain Chowk, Lahore. ELI-01277 6022-P 31,000/-	Legal Manufacturer: Sonova AG Laubisrutistrasse 28, CH-8712 Stafa, Switzerland. FSC: Switzerland Validity: 09-09-2027. LOA validity issuance 04-02-2024 ISO 13485 validity 28- 02-2028 EU QMS certificate (MDR) validity 21-04- 2027	Sonova Phonak Audeo I- Sphere Hearing Aid Class-B Shelf Life: 5 Years Models: Phonak Audeo ISphere Trial (Atlantic green) Phonak Audeo ISphere Trial (Silver grey)	Approved.
27.	M/s SZ Surgical Supplier, Office #S, 12, 2nd Floor Ghulam Said Medicine Market Namak Mandi, Peshawar ELI-00662 Date of R& I 20-05-2025 Fee: PKR 25000/- Slip # 69256338410	M/s Taian Dalu Medical Instruments Co., Ltd., NO. 3988 Yitianmen Street, Hi- Tech Zone, Taian, Shandong, China 27100 LOA Issue date: FSC: China Validity: 05-02-2027 ISO Validity: 21-10-2027 EU QA Certificate Issue :20-04-2028	Brand name: Spacer for Aerosol Generic Name: Spacer for Aerosol Class-B Shelf life / service life: 5 Years Models/ Specification: DL-01. DL-01A, DL-01B, DL-01C, DL-01D, DL-02, DL-02A. DL-02B. DL-03B. DL-03C. DL-04, DL-05, DL-06, DL-06A, DL-06B. DL-06C, DL-07. DL-08, DL-03A DL-08B. DL-08C, DL-08D, DL-09, DL-10, DL-11, DL-12, DL-13, DL- 14. DL-15. DL-16. DL- 17. DL-18. DL-19, DL-20, DL-21, DL-22, DL-23, DL- 24, DL-25, DL-26, DL- 27. DL. DD petite. La grande, Tur bo, Aeroget, Maclife, Salbomatic. Intec, Aeromate Plus, Aerospacer zeolos. Esencia, Soldist. Farmasol. Instaspacer. Universal-Chamber. AS175. Transpacer VM	Approved only code DL-03B.
28.	M/s SZ Surgical Supplier, Office No.	Name of Manufacturer:	Brand name: Dry Powder Inhaler	Approved only code DL-04A.

	S-12, 2nd Floor, Ghulam Said Medicine Market, Namak Mandi, Peshawar. (ELI-00662) Date of R&I 20-05-2025 Fee Details: Paid Fee: 6,000/- Slip: 305574915006	M/s. Taian Dalu Medical Instrument Co., Ltd., West Part of Yitianmen Street, Hi- Tech Zone, Taian, Shandong, China. • LOA Type: Copy of attested Notarization: By CCPIT Validity: 23-04-2030 • FSC Type: Copy of apostilled Issued By: Govt. Body Attested By: CCPIT Legalization: Appostilled Validity: 14-01-2026 • ISO Certificate Type: Copy of attested Attested By: CCPIT Validity: 21-10-2027	Generic Name: Dry Powder Inhaler Class: A Codes/Sizes: Not mentioned in application Applied as: Single Shelf life: 5 Years	
29.	Name Hospital Supply Corporation Address of Importer 42 Darul Aman Housing Society, Block 7& 8, Karachi, Pakistan	Name: Zhejiang Kindly Medical Devices Co. Ltd Address: No. 758 5th Binhai Road, Binhai Industrial Park, Longwan Distrit 325025, Wenzhou, Zhejiang China	YMS disposable Infusion set with Burette	Board observed that product was already registered as Drug. The board decided to approve the same as device.
30.	M/S Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7 & 8, Karachi ELI-00005 R&I Date: 25.06.2020 Fee: 12,500/- Slip #2045103 Dated 24.06.2025 Diff. Fee: 12,500/- Slip# 34110862712 Dated: 28.12.2021 This evaluation is based on the on-line data submitted	Manufacturer: Zhejiang Kindly Medical Devices Co., LTD Address: No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District 325025 Wenzhou, Zhejiang LOA Type: scanned copy Notarization: No Validity: 31.12.2025 FSC Type: scanned copy Issued by: Zhejiang	Brand Name: YMS Infusion Set Generic Name: Scalp Vein Set Applied as: Single Class: B Models/Code/sizes (as per FSC & application: 27G, 26G, 25G. 24G, 23G. 22G, 21G, 20G, 19G, 18G (With corresponding size / caliber in FSC) Shelf Life: 36 months	Board observed that product was already registered as Drug. The board decided to approve the same as device.

	through E-App. Tracking ID: TRX-1LZ-A145	Medical Products Administration Legalization: NIL Validity: 14.01.2026 ISO – Certificate: Type: Scanned copy Notarization: No Validity: 31.10.2026 CE certificate / EU QMS certificate (MDR) Type: scanned copy Notarization: NIL Validity: 14.04.2026		
31.	M/s HealthBee Projects Private Limited. Ground floor, Momi Plaza, Plot # 43, Business Square Phase 7, Bahria Town, District Rawalpindi. (ELI-00814) D.O.I: 24-11-2021 Dy. No.: 13072 DRAP (R&I) Dated: 09-08-2024 Fee Challan No.: 9427036167 PKR: 50000/- Dated: 09-08-2024	Legal Manufacturer: Name: M/s Maxigen Biotech Inc. <i>(Main Manufacturer, design, development, manufacture, aseptic filling, Moist heat sterilization & distribution)</i> Address 01: No. 88, Keji 1 st Road, Guishan District, Taoyuan City 33383, Taiwan (R.O.C). <i>(Contract Sterilization-Gamma Sterilization)</i> China Biotech Corporation Address 02: No. 10, 33 rd road, Taichung Industrial Park, Taichung, Taiwan. <i>(Contract Sterilizer-Ethylene Oxide Sterilization)</i> Taiwan Advanced Sterilization Technology Inc. Address 03: No. 17-1, Chien Kuo Road, Tan Tze, Taichung City, 427, Taiwan.	ArtiBest Intra-Articular Injection Catalogue No.: AB-305 Product Specification: 3.0 ml containing 2.0% Sodium Hyaluronate Class: D MD group: not a group type Medical device. LOA Validity: 31-12-2026 FSC Validity: 13-10-2026 Shelf life: 03 years Storage Conditions: 2°C – 25°C	Approved.
32.	M/s Vertex Medical Pvt. Ltd.	Name of Manufacturer:	Brand Name: Inomed	Approved ZD System.

	Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 19-05-2020 CMS tracking ID: 9DS-6AD-H53A Fee: 25,000/-	Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29 79312 Emmendingen Germany LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Yes Issued by: German Authority Issue date: 04-07-2022 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 16-01-2026 EC Certificate Extension Valid till: 31-12-2028	Generic Name: Stereotactic System Applied as: System Class: A Models/Code/sizes (as per FSC & application): ZD, RM and OSS Shelf Life: 5 Years	
33.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 19-05-2020 CMS tracking ID: V2V-XG6-V9YT Fee: 25,000/-	Name of Manufacturer: Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29 79312 Emmendingen Germany LOA Type: Copy Notarization: Yes Issue date: 31-12-2024 • FSC Type: Copy Legalized: Yes Issued by: German Authority Issue date: 04-07-2022 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 16-01-2026 EC Certificate	Brand Name: Inomed Generic Name: ISIS MER System Applied as: System Class: B Models/Code/sizes (as per FSC & application): ISIS MER System Shelf Life: 10 Years	Approved 504270 ISIS Headbox U8DRD. 3. 590210 ISIS Headbox U5S-MER

		Extension Valid till: 31-12-2028		
34.	M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 19-05-2020 CMS tracking ID: QYV-VMG-SE9V Fee: 25,000/-	Name of Manufacturer: Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29 79312 Emmendingen Germany LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Yes Issued by: German Authority Issue date: 04-07-2022 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 16-01-2026 EC Certificate Extension Valid till: 31-12-2028	Brand Name: Inomed Generic Name: Microdrive Applied as: Family Class: A Models/Code/sizes (as per FSC & application): Inomed Micro Drive Shelf Life: 10 Years	Approved code 590580.
35.	M/s SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan (ELI-00582) R&I Date: 27.10.2021 CMS tracking ID: DX5-R9P-4JLN Fee: 5,000/-	Name of Manufacturer: TELE-PAPER (M) SDN BHD Address: Lot 2C, Jalan KELULI 15/16, Section 15, 40200 Shah Alam, Selangor Darul Ehsan, Malaysia LOA Type: Copy Notarization: Yes Validity date: 02-07-2026 • FSC Type: Copy Issued By: Ministry of Health Malaysia Legalization: Legalized Validity: 13-10-2024 Another FSC submitted with validity upto 25-08-2026 but its not legalized. • ISO – Certificate: Notarization: No Validity: 10-12-2025	Brand Name: SONOMED Generic Name: ECG Paper Applied as: Family Class: A Models/Code/sizes (as per FSC & application): -- Shelf Life: 3 years	Approved ECG Roll Sonomed 45mm x 30m x 16mm

		CE certificate: Extension letter of CE certificate till 31-12- 2028		
36.	M/s SAA INTERNATIONAL B-296, Ground floor, Block 10, F.B. Area, Karachi - Pakistan (ELI-00582) R&I Date: 27.10.2021 CMS tracking ID: NTJ-UZ2-5TY2 Fee: 5,000/	Name of Manufacturer: TELE-PAPER (M) SDN BHD Address: Lot 2C, Jalan KELULI 15/16, Section 15, 40200 Shah Alam, Selangor Darul Ehsan, Malaysia LOA Type: Copy Notarization: Yes Validity date: 02-07- 2026 • FSC Type: Copy Issued By: Ministry of Health Malaysia Legalization: Legalized Validity: 13-10-2024 Another FSC submitted with validity upto 25- 08- 2026 but its not legalized. • ISO – Certificate: Notarization: No Validity: 10-12-2025 CE certificate: Extension letter of CE certificate till 31-12- 2028	Brand Name: SONOMED Generic Name: CTG Paper Applied as: Family Class: A Models/Code/sizes (as per FSC & application: -- Shelf Life: 3 years	Approved Sonomed 120mm x 100mm x150s.
37.	Microport Scientific Pakistan Pvt. Ltd., Office No. 02/03, 2 nd Floor, Hive Gizri Road, Block 9, Clifton Karachi ELI-01182 Date of R& I 06-05.2025 Fee: Rs.100000/ through slip no. 33190092746	Legal Manufacturer: Hemovent GmbH, Pascalstrasse 59, 52076, Aachen, Germany. LOA: Valid till: 31-12-2025 (Copy) FSC: Not Provided ISO - Validity Date: 17- 09-2027(Copy) EU Quality Management Certificate: 22-06-2027 (Copy)	MobyBox Systems ECMO System Class C Shelf Life 24 months Part number as per the EU/CE and DoC provided: HVEU-009 Component: MOBYBOX Part number: HVEL-006 Component: MOBYBOX Runner, analog Part number: HVCEU-003 Component: MOBYBOX Runner, digital	Approved.

			Part number: HVCEU-005	
38.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 35816499523 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	DYMIND Auto Hematology Analyzer Class-B Shelf life: 8 Years Models/ Specification UN73	Approved.
39.	Applicant Name: Moody global services Address of Importer: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 4854440718 Dated: 08-04-2025	Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	DYMIND Auto Hematology Analyzer Class-B Shelf life: 8 Years Models/ Specification DF50	Approved.
40.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad	Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road,	DYMIND Auto Hematology Analyzer Class-B Shelf life: 8 Years Models/ Specification	Approved.

	(ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 9821577607 Dated: 08-04-2025	Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	DH36X	
41.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/- Fee Challan No: 72626957 Dated: 08-04-2025	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026	DYMIND Auto Hematology Analyzer Class-B Shelf life: 8 Years Models/ Specification DH36	Approved.
42.	Applicant Name: Moody global services Address of Importer : Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad (ELI-01038) Date of R&I 09-04-2025 Fee Details: Paid Fee: 31,000/-	Name of Manufacturer: Shenzhen Dymind Biotechnology Co., Ltd. Address: 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R.	DYMIND Auto Hematology Analyzer Class-B Shelf life: 8 Years Models/ Specification DH21	Approved.

	Fee Challan No: 1727532724 Dated: 08-04-2025	China LOA Validity: 31-12-2029 FSC: China Validity: 18-01-2026 ISO Validity: 30-05-2026		
43.	M/s ENDOVISION ENTERPRISES A-173, Block - 3, Gulistan-e-Jauhar, Karachi Establishment License No: ELI 00730	M/s CHANGZHOU NEW DISTRICT GARSON MEDICAL STENT APPARATUS Co., Ltd Address: No. 06, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu, China Embassy attested FSC: China, Valid until: 15-05-2025 LOA Valid until 30th April 2025 ISO 13485 Valid until 25-05-2024 Copy of EC Certificate FQA Valid until 31-08-2024 An undertaking form Manufacturer	Garson Flextent Biliary Stent System Non-Covered Sizes and Codes: As per FSC Class C Shelf life: 1 years Application submission date: 03-11-2021 Fee submitted: Rs 50,000/-	Deferred for the following: 1. CE certificate notarized from the country of origin required. 2. Submission of the apostille/ legalized FSC (Germany) including its 10-page annex. 3. clarification that name and address of the manufacturer in CE extension certificate is and FSC is Changzhou Garson medical apparatus Co., Ltd., Floor 3 and 4, Building B, No.277 Xingdong Road, economic Development District 213000 Changzhou Jiangsu, P.R. China.”
44.	Endovision Enterprises, A-173, Block 3 Gulistan-e-Jauhar Karachi-75290. (ELI-00730) Evaluator AD-III 4244	Legal Manufacturer: Changzhou New District Garson Medical Stent Apppartus. No. 6, Huanbao BA Road, Huanbao Industrial Area, New District, Changzhou, Jiangsu China	GARSON (FLEXTENT) Duodenum Stent Class-C Shelf life: 1 year Codes as per FSC	Deferred for the followings: 1. signed and stamped Form 7A along with undertaking on stamp paper required. 2. clarification that as per Form 7A, brand name is Garson and generic name is Duodenal/clonic stent (Non-covered system). 3. CE certificate not enclosed.

		FSC China Valid Till: 27-2-2022		4. The FSC (Germany) is not apostille/ legalized. The 10 pages' annexures not enclosed. 5. FSC China valid till 06.02.2025 issued by Jiangsu Association for medical device Industry. 6. FSC certifies that the product is neither resisted in china not in Chinese market. 7. product not mentioned in the FSC. 8. Labels with name of device Sterile Inner- Cavity Medical stent and Introducer System. 9. manufacturer as per Form 7A is Changzhou New District Garson Medical Stent Apparatus. Co., Ltd. while as per FSC Germany and ISO13485 name is Changzhou Garson medical apparatus Co., Ltd. 10. Complete details of the product. 11. Provide complete details of the manufacturing and QC processes. 12. Provide the shelf life studies for the claimed shelf life of 1 year.
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Case No.01: REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

1.	Cardioline Systems (Pvt) Ltd, H. No. 168, Block-E, PIA Housing Society, Johar Town, Lahore.	<u>Legal Manufacturer:</u> Dongguan TT Medical, Inc. Bld-1, 1 Taoyuan Road, Songshan Lake	EverFlow (Paclitaxel Coated PTCA Balloon Catheter)	Deferred in 89 th meeting Decision: Deferred for clarification since the subject	Decision of MDB: The Board approved the device in the name of M/s CardiolineSystem (Pvt) Ltd. subject to submission of the fee for the family of class D and fee per code exceeding 20 codes.
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	ELI-01265 5980-P 62,000/-	National High-Tech Industrial Park, Dongguan, Guangdong, PR China. <u>FSC:</u> Netherlands. <u>Validity:</u> 31-12-2027.	Class-D Shelf life: 2 years Codes as per FSC	device is already applied by The Cure, Lahore and addressed in M-69 and decided as “Deferred for the provision of original and attested FSC mentioning the applied device, since the applied device is not mentioned in the submitted FSC of Netherland The board decide to call both the parties in person	.
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