

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

DECISIONS OF 112th MEETING OF THE MEDICAL DEVICE BOARD (MDB)
HELD ON 11-12-2025 (MANUAL APPLICATION PART-II)

112th 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 11th December, 2025. The meeting was chaired by Dr. Babar Khan, Chairman Medical Device Board, DRAP, Islamabad and attended by the following:

| S.No. | Name and Designation/Department | Position in the MDB |
|--------------|--|---|
| 1. | Dr. Babar Khan, Director, Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan, Islamabad. | Chairman |
| 2. | Mr M Salik Zahid, Chief Drugs Inspector, Nominee of DGHS Baluchistan | Member (attended meeting through videolink) |
| 3. | Prof Dr Saqib Shafi Sheikh, Interventional Cardiologist, 98 Babar block, New Garden Town, Lahore | Member (attended meeting through videolink) |
| 4. | Prof. Dr. Mehmood Ahmad, Former Dean, Islamia University, Bahawalpur, House No. 144-D, St. No.14, OPF Housing Scheme, Phase-1, Khayaban Jinnah, Near Raiwind Road, Lahore. | Member (attended meeting through videolink) |
| 5. | Abdul Aleem Awan, Assistant Prof. Pharmacy Department, Abbottabad University of Science & Technology, Havelian. | Member (attended meeting through videolink) |
| 6. | Dr. Farid Khan, Senior Consultant Neuro Surgery/Director Trauma & Emergency/Focal Person MSDS, Primary & Secondary Healthcare Department, Punjab. | Member (attended meeting through videolink) |
| 7. | Dr. Ayesha Ali, Department of Pharmacy, Pakistan Institute of Medical Sciences, Islamabad (Hospital Pharmacist). | Member |
| 8. | Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad. | Member |
| 9. | Mr. Wajahat Ali, Biomedical Engineer, Liaquat College of Medicine and Dististry & Darul Sehat Hospitaol, Karachi. | Member (attended meeting through videolink) |
| 10. | Ms. Tazeen Saeed Bukhari, Biomedical Engineer | Co-Opted Expert (attended meeting through videolink) |
| 11. | Mr. Ayyaz Ahmed, Additional Director (MD&MC), DRAP, Islamabad. | Member-cum-Secretary |

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

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

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

FRESH CASES-ELM:

| S.# | Name and Address of Establishment | Name of Production Incharge | Name of QC Incharge | Decision of MDB |
|-----|--|--|---|---|
| 1 | Surgicare Cotton Industries, Office/godwon: Chak No. 38-G.D, Faisalabad Road Okara | Sabir Hussain B-Pharm Drug Testinf Laboratory Balochistan Deputy Director Experience: 5 Years | Nasira Muhammad BS (Hons.) Biochemistry QC Analyst Experience 6 Years | The board considered the inspection report and recommendations of panel and approved establishment licence to manufacture medical devices for following sections: <ul style="list-style-type: none">• Absorbent cotton wool section.• Crepe Bandage section• Gauze Section (Sterile / Non Sterile).• Cotton Bandage section.” N.B: The firm shall not perform sterilization procedure of Sterile Gauze Bandages from M/s Paras Radiation Services (PARAS), Lahore unless get approval of outsourcing for the same in light of Rule 67 of Medical Devices Rules, 2017. |

Item No. 1B: APPLICATION FOR GRANT OF ESTABLISHMENT LICENCE TO IMOPRT MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.

FRESH CASES ELI

| S.# | Name of Establishment | Name of Qualified Technical Person | Name of Management | Decision |
|-----|---|--|--|-----------------|
| 1. | M/s Biomedics Pharmaceutica (Pvt.) Ltd, Office: 368-DD Phase IV, DI-IA Lahore, Cantonment, Lahore Godown: Office No. 3, Rehmat Ullah building Green Homes street 308, Multan road, Lahore. | Syeda Nazia Hassan Naqvi Pharm D | Nasir Ali Niala Aziz Partner | Approved |
| 2. | M/s Vertex International, first floor, 51/C-I, Park Avenue, university town, Peshawar. | Muhammad Usama Medical Lab Technologist | James Iqbal CEO | Approved |

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| 3. | M/s RAAB Scientific Solutions, Office/Godown: 4/2 Canal park, Gulberg-II, Lahore Lahore. | Khubaib Shakeel Bsc Biomedical Engineering | Uzair Zahid CEO | Approved |
| 4. | M/s AR Enterprises, Office/godown: P-8/1, Muslim town- B, Sargodha road, Faisalabad. | Muhammd Shan Pharm D | Muhammad Rashid CEO | Approved |
| 5. | M/s Baihe Medical Group (SMC- Pvt.) Ltd, Office/godown: Apartment No. 102, 1 st Floor, Florets Luxury Apartment, Ahmad Block, New Garden Town, Lahore. | Muhammad Asghar Pharm D | Muhammad Asghar CEO | Approved |
| 6. | M/s Hcare International Office/godwon: Plot No A-54 ground floor RECHS society bock 13-A Gulshan e Iqbal karachi Karachi | Naima Safdar Pharm D | Azhan ul Hassan Syeda Hiba Ali Partner | Approved |
| 7. | M/s MEDI CRAFT DEVICES (PRIVATE) LIMITED Office/godown: 547-F, Canal View Society, 12-KM, Multan Road Lahore | MRS. SUMRA ASHFAQ Pharm D | MR. SHAHID AKHTAR Sufian Shahid Hasan Naeem Abdul Rehman Mrs. Zunera Muneeb | Approved |
| 8. | M/s SUZEM INTERNATIONAL; Office/godown: House No.16 block A-5 bismillah city unit no.10 latifabad, Hyderabad | Muhammad ahmed B.Sc Biomedical Engineering | Muhammad Umer Khan CEO | Approved |
| 9. | M/s Alexiz Solution (private) laimited, Karachi. | | Syed Afaq Ahmad CEO | Deferred. The board deferred the case and approved request of the firm to delay inspection for one month. |

**ITEM NO. I(C): INCOMPLETE APPLICATIONS FOR GRANT OF ESTABLISHMENT
LICENSE TO IMPORT**

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| 1. | M/s Ibne-Seena Health and Care Society , | Hira Quddos Pharm D | Muhammd Irfan CEO | The firm was asked to submit below mentioned documents for further processing their application for grant of ELI: |
|----|---|----------------------------|--------------------------|---|

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|--|--|--|---|
| Office: Street No. 22, Block 6, Main University road, gulshan e Iqbal, Karachi. | | | 1. Registration of firm as commercial entity with FBR or any other competent authority. 2. NOC from Ministry of Interior. |
| Godown: Ibne Seena Hospital, 3 rd Floor, Street 22/B, Main University road, block 6, Gulshan e Iqbal, Karachi. | | | However, the firm failed to provide the requisite information. Submitted for consideration of board please |

Decision:

The board deliberated on the application of the firm for grant of establishment license to import medical devices and response submitted by the firm subsequent to the communication of shortcomings.

The board also took opinion of Legal Affairs Division and observed that the firm is an NGO which is primarily a non-commercial activity and rule 24 of Medical Devices Rules 2017 to which applicant is referring for grant of license is for personal and hospital use of medical devices. Therefore, applicant need to register their organization as commercial entity with FBR/ SECP and/or Registrar of firms.

In view of above, the board decided to reject application of M/s Ibn-e-Seena Health and Care Society Karachi for establishment license to import medical devices under Medical Devices Rules 2017.

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

DEFERRED CASES OF ELI:

| S.# | Name of Establishment | Name of Qualified Technical Person | Decision |
|-----|--|---|--|
| 1. | M/s Precimmo (Pvt) Ltd., F-748/N, Old Star Labour Colony, S.I.T.E, Karachi | Dr. Shoaib Rao Dr. rer. nat (Cancer Biology) | he board considered request of the applicant in the light of Rule 6(4) of Medical Devices Rules 2017 regarding qualifications of technical staff/ qualified person for establishment license to import medical devices and accepted degree in Molecular Genetics (BS) and Cancer Biology (Ph.D) as a degree in broader field of Biotechnology which is primary requirement of law. Therefore, board approved establishment license to import medical devices in favor of M/s Precimmo (Pvt) Ltd., F-748/N, Old Star Labor Colony, S.I.T.E, Karachi and approved Dr. Shoaib Rao (Ph.D) as qualified person. |

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

FRESH CASES FOR RENEWAL OF ELI:

| S.# | Name of Establishment | Name of Qualified Technical Person | Name of Management | Decision |
|-----|--|------------------------------------|--|----------|
| 1. | M/s Sorabjee Patel & Co, Office/Godown: 45 Badri Building 1.1, Chundrigar road, Karachi. ELI-00067 | Asif Wazir Pharm D | Romina Mansoor, CEO | Approved |
| 2. | M/s ACP System, Office/godown: 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed road, Karachi. ELI-00001 | Samara Ahmed Pharm D | Jawad Akhtar Tahir Mahmood Shaikh Asadullah tahir Partner | Approved |
| 3. | M/s K.S Agencies, Office: Office No. 210, Business arcade, Main University Road, Karachi. Godown: 33 & 34 Business arcade, Main University Road, Karachi. ELI-00382 | M Shafi Fahad Pharm D | M Idress Memon CEO | Approved |
| 4. | M/s Save on Healthcare Office/godown: House number 06, Street no. 2, Ibraheem colony, Link road, aziz bhatti town, Lahore ELI-00027 | Muhammad RAzi Butt Pharm D | M Jamil Hassan Shahbaz idress khan Muhammad Amir | Approved |
| 5. | M/s Shams Scientific traders, Office: Office NO. 7, First Floor, Sadiq plaza, Faisalabaf. Godown: 22-Y-J, Madina Town, Lahore ELI-00459 | Aqsa Sheikh Pharm D | Irfan Ayaz CEO | Approved |
| 6. | M/s Ahmad Medix (Pvt) Ltd, | Rabia Itaiz Pharm D | Dr Sohail Mukhtar Ahmad Adeel Ahmad Kashif Sohail | Approved |

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| | Offic/godown: 129/6, Quaid-e-azam Industrial estate, Lahore. ELI-00380 | | Partner | |
| 7. | M/s Ali Noor Industries, Office/Godown: office no. 1, 2 nd floor, central point plaza, Gulberg III, Lahore. ELI-00816 | Ms Tabinda | Ahsun Ali Noor Rao Ali Athar khan Partner | Approved |
| 8. | M/s Advance Cardiology system., Office/Godown: 316,317, Building -11, 3 rd Floor, Panorama centre, Raja Ghanzafar Ali Khan road, Near Hotel Avari tower, Karachi. ELI-00074 | Hina Pharm D | Mohammad Sadiq CEO | Approved |
| 9. | M/s DIA SCIENT INTERNATIONAL Office: 11,12,13,14, EMAAN ARCADE, IQBAL STADIUM ROAD, NEW CIVIL LINE, Faisalabad Godown: 35-G , DIA, Scient Medical Complex, Building Raja road, Gulistan Colony No. 01 Near Aziz Fatima Hospital Raja Road Faisalabad ELI-00439 | Khuram Shehzad Post Diploma of Associate Engineer in biomedical Technology | Muhammad Ehsan CEO | Approved |
| 10. | M/s HSB Innovation in Health Offic/godown: Suite No. C-3A, Third Floor, First City Tower, More Samanabad, Lahore ELI-00435 | Ms Sadaf Naz Pharm D | Sarfraz Ali Shah CEO | Approved |

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| 11. | M/s Sindh Medical Stores, Office/godown: 13-B, Block 6, PECHS, Shahrah E faisal Karachi. ELI-00010 | Usman Ghani B-Pharm | M Younas Billoo Kishwar Billoo Tasmia Abeer | Approved |
| 12. | M/s Uniferoz (Pvt) Limited, Office: Plot No. 32/8 and 33/2, Sector-15, Korangi Industrial Area, Karachi. Godown: Plot No. 108 & 109 Sector-23, Korangi Industrial Area, Karachi ELI-00284 | Nazeen Ayub Pharm D | Tariq Mehtab Feroz M Sadiq Mehtab Feroz Muneer Mehtab feroz Mehtab Udidn feroz | Approved |
| 13. | M/s MIRAJ CORPORATION, Office/Godwon: Office no 13-14, second floor, Jinnah Business center, Chandni Chowk, Rawalpindi ELI-00326 | Qindeel Mushtaq Ahmed M.Phil Biotechnology | Mushtaq Ahmad CEO | Deferred for approval of technical staff and fee. |
| 14. | M/s Nimrall Farma Office: 15E 2nd Floor Sheikh Building Bata Chowk, Aziz Bhatti Road Lalkurti Rawalpindi Godown: Nimrall Farma Flat No. E-15, Aziz Bhatti Road, 2nd Floor, LalKurti, District Rawalpindi ELI-00251 | Ms Tanya Waseem Pharm D | Shahzad Saeed Muhammad Kashif Kalsoom Mubbshir | Deferred for approval of technical staff and fee |
| 15. | M/s Surgi vision, Office/Godown: 108-H, Model town, Lahore. ELI-00384 | Ayza Nawaz Pharm D | Babar Abbas CEO | Deferred for approval of technical staff and change of godown with complete fee and relevant documents. |

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| | | | | The firm shall also submit an undertaking that the facility shall not be used for residential purposes and this can be inspected any time without hindrance. |
| 16. | <p>M/s Cabbot Surgicals,</p> <p>Office: Ho No CB 6060 Rose Lane 3-A New Lalazar Rawalpindi.</p> <p>Godown: 09 Rose Lane 01, Gulberg Avenue, New Lalazar Rawalpindi.</p> <p>ELI-00415</p> | <p>Firdous Rasheed</p> <p>Pharm D</p> | <p>Muhammad Attique Shahid</p> <p>CEO</p> | Deferred for approval of technical staff and change of godown with fee and relevant documents |
| 17. | <p>M/s Biomax international,</p> <p>Office/godown: P-150, Street No. 8, Opposite allied hospital near Daewoo terminal Akbarabad , Chowk ,Faisalabad.</p> <p>ELI-00950</p> | <p>Rubab asghar</p> <p>Bs Hons Medical Laboratory technology</p> | <p>Kashif Javed</p> <p>CEO</p> | Deferred for approval of management change with fee and relevant documents |
| 18. | <p>M/s SAFEWAY SYSTEMS PAKISTAN</p> <p>Office: Office No 4 Second Floor Amna Shopping, Centre Misrial Road Chur Choke, Rawalpindi</p> <p>Godown: First Floor, Ayub Plaza, Misrial Road, Near Bhata Choke</p> <p>ELI-00308</p> | <p>Muhammad Luqam</p> <p>BS Biotechnology</p> | <p>Zeeshan Haider</p> <p>CEO</p> | Deferred for approval of change of godown with fee and relevant documents |
| 19. | <p>M/s Yousaf & Co.,</p> <p>Office / godown: 79-M, Gulberg- III, Lahore.</p> <p>ELI-00302</p> | <p>Wajiha Ghalib</p> <p>Pharm D</p> | <p>Mohammad Yousaf</p> <p>CEO</p> | Deferred for approval of technical staff and change of godown with complete fee and |

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| | | | | <p>relevant documents.</p> <p>The firm shall also submit an undertaking that the facility shall not be used for residential purposes and this can be inspected any time without hindrance</p> |
| 20. | <p>M/s Medi Bridge,</p> <p>Office: Plot No. 500, Block-D, 2nd Floor, M.A Jinnah Road, Lahore.</p> <p>Godown: Plot No. 500, Block-D, Ground Floor, M.A Jinnah Road, Lahore.</p> <p>ELI-00058</p> | <p>Haroon Ahmad</p> <p>Bio Medical Engineer</p> | <p>Iftikhar Ahmad</p> <p>CEO</p> | <p>Deferred for approval of technical staff and fee</p> |
| 21. | <p>M/s Accu Sight,</p> <p>Office /Godown: 131 - Nasheman-e-Iqbal, Housing Society, Lahore</p> <p>ELI-00049</p> | <p>Maryam Ishaq</p> <p>Pharm D</p> | <p>Zaigham Mansoor Khan</p> <p>CEO</p> | <p>Deferred for change of premises to a non-residential area within 02 months failing which show cause notice to be issued for cancellation of license.</p> |
| 22. | <p>M/s IRTEQA BIOTEK,</p> <p>Office/Godown: H 159, St 8 Chaklala Scheme 3</p> <p>ELI-00218</p> | <p>Mahwish Dar</p> <p>M.phil biochemistry</p> | <p>Muhammad Azm Saeed Dar</p> <p>CEO</p> | <p>Show cause notice. The board considered the inspection findings and observed grave violations of conditions of license under Medical Devices Rules 2017. Therefore, it was decided to issue show cause notice to the firm for cancellation of</p> |

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| | | | | license and to provide opportunity of personal hearing to the firm. |
| 23. | 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 | The board considered the written statement of the firm and decided to issue notice of personal hearing before cancellation of license to comply with conditions of law. |
| 24. | 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 | The board considered the written statement of the firm and decided to issue notice of personal hearing before cancellation of license to comply with conditions of law. |

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

DEFERRED CASES FOR RENEWAL OF ELI:

| S.# | Name of Establishment | Name of Qualified Technical Person | Name of Management | Decision |
|------------|--|--|--|-----------------|
| 1. | M/s Meximp Technologies, B-62 , Block-5, Gulshan-e-Iqbal, Karachi (ELI- 00052) | Muhammad Samiulahaq B-Pharmacy | Faiyaz Ahmad Mudassir Ahmad Inamdar | Approved |
| 2. | M/s AA Enterprizes, Office: 57, 15-16 First Floor Mobi Plaza, Haider Road, Saddar, Rawalpindi Godown: Plot No. 4, House No. 286/4 , Main Peshawar Road, Rawalpindi Westridge, | Abu Bakar Siddique Bs Bio medical Engineering | Muhammad Waqas | Approved |

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| | Adjacent to Am-Anglo School, Near Polo Ground, Rawalpindi. ELI-00525 | | | |
| 3. | M/s Optical Palace, Hemani Mension, M.A Jinnah Road Opposite KMC , G.P.O, Box No. 1249, Karachi(ELI-00527) | Muhammand Ovais Siddiqui Pharm D | Atif Jamil Ur Rehman Aamir Rahman Akif Rehman | Approved |
| 4. | M/s Surebio Diagnostic, EE-10, Defense View Phase II, Near Iqra University, Shaheed-e-Millat, Express Way, Karachi ELI: 00084 | Romana Adil B-Pharm | Shaikh Shakeel Ahmed CEO | Approved |

Agenda Item No. II ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**Dr. Hanif Ullah (Deputy Director-XI)****Agenda Item II (a) APPLICATIONS SUBMITTED ON CASE MANAGEMENT SYSTEM:**

| S.# | Name of Firm | Manufacturer Name | Name of Medical Device | Decision |
|-----|---|---|---|---|
| 1. | TOP TRADER, 2 nd Floor, Usman Plaza, Commercial Area, Chaklala Scheme-3, Rawalpindi ELI -01045 R&I Date: NIL Fee: 31000/- Slip # 70191730288 This evaluation is based on the on-line data submitted through E-App. Tracking ID: 55J-Z6B-Q45J | Legal Manufacturer: Xuzhou Kaixin Electronic Instrument Co., Ltd. Kaixin Mansion C -01, Economic Development Zone, Xuzhou, Jiangsu, China LOA Type: scanned copy Notarization: Yes, CCPIT Validity: NIL FSC Type: scanned copy Issued by: Jiangsu Medical Products Administration Legalization: Apostilled the notarization of CCPIT Validity: 12.11.2026 ISO – Certificate: Type: scanned copy Notarization: yes, CCPIT Validity: 31.03.2026 CE certificate: Type: scanned copy Notarization: CCPIT notarized the declaration of the firm, not CE certificate. Validity: 26.05.2024 Extended till 31.12.2028 | Brand Name: AB SCAN ODU5 Generic Name: Ophthalmological A/B Mode Ultrasound Scanner ODU5 Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): ODU5 Shelf Life: NIL | Deferred for: Submit the R&I record the application. Submit the scanned copy of Form-7A. Submit notarized copy of LOA with validity. Submit legalized copy of valid FSC in the country of origin. The device Ophthalmologic al AB mode ultrasound scanner ODU5 has been written as “Ophthalmologic al AB mode ultrasound scanner ODU3/5. Clarification is required. Submit notarized copy of valid ISO 13485 certificate. Shelf life verification / stability studies report is required. Submit DOC on the letterhead of the firm. Clarification is required about the applied grouping. You have mentioned the Probe covers or gel. footswitch (as optional) ultrasound gel, thermal printer, and disposable probe sleeves as part of the kit along with correction of the grouping. Clarification is required. Notarized copy of CE certificate is required. |
| 2. | TOP TRADER, 2 nd Floor, Usman Plaza, Commercial Area, | Legal Manufacturer: Xuzhou Kaixin Electronic | Brand Name: ASCAN OD1-A | Deferred for: Submit the R&I record the application. |

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| | <p>Chaklala Scheme-3, Rawalpindi ELI -01045 R&I Date: NIL Fee: 31000/- Slip # 7069649429 This evaluation is based on the on-line data submitted through E-App. Tracking ID: T8Z-8ZY-HTL9</p> | <p>Instrument Co., Ltd. Kaixin Mansion C -01, Economic Development Zone, Xuzhou, Jiangsu, China LOA Type: scanned copy Notarization: Yes, CCPIT Validity: NIL FSC Type: scanned copy Issued by: Jiangsu Medical Products Administration Legalization: Apostilled the notarization of CCPIT Validity: 12.11.2026 ISO – Certificate: Type: scanned copy Notarization: yes, CCPIT Validity: 31.03.2026 CE certificate: Type: scanned copy Notarization: CCPIT notarized the declaration of the firm, not CE certificate. Validity: 26.05.2024 Extended till 31.12.2028</p> | <p>Generic Name: Bio & Pachy Meter Applied as: Kit Class: B Models/Code/sizes (as per FSC & application: ODU5 Shelf Life: NIL</p> | <p>Submit the scanned copy of Form-7A. Submit notarized copy of LOA with validity. Submit legalized copy of valid FSC in the country of origin. The device “Bio & Pachy Meter” has been written as “Ophthalmological ultrasonic measuring instruments OD1-A/P/AP”. Clarification is required. Submit notarized copy of valid ISO 13485 certificate. Shelf life verification / stability studies report is required. Submit DOC on the letterhead of the firm. Clarification is required about the applied grouping. You have mentioned the gel, probe covers, footswitch (as optional), printer, and system calibrator as part of the kit. Clarification is required along with correction of the grouping. Notarized copy of CE certificate is required.</p> |
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Agenda Item II (b) APPLICATIONS SUBMITTED (HARD DOSSIERS):

| S.# | Name of Firm | Manufacturer Name | Name of Medical Device | Decision |
|-----|---|---|--|---|
| 1. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15,</p> | <p>Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China Mfg site:</p> | <p>Brand Name: iFlash-NT-proBNP Generic Name: Chemiluminescent Immunoassay (2 x 50 test/kit) Applied as: Kit Class: C</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the</p> |

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| | <p>Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 Fee: 62000/- Slip # 7229139749 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: original Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested Issue date: 21.01.2025 ISO – Certificate: Type: scanned copy Notarization: CCPIT notarized the declaration of the firm, not certificate. Validity: 09.06.2028</p> | <p>Code/sizes (as per FSC & application): C89244-S C89244 Shelf Life: 18 month</p> | <p>name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.</p> |
| 2. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3241-C-Sindh Fee: 62000/- Slip # 18631516 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control, and and FSC (origin) ISO certificate in iFlash-NT-proBNP dossier.</p> | <p>Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China Mfg site: Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization:</p> | <p>Brand Name: iFlash-CA242 Generic Name: Chemiluminescent Immunoassay (2 x 50 test/kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86069-S C86069 Shelf Life: 18 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.</p> |

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| | | <p>No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028</p> | | |
| 3. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e- Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3249-C-Sindh Fee: 62000/- Slip # 18631516 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control, and FSC (origin) ISO certificate in iFlash- NT-proBNP dossier.</p> | <p>Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China Mfg site: Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028</p> | <p>Brand Name: iFlash- Gastrin-17 Generic Name: Chemiluminescent Immunoassay (2 x 50 test/kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86055-S C86055 C86055-L Shelf Life: 18 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.</p> |
| 4. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6,</p> | <p>Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd., Building 1, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict,</p> | <p>Brand Name: iFlash- SCC Generic Name: Chemiluminescent</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for</p> |

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| | <p>PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3242-C-Sindh Fee: 62000/- Slip # 114602501 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control, and FSC (origin) ISO certificate in iFlash-NT-proBNP dossier.</p> | <p>Longgang District, Shenzhen, Guangdong, China Mfg site: Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy attested Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028</p> | <p>Immunoassay (2 x 50 test/kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86067-S C86067 Shelf Life: 18 month</p> | <p>the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.</p> |
| 5. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3061-C-Sindh Fee: 62000/- Slip # 88042480876 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL</p> | <p>Brand Name: EB VCA IgG, IgM & IgA Control Generic Name: Immunoassay Controls</p> <ul style="list-style-type: none"> EB VCA IgG (Negative control 2x2ml) (positive control 2x2ml) EB VCA IgM (Negative control 2x2ml) (positive control 2x2ml) EB VCA IgA (Negative control 2x2ml) (positive control 2x2ml) <p>Applied as: Kit Class: C Code/sizes (as per FSC & application): CC853</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A,</p> |

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| | | <p>Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of Embassy attested document Issued by: TGA, Australia Legalization: -- Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>CC854 CC855 Shelf Life: 48 month</p> | <p>LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate devices in the FSC. Clarification is required about the applied grouping.</p> |
| 6. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3072-C-Sindh Fee: 62000/- Slip # 98155929 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of Embassy attested document Issued by: TGA, Australia Legalization: -- Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>Brand Name: Toxo IgG and IgM Control Generic Name: Immunoassay Controls</p> <ul style="list-style-type: none"> Toxo IgG (Negative control 2x2ml) (positive control 2x2ml) Toxo IgM (Negative control 2x2ml) (positive control 2x2ml) <p>Applied as: Kit Class: C Code/sizes (as per FSC & application): CC841 CC842 Shelf Life: 48 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate device in the FSC. Clarification is required about the applied grouping.</p> |

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| 7. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3066-C-Sindh Fee: 62000/- Slip # 67063477621 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: Apostilled the notarization of CCPIT Validity: 15.03.2027 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>Brand Name: Tumor Marker Multi Control Generic Name: Immunoassay Controls • Level 1 (2x3ml) • Level 2 (2x3ml) Applied as: Kit Class: C Code/sizes (as per FSC & application): CC816 Shelf Life: 36 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate.</p> |
| 8. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3066-C-Sindh Fee: 62000/- Slip # 017472652090</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China</p> | <p>Brand Name: M. Pneumoniae IgG and IgM Control Generic Name: Immunoassay Controls • M. Pneumoniae IgG (Negative control 2x2ml) (positive control 2x2ml) • M. Pneumoniae IgM (Negative control 2x2ml)</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required.</p> |

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| | <p>The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>(positive control 2x2ml) Applied as: Kit Class: C Code/sizes (as per FSC & application): CC847 CC848 Shelf Life: 48 month</p> | <p>The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate device in the FSC. Clarification is required about the applied grouping.</p> |
| 9. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3071-C-Sindh Fee: 62000/- Slip # 54847950240 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia</p> | <p>Brand Name: CMV IgG and IgM Control Generic Name: Immunoassay Controls • CMV IgG (Negative control 2x2ml) (positive control 2x2ml) • CMV IgM (Negative control 2x2ml) (positive control 2x2ml) Applied as: Kit Class: C Code/sizes (as per FSC & application): CC843 CC844 Shelf Life: 48 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate device in the FSC. Clarification is</p> |

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| | | <p>Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | | required about the applied grouping. |
| 10. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3059-C-Sindh Fee: 62000/- Slip # 7694497778 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>Brand Name: Rubella IgG and IgM Control Generic Name: Immunoassay Controls</p> <ul style="list-style-type: none"> Rubella IgG (Negative control 2x2ml) (positive control 2x2ml) Rubella IgM (Negative control 2x2ml) (positive control 2x2ml) <p>Applied as: Kit Class: C Code/sizes (as per FSC & application): CC845 CC846 Shelf Life: 48 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The applied group is separate devices in the FSC. Clarification is required about the applied grouping.</p> |
| 11. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15,</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site:</p> | <p>Brand Name: EB EA IgM Control Generic Name: Immunoassay Controls</p> <ul style="list-style-type: none"> EB EA IgM (Negative control 2x2ml) (positive control 2x2ml) | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the</p> |

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| | <p>Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3068-C-Sindh Fee: 62000/- Slip # 50730774 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>Applied as: Kit Class: C Code/sizes (as per FSC & application): CC856 Shelf Life: 48 month</p> | <p>name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate.</p> |
| 12. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3062-C-Sindh Fee: 62000/- Slip # 206375176 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization:</p> | <p>Brand Name: Anti-HBc Control Generic Name: Immunoassay Controls • (Negative control 2x2ml, positive control 2x2ml) Applied as: Kit Class: D Code/sizes (as per FSC & application): CC867 Shelf Life: 18 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC</p> |

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| | | <p>No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | | <p>(RRA), and ISO certificate. Submit Ce design examination certificate and applicable requirements for class D device.</p> |
| 13. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3069-C-Sindh Fee: 62000/- Slip # 37271390485 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy of embassy legalized document Issued by: TGA, Australia Legalization: No Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>Brand Name: HBeAg Control Generic Name: Immunoassay Controls • (Negative control 2x2ml, positive control 2x2ml) Applied as: Kit Class: D Code/sizes (as per FSC & application): CC865 Shelf Life: 18 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. Submit Ce design examination certificate and applicable requirements for class D device.</p> |
| 14. | <p>Martin Dow Specialties Private Limited, Nice Trade</p> | <p>Legal Manufacturer:</p> | <p>Brand Name: HSV 1 & 2 IgG Control</p> | <p>Deferred for:</p> |

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| | <p>Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 10.07.2025 3063-C-Sindh Fee: 62000/- Slip # 96072293</p> | <p>Shenzhen Ever-Blue Biotech CO., Ltd, Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 20.12.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy legalized Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 14.11.2025</p> | <p>Generic Name: Immunoassay Controls</p> <ul style="list-style-type: none"> • HSV – 1 IgG (Negative control 2x2ml, positive control 2x2ml) • HSV – 2 IgG (Negative control 2x2ml, positive control 2x2ml) <p>Applied as: Kit Class: D Code/sizes (as per FSC & application): CC837 CC839 Shelf Life: 48 month</p> | <p>The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. The address of legal manufacturer shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. The address of manufacturing site shall be the same in Form 7A, LOA, FSC (origin), FSC (RRA), and ISO certificate. Submit Ce design examination certificate and applicable requirements for class D device. The applied group is separate devices in the FSC. Clarification is required about the applied grouping.</p> |
| 15. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3237-C-Sindh Fee: 62000/- Slip # 342994579819 The firm has referred to RRA FSC</p> | <p>Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA</p> | <p>Brand Name: iFlash-hs-cTnI Generic Name: Chemiluminescence Immunoassay (2x50 tests /kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86304 Shelf Life: 18 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.</p> |

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| | submitted in the dossier of HSV 1 & 2 IgG control. | <p>Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy legalized Issue date: 21.01.2025 ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028</p> | | |
| 16. | <p>Martin Dow Specialties Private Limited, Nice Trade Orbit Building 7th Floor, 44-A, Block-6, PECHS, Shahrah-e-Faisal, Karachi Godown: Plot No. 130, Sector-15, Korangi Industrial Area, Karachi ELI-00160 R&I Date: 17.07.2025 3231-C-Sindh Fee: 62000/- Slip # 0788391427 The firm has referred to RRA FSC submitted in the dossier of HSV 1 & 2 IgG control.</p> | <p>Legal Manufacturer: Shenzhen Yhlo Biotech Co., Ltd. Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116, China Mfg site: Shenzhen Yhlo Biotech Co., Ltd. Building 2, Yhlo Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong, China LOA Type: photocopy of notarized document Notarization: Yes, CCPIT Validity: 31.12.2025 FSC Type: photocopy Issued by: NIL Legalization: No Validity: 12.01.2026 FSC in RRA Type: photocopy Issued by: TGA, Australia Legalization: Embassy legalized Issue date: 21.01.2025</p> | <p>Brand Name: iFlash-D-dimer Generic Name: Chemiluminescence Immunoassay (2x50 tests /kit) Applied as: Kit Class: C Code/sizes (as per FSC & application): C86238 Shelf Life: 18 month</p> | <p>Deferred for: The application form has been signed by Director Regulatory Affairs. Authorization letter for the signatory is required. Declaration on stamp paper to be issued in the name of the firm / signatory is required. English translation of the issuing authority in FSC is required. Notarized copy of LOA and legalized copy of FSC (origin) is required.</p> |

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| | | ISO – Certificate: Type: photocopy Notarization: No Validity: 09.06.2028 | | |
| 17. | Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e- Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2354-B-Sindh Fee: 31000/- Slip # 43526358934 | Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani- ro, Ochang-eup, Cheongwon- gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: Apostilled Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026 | Brand Name: Optical Q, CRP, Detection Buffer CRP Generic Name: CRP (C-Reactive Protein), Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month | Deferred for: The firm has applied CRP (C-Reactive Protein) and Buffer. The submitted FSC of Korea contains Optical Q, CRP only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The firm has submitted fee challan meant for various products. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO- 13485 certificate. |
| 18. | Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e- Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2360-B-Sindh Fee: 31000/- Slip # 43526358934 | Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani- ro, Ochang-eup, Cheongwon- gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC | Brand Name: Optical Q, PCT, Detection Buffer PCT Generic Name: PCT (Prolactonin), Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month | Deferred for: The firm has applied PCT and Buffer. The submitted FSC of Korea contains Optical Q, PCT only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The firm has submitted copy of fee challan meant for various products. Original fee challan in respect of the |

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| | | <p><u>Type: photocopy (original attached in Optical Q, CRP)</u> Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: Original apostilled Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026</p> | | <p>applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO-13485 certificate.</p> |
| 19. | <p>Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e-Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2356-B-Sindh Fee: 31000/- Slip # 96729712469</p> | <p>Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy (original attached in Optical Q, CRP) Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: Original apostilled Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026</p> | <p>Brand Name: Optical Q, Reagent Generic Name: TSH (Thyroid stimulating hormone), Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month</p> | <p>Deferred for: Specifying the brand names. The firm has applied Reagent (TSH) and Buffer. The submitted FSC of Korea contains Optical Q, TSH only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The firm has submitted copy of fee challan meant for various products. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO-13485 certificate.</p> |

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| 20. | Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e- Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2368-B-Sindh Fee: 31000/- Slip # 96436550 | Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani- ro, Ochang-eup, Cheongwon- gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy (original attached in Optical Q, CRP) Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: Original apostilled Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026 | Brand Name: Optical Q HbA1c Reagents Generic Name: Hemoglobin A1c (glycatedhaemoglobin) Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month | Deferred for: Code is not mentioned in the FSC. Clarification is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO- 13485 certificate. |
| 21. | Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e- Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2370-B-Sindh Fee: 31000/- Slip # 8254046051 | Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani- ro, Ochang-eup, Cheongwon- gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy (original attached in Optical Q, CRP) Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: Original apostilled Issue date: 02.10.2024 ISO – Certificate: | Brand Name: Optical Q Ferritin, Detection Buffer Generic Name: Ferritin, Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month | Deferred for: The firm has applied Reagent (Ferritin) and Buffer. The submitted FSC of Korea contains Optical Q, Ferritin only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. |

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| | | Type: photocopy Notarization: No Validity: 28.04.2026 | | Submit notarized copy of valid LOA and ISO-13485 certificate. |
| 22. | Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e-Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2363-B-Sindh Fee: 31000/- Slip # 416934793 | Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: Original Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: No Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026 | Brand Name: Optical Q, Prolactin, Detection Buffer Prolactin Generic Name: Prolactin, Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month | The firm has applied Reagent (Prolactin) and Buffer. The submitted FSC of Korea contains Optical Q, PRL only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The applied product is a strip in the FSC. The firm has applied as kit. Clarification is required. The firm has submitted copy of fee challan meant for various hormones. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO-13485 certificate. |
| 23. | Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e-Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2355-b-Sindh Fee: 31000/- Slip # 416934793 | Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No | Brand Name: Optical Q, FSH, Detection Buffer FSH Generic Name: Follicle stimulating hormone, Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month | Deferred for: The firm has applied Reagent (FSH) and Buffer. The submitted FSC of Korea contains Optical Q, FSH only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The applied product is a strip in the FSC. The |

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| | | <p>Validity: 31.12.2024 FSC Type: photocopy of apostilled certificate (original in Prolactin dossier. Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: No Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026</p> | | <p>firm has applied as kit. Clarification is required. The firm has submitted fee challan meant for various hormones. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO-13485 certificate.</p> |
| 24. | <p>Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e-Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2362-B-Sindh Fee: 31000/- Slip # 416934793</p> | <p>Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy of apostilled certificate (original in Prolactin dossier. Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: No Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026</p> | <p>Brand Name: Optical Q, LH, Detection Buffer LH Generic Name: Luteinizing hormone, Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month</p> | <p>Deferred for: The firm has applied Reagent (LH) and Buffer. The submitted FSC of Korea contains Optical Q, LH only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The applied product is a strip in the FSC. The firm has applied as kit. Clarification is required. The firm has submitted fee challan meant for various hormones. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required.</p> |

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| | | | | <p>Legalized FSC in reference country or notarized CE certificate is required.</p> <p>Submit notarized copy of valid LOA and ISO-13485 certificate.</p> |
| 25. | <p>Global EngiTech, Office Suite 8, First Floor, AL-Sehat Centre, Rafiq Shaheed Road, Off Shahrah-e-Faisal, Karachi ELI-01262 R&I Date: 29.05.2025 2365-B-Sindh Fee: 31000/- Slip # 416934793</p> | <p>Legal Manufacturer: OptiBio Co., Ltd., No. 301, 401, 404, 405, 406, 409, 414, Chungbuk TP Bonbukwan, 76, Yeongudani-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea LOA Type: photocopy of notarized document Notarization: No Validity: 31.12.2024 FSC Type: photocopy of apostilled certificate (original in Prolactin dossier. Issued by: National Institute of Medical Device Safety Information, Seoul, Korea Legalization: No Issue date: 02.10.2024 ISO – Certificate: Type: photocopy Notarization: No Validity: 28.04.2026</p> | <p>Brand Name: Optical Q, beta-hCG, Detection Buffer LH Generic Name: beta human chorionic gonadotropin hormone, Buffer Applied as: Kit Class: B Code/sizes (as per FSC & application): NIL Shelf Life: 24 month</p> | <p>Deferred for: The firm has applied Reagent (LH) and Buffer. The submitted FSC of Korea contains Optical Q, LH only. Clarification is required. Code is not mentioned in the FSC. Clarification is required. The applied product is a strip in the FSC. The firm has applied as kit. Clarification is required. The firm has submitted fee challan meant for various hormones. Original fee challan in respect of the applied product is required. The address of importer in LOA and Application Form shall be the same as in ELI. Declaration on stamp paper to be issued in the name of the firm / signatory is required. Legalized FSC in reference country or notarized CE certificate is required. Submit notarized copy of valid LOA and ISO-13485 certificate.</p> |

AGENDA ITEM II (C):

ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR IMPORT.

Evaluator: Muhammad Ashfaq, Deputy Director (DD-VI)

| S. No. | Name of Applicant(s) | Name of Manufacturer | Medical Device | Decision |
|--------|--|---|---|----------|
| 1. | M/s Mediserve, 4 Canal Park Fountain Corner Near Edhi Homes Gulberg II Lahore. (ELI- 00705) R&I detail 03-02-2025 Fee: 6,000/- Slip: 68902593015 Fee: 20,100/- Slip: 57771484608 | Name of Manufacturer: Leboo Healthcare Product Limited, No. 18 Tiaxian Street, Tianmen Hubei, P.R. China. • LOA Type: Copy of apostilled Attested By: Apostilled Validity: 31-12-2026 • FSC (China) Type: Copy of apostilled Issued By: NMPA Legalization: Apostilled Validity: 23-06-2026 • ISO Certificate Type: Copy Notarization: by CCPIT Validity: 20-10-2026 | Brand name: Leboo Generic Name: Surgical Gown Applied as: Family Class: A Model/Codes/Sizes as Per FSC and application: Standard Surgical Gown: • XS (105cm x 130cm) • S (115cm x 135cm) • M (120cm x 140cm) • L (125cm x 145cm) • XL (130cm x 150cm) • XXL (135cm x 155cm) Shelf life: 3 Years | Approved |
| 2. | M/s Mediserve, 4 Canal Park Fountain Corner Near Edhi Homes Gulberg II Lahore. (ELI- 00705) R&I detail 03-02-2025 Fee: 6,000/- Slip: 656798948497 | Name of Manufacturer: Leboo Healthcare Product Limited, No. 18 Tiaxian Street, Tianmen Hubei, P.R. China. • LOA Type: Copy of apostilled Attested By: Apostilled Validity: 31-12-2026 • FSC (China) Type: Copy of apostilled Issued By: NMPA Legalization: Apostilled Validity: 23-06-2026 • ISO Certificate Type: Copy Notarization: by CCPIT Validity: 20-10-2026 | Brand name: Leboo Generic Name: Mob Cap Applied as: Single Class: A Model/Codes/Sizes as Per FSC and application: N62D01 Shelf life: 3 Years | Approved |
| 3. | M/s Mediserve 4 Canal Park Fountain Corner Near Edhi Homes Gulberg II Lahore. (ELI- 00705) | Name of Manufacturer: Leboo Healthcare Product Limited, No. 18 Tiaxian Street, Tianmen Hubei, P.R. China. • LOA | Brand name: Leboo Generic Name: Surgical Face Mask | Approved |

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| | R&I detail 03-02-2025 Fee: 6,000/- Slip: 62923152 Fee: 20,100/- Slip: 6160865637 | Type: Copy of apostilled Attested By: Apostilled Validity: 31-12-2026 • FSC (China) Type: Copy of apostilled Issued By: NMPA Legalization: Apostilled Validity: 23-06-2026 • ISO Certificate Type: Copy Notarization: by CCPIT Validity: 20-10-2026 | Applied as: Family Class: A Model/Codes/Sizes as Per FSC and application: Surgical Face mask with Ear Loop A (Non-sterile) (17.5cm x 9.5cm, 14.5cm x 9.5cm) Shelf life: 3 Years | |
| 4. | M/s Mediserve 4 Canal Park Fountain Corner Near Edhi Homes Gulberg II Lahore. (ELI- 00705) R&I detail 03-02-2025 Fee: 6,000/- Slip: 18533277567 Fee: 20,100/- Slip: 64951309371 | Name of Manufacturer: Leboo Healthcare Product Limited, No. 18 Tiaxian Street, Tianmen Hubei, P.R. China. • LOA Type: Copy of apostilled Attested By: Apostilled Validity: 31-12-2026 • FSC (China) Type: Copy of apostilled Issued By: NMPA Legalization: Apostilled Validity: 23-06-2026 • ISO Certificate Type: Copy Notarization: by CCPIT Validity: 20-10-2026 | Brand name: Leboo Generic Name: CPE Shoe cover Applied as: Family Class: A Model/Codes/Sizes as Per FSC and application: CPE Shoe Cover Shelf life: 3 Years | Deferred since the applied device has not been mentioned in FSC. Moreover, sizes required have not been mentioned in application. |

AGENDA ITEM II (D): ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURING.

| S. No. | Name of Applicant(s) | Name of Manufacturer | Medical Device | Decision |
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| 1. | Sayyed Healthcare Limited, 37 Allama Iqbal Industrial City, Faisalabad [ELM-0079] Fee: 25000 Fee Slip No. 66689967 | Sayyed Healthcare Limited, 37 Allama Iqbal Industrial City, Faisalabad [ELM-0079] | Healthcare + Disposable Syringe 10cc Class B Model/Size: 10ml (21G x 1.5" TW) Shelf Life: 5 Years | Approved |
| 2. | Sayyed Healthcare Limited, 37 Allama Iqbal Industrial City, Faisalabad [ELM-0079] Fee: 25000 | Sayyed Healthcare Limited, 37 Allama Iqbal Industrial City, Faisalabad [ELM-0079] | Healthcare + Disposable Syringe 1cc Class B Model/Size: 1ml (26G x ½" TW) | Approved |

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| Fee Slip No. 620916212567 | | Shelf Life: 5 Years | |
| Fee: 6000 Fee Slip No. 30637431329 | | | |
| R& I: 16-05-2025 | | | |

Evaluator: Mr. Ammar Ashraf

Agenda Item II (e) Hard Copy Cases

| Sr. No. | Name of Applicant(s) | Name of Manufacturer | Medical Device | |
|---------|--|--|--|----------|
| 1. | M/s. MEDICO INTERNATIONAL, 235-B, B-BLOCK SATELLITE TOWN, RAWALPINDI (ELI-01038) R&I Date: 24-06-2025 Fee: PKR 31,030.00 Slip # 3554830191 | Name of Manufacturer: Shenzhen Fitconn Technology Co., Ltd Address: <ul style="list-style-type: none">7th Floor, No. 116 Xiangshan Road, Luotian community, Songgang Street, Bao'an Shenzhen, Guangdong, P.R.CLOA Type: Original Notarization: Notarized Validity: 20-03-2030FSC Type: Original Issued By: NMPA Legalization: Apostille Validity: 11-05-2027ISO – Certificate: Type: Original Notarization: Notarized Validity: 02-11-2027CE Certificate Type: Original Notarization: Notarized Validity: 15-01-2027 | Brand Name: MEDICO MESH NEBULIZER (MY-135) Generic Name: NEBULIZER Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 1 PCS Shelf Life: 3 YEARS | Approved |
| 2. | M/s. MEDICO INTERNATIONAL, 235-B, B-BLOCK SATELLITE TOWN, RAWALPINDI (ELI-01038) R&I Date: 24-06-2025 Fee: PKR 31,030.00 | Name of Manufacturer: Shenzhen Fitconn Technology Co., Ltd Address: <ul style="list-style-type: none">7th Floor, No. 116 Xiangshan Road, Luotian community, Songgang Street, Bao'an Shenzhen, Guangdong, P.R.CLOA Type: Original Notarization: Notarized | Brand Name: MEDICO MESH NEBULIZER (MY-135) Generic Name: NEBULIZER Applied as: Single Class: B Models/Code/sizes (as per FSC & application) 1 PCS Shelf Life: 3 YEARS | Approved |

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| | Slip # 02295281778 | Validity: 20-03-2030 <ul style="list-style-type: none"> • FSC Type: Original Issued By: NMPA Legalization: Apostille Validity: 11-05-2027 • ISO – Certificate: Type: Original Notarization: Notarized Validity: 02-11-2027 • CE Certificate Type: Original Notarization: Notarized Validity: 15-01-2027 | | |
| 3. | Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 04-07-2025 Fee: 6030/- Slip # 4087594889 Differential Fee: 330/- Slip # 983046178 | M/s: Wuxi Exanovo Medical Instrument Co., Ltd Manufacturing Site Address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi 214194 Jiangsu P.R. China. LOA Type: Copy Notarization: Yes Validity: 05-04-2030 <ul style="list-style-type: none"> • FSC Type: Original Legalization: Apostille Issued by: Jiangsu Medical Product Administration Validity: 26-03-2027 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 21-10-2026 CE certificate: | Brand Name: Metro Aneroid Sphygmomanometer Generic Name: Aneroid Sphygmomanometer Applied as: Single Class: A Models/Code/sizes: MC-20-(50) Shelf Life: 5 Years | Approved |
| 4. | Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 04-07-2025 Fee Rs. 6,000/- Slip # 30172546461 | M/s: Wuxi Exanovo Medical Instrument Co., Ltd Manufacturing Site Address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi 214194 Jiangsu P.R. China. LOA Type: Original Notarization: Yes Validity: 05-04-2030 <ul style="list-style-type: none"> • FSC Type: Original Legalization: Apostille | Brand Name: Metro Stethoscope Generic Name: Stethoscope Applied as: Single Class: A Models/Code/sizes: MC-230 MC-220 Shelf Life: 5 Years | Approved. Firm is advised to select one model before issuance of enlistment certificate |

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| | | Issued by: Jiangsu Medical Product Administration Validity: 31-03-2027 • ISO – Certificate: Type: Original Notarization: Yes Validity: 21-10-2026 CE certificate: N/A | | |
| 5. | Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 17-07-2025 Fee: 31030/- Slip # 5018230514 | M/s: Huaian Angel Medical Instrument Co Ltd. Manufacturing Site Address: No. 19 East Zhuhai Road Huaian Jiangsu P.R. China. LOA Type: Copy Notarization: Yes Validity: 23-12-2029 • FSC Type: Copy Legalization: Apostille Issued by: CCMHPIE Validity: 18-12-2026 • ISO – Certificate: Type: Copy Notarization: Yes Validity: 26-04-2025 CE certificate: N/A | Brand Name: Metro Umbilical Cord Clamp Generic Name: Umbilical Cord Clamp Applied as: Single Class: B Models/Code/sizes: -- Shelf Life: 5 years | Deferred for following: <i>Valid notarized copy of ISO certificate shall be submitted.</i> <i>Original legalized FSC issued by the relevant regulatory authority of country of origin shall be submitted.</i> |
| 6. | Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676) R&I Date: 17-07-2025 Fee: 31030/- Slip # 47255990434 | M/s: Huaian Angel Medical Instrument Co Ltd. Manufacturing Site Address: No. 19 East Zhuhai Road Huaian Jiangsu P.R. China. LOA Type: Original Notarization: Yes Validity: 23-12-2029 • FSC Type: Original Legalization: Apostille Issued by: CCMHPIE Validity: 18-12-2026 • ISO – Certificate: Type: Original Notarization: Yes Validity: 26-04-2025 CE certificate: Notarized Quality Assurance certificate submitted | Brand Name: Metro Sterile Surgical Blade Generic Name: Sterile Surgical Blade Applied as: Single Class: B Models/Code/sizes: 9, 10, 11, 12, 13,14,15,16,18,19,20,21,22,2 3,24,25,26,27,34,36 Shelf Life: 5 years | Deferred for following: <i>Valid notarized copy of ISO certificate shall be submitted.</i> <i>Original legalized FSC issued by the relevant regulatory authority of country of origin shall be submitted along with differential fee for applying family of different sizes</i> |

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| 7. | <p>Sohail Corporation Address: Plot no 7, SR-5 Serai Quarters, Techno City, Warehouse No 42, Karachi-Pakistan. (ELI-00676)</p> <p>R&I Date: 17-07-2025 Fee: 31030/- Slip # 19544972</p> | <p>M/s: Huaian Angel Medical Instrument Co Ltd. Manufacturing Site Address: No. 19 East Zhuhai Road Huaian Jiangsu P.R. China.</p> <p>LOA Type: Original Notarization: Yes Validity: 23-12-2029</p> <p>• FSC Type: Copy Legalization: Apostille Issued by: CCMHPIE Validity: 18-12-2026</p> <p>• ISO – Certificate: Type: Original Notarization: Yes Validity: 26-04-2025 CE certificate: Notarized Quality Assurance certificate submitted</p> | <p>Brand Name: Metro Sterile Blood Lancet Generic Name: Sterile Blood Lancet</p> <p>Applied as: Single Class: B Models/Code/sizes: (as per FSC & Product Brochures)</p> <p>Shelf Life: 5 years</p> | <p>Deferred for following: <i>Valid notarized copy of ISO certificate shall be submitted.</i></p> <p><i>Original legalized FSC issued by the relevant regulatory authority of country of origin shall be submitted along with details of intended model/size</i></p> |
| 8. | <p>M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahr-e-Faisal, Karachi (ELI-00160)</p> <p>R&I Date: 10-07-2025 Fee: 62,000/- Slip # 017472652090</p> | <p>Name of Manufacturer: Legal Manufacturer: Shenzhen Ever-Blue Biotech Co., Ltd, Address: Building 1, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong</p> <p>Manufacturing Site: SHENZHEN YHLO BIOTECH CO., LTD. Address: Building 2, YHLO Biopark, Baolong 2nd Road, Baolong Subdistrict, Longgang District, Shenzhen, Guangdong 518116 China</p> <p>LOA Type: Copy Notarization: No Validity: 31-12-2025</p> <p>• FSC Type: Copy Issued By: China Chamber of International Commerce (Country of Origin) RRA FSC issued by Australian Government (TGA)</p> | <p>Brand Name: M. Pneumoniae IgG & IgM Control</p> <p>Generic Name: Immunoassay Controls • M. Pneumoniae IgG Control (Negative: 2×2.0ml) (Positive: 2×2.0ml) • M. Pneumoniae IgM Control (Negative: 2×2.0ml) (Positive: 2×2.0ml)</p> <p>Applied as: Kit Class: C</p> <p>Models/Code/sizes (as per FSC & application): M. Pneumoniae IgG Control: CC847 M. Pneumoniae IgM Control: CC848</p> <p>Shelf Life: M. Pneumoniae IgG Control: 48 Months</p> | Approved |

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| | | Legalization: No Validity: 20-12-2026 (Country of Origin FSC) Date of Issue: 21-01-2025 (RRA FSC) • ISO – Certificate: Type: Copy Notarization: No Validity: 14-11-2025 CE certificate: N/A | M. Pneumoniae IgM Control: 48 Months | |
| 9. | M/s Intra Health, 56A, Unit No. 1, Justice Inamullah Road, Block 7/8, KCHS - Karachi ELI-00049 R&I Date: 30-05-2025 Fee: 6,000/- | Name of Manufacturer: Prime Medical Inc. Address: 335 Namyang-ro, Namyang-eup, Hwaseong-si, Gyeonggi-do, South Korea LOA Type: Copy Notarization: Notarized Validity: 23-01-2030 • FSC Type: Original Legalized: Apostille Issued by: National Institute of Medical Device Safety Information, Korea Issue date: 25-07-2025 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 11-09-2027 EU MDR Certificate Issued dated 01-03-2024 | Brand Name: Prime Splint Generic Name: Splint General purpose Applied as: Single Class: A Models/Code/sizes (as per FSC & application): PrimeSplint F21 0 (5cm x 25cm) PrimeSplintF335 (7.5cm x 90cm) PrimeSplint F430 (10.0cm x 76cm) PrimeSplint F545 (12.5cm x 115cm) ,, PrimeSplint P312 (7.5cm x 30cm) PrimeSplint P415 (1 0cm x 40cm) PrimeSplint P530 (12.5cm x 76cm) PrimeSplint R002 (5.0cm • 4.Sm) PrimeSplint R004 (1 0.2cm • 4.Sm) PrimeSplint R006 (15.2cm • 4.Sm) PrimeSplint F312 (7.5cm x 30cm) PrimeSplint F415 (10.0cm x 40cm) PrimeSplint F530 (12.5cm x 76cm) PrimeSplint P21 0 (5cm x 2 5cm) | Approved |

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| | | | PrimeSplint P335 (7.5cm x 90cm) PrimeSplint P430 (1 0cm x 76cm) PrimeSplint P545 (1 2.5cm x 115cm) PrimeSplint R003 (7.6cm • 4.Srn) PrimeSplint ROOS (12.7cm • 4.Sm) Shelf Life: 3 Years | |
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Agenda Item II (f) CMS Cases

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| 10. | M/s Bright Vision Suit No 103, 1st Floor, Fine Centre Commercial Block V Gulshan-e-Iqbal Karachi (ELI-00474) R&I Date: 03-09-2021 CMS tracking ID: 5D7-2J2-3WRU Fee: 25,000/- | Name of Manufacturer: Shenzhen GLD Biotechnology Ltd.. Address: 25 Bldg., MeiBao Industrial Zone, Lian Tang Industrial City, ShangCun Village, GongMing Town, Gunagming District Shenzhen PR China LOA Type: Copy Notarization: Yes Validity date: 07-03-2024 • FSC Type: Copy Issued By: Provincial Drug Administration Legalization: Legalized Validity: 14-04-2022 • ISO – Certificate: Type: Not submitted Notarization: -- Validity: -- CE certificate: Not submitted | Brand Name: 1 Answer Ovulation Test Generic Name: Ovulation LH Test Applied as: Single Class: B Models/Code/sizes (as per FSC & application: 1pcs/pouch, 1pcs/box,2pcs/box,3pcs/box,5pcs/box,6pcs/box, 7pcs/box, 10pcs/box,12pcs/box,15ps/box,20pcs/box,25pcs/box,30pcs/box,50pcs/box,100 pcs / box. Shelf Life: 2 years | Deferred for following: <i>Valid FSC, LOA shall be submitted. Valid ISO & CE certificates shall be submitted</i> |
| 11. | M/s Bright Vision Suit No 103, 1st Floor, Fine Centre Commercial Block V Gulshan-e-Iqbal Karachi (ELI-00474) R&I Date: 03-09-2021 | Name of Manufacturer: Shenzhen GLD Biotechnology Ltd.. Address: 25 Bldg., MeiBao Industrial Zone, Lian Tang Industrial City, ShangCun Village, GongMing Town, Gunagming District Shenzhen PR China LOA | Brand Name: 1 Answer Midstream Pregnancy Test Generic Name: Pregnancy HCG Test Applied as: Single Class: B | Deferred for following: <i>Valid FSC, LOA shall be submitted. Valid ISO & CE certificates shall be submitted</i> |

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| | CMS tracking ID: XZH-JUM-ZDVW Fee: 25,000/- | Type: Copy Notarization: Yes Validity date: 07-03-2024 • FSC Type: Copy Issued By: Provincial Drug Administration Legalization: Legalized Validity: 14-04-2022 • ISO – Certificate: Type: Not submitted Notarization: -- Validity: -- CE certificate: Not submitted | Models/Code/sizes (as per FSC & application): 25 pcs/plastic drum, 50 pic/plastic drum, 1 pcs/pouch, 1pcs/box, 2pcs/box, 3pcs/bo, 5pcs/box, 6pcs/box, 7pcs/box, 10p cs/box, 12pcs/box, 15pcs/box, 20pcs/box, 25pcs/box, 30pcs/box, 50pcs/box, 100pcs/box Shelf Life: 2 years | |
| 12. | M/s Bright Vision Suit No 103, 1st Floor, Fine Centre Commercial Block V Gulshan-e-Iqbal Karachi (ELI-00474) R&I Date: 03-09-2021 CMS tracking ID: GPP-S4Q-5EQE Fee: 25,000/- | Name of Manufacturer: Shenzhen GLD Biotechnology Ltd.. Address: 25 Bldg., MeiBao Industrial Zone, Lian Tang Industrial City, ShangCun Village, GongMing Town, Gunagming District Shenzhen PR China LOA Type: Copy Notarization: Yes Validity date: 07-03-2024 • FSC Type: Copy Issued By: Provincial Drug Administration Legalization: Legalized Validity: 14-04-2022 • ISO – Certificate: Type: Not submitted Notarization: -- Validity: -- CE certificate: Not submitted | Brand Name: 1 Answer Pregnancy Rapid Test Strip Generic Name: Pregnancy HCG Test Applied as: Family Class: B Models/Code/sizes (as per FSC & application): 1 pc/pack 25pc/pack Shelf Life: 2 years | Deferred for following: <i>Valid FSC, LOA shall be submitted. Valid ISO & CE certificates shall be submitted</i> |
| 13. | M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 10-12-2020 CMS tracking ID: M85-Z8M-BT7U Fee: 5,000/- | Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Diatron MI Plc Address: Tablas Str. 39 Budapest, Hungary H1097 LOA Type: No | Brand Name: ADVIA 360 Hematology System Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application): 11170841 | Deferred for following: <i>Clarification shall be submitted for the intended product as Class A. CE certificate shall be submitted.</i> |

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| | | Validity date: 16-01-2026 • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 04-06-2024 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A | Shelf Life: N/A | Valid legalized FSC shall be submitted |
| 14. | M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 14-06-2021 CMS tracking ID: QZ8-Z9Y-JGDM Fee: 5,000/- | Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Diatron MI Plc Address: Tablas Str. 39 Budapest, Hungary H1097 LOA Type: Original Notarization: No Validity date: 16-01-2026 • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 04-06-2024 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A | Brand Name: ADVIA 560 Hematology System Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application): 11170842 Shelf Life: N/A | Deferred for following: <i>Clarification shall be submitted for the intended product as Class A.</i> <i>CE certificate shall be submitted. Valid legalized FSC shall be submitted</i> |
| 15. | M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 14-01-2021 CMS tracking ID: T93-Y42-HUWY Fee: 5,000/- | Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: Chapel Lane Swords, Co. Dublin, Ireland LOA Type: Original Notarization: No Validity date: 16-01-2026 | Brand Name: Advia 2120i Hematology System with its accessories Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application): 11219531: ADVIA 2120i without Autosampler | Deferred for following: <i>Clarification shall be submitted for the intended product as Class A.</i> <i>CE certificate shall be submitted.</i> |

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| | | <ul style="list-style-type: none"> • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 20-11-2024 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 <p>CE certificate: N/A</p> | 10488923: ADVIA 2120i with SAA Autosampler Instrument 11219529: ADVIA 2120i with DAA Autosampler 11170843: ADVIA Autoloader Shelf Life: N/A | |
| 16. | M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 10-12-2020 CMS tracking ID: V7H-HLB-7LDE Fee: 5,000/- | Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: INPECO SA Address: Inpeco S.p.a Production Plant in Via Givoletto 15-10040 -Val Della Torre (TO)-Italy LOA Type: No Validity date: 16-01-2026 <ul style="list-style-type: none"> • FSC Type: Original Issued By: US FDA Legalization: Apostille Valid: 12-01-2027 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 <p>CE certificate: N/A</p> | Brand Name: Aptio® Automation System with its Accessories Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application): 1701360 Shelf Life: N/A | Deferred for following: <i>Clarification shall be submitted for applying the intended product as Class A.</i> <i>CE certificate shall be submitted along with details of the function of each constituent part</i> |
| 17. | M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 28-04-2021 CMS tracking ID: NV7-72A-4V3D Fee: 5,000/- | Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: 62 Flanders-Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 16-01-2026 | Brand Name: Atellica CH 930 Analyzer Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application): 11067000 Shelf Life: N/A | Deferred for following: <i>The submitted FSC declares that the applied product can be marketed in Ireland till May, hence afresh valid FSC shall be submitted</i> <i>Clarification, hence shall be submitted for</i> |

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| | | <ul style="list-style-type: none"> • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 22-05-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 <p>CE certificate: N/A</p> | | <p><i>applying the intended product as Class A.</i></p> <p><i>CE certificate shall be submitted.</i></p> |
| 18. | <p>M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 14-01-2021 CMS tracking ID: D1D-NHJ-MVNY Fee: 5,000/-</p> | <p>Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd. Address: 62 Flanders-Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 12-05-2025</p> <ul style="list-style-type: none"> • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 22-05-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 <p>CE certificate: N/A</p> | <p>Brand Name: Atellica IM 1600 & Atellica IM 1300 Analyzer with its Accessories Generic Name: N/A Applied as: System Class: A</p> <p>Models/Code/sizes (as per FSC & application): 11066000 11066001 Accessories: 1106900I SH Prime 11069004 SH Additional 11068008 Atellica DL Shelf Life: N/A</p> | <p>Deferred for following: <i>The submitted FSC declares that the applied product can be marketed in Ireland till May, hence afresh valid FSC shall be submitted</i></p> <p><i>Clarification, hence shall be submitted for applying the intended product as Class A.</i></p> <p><i>Valid Notarized LOA shall be submitted</i> <i>Justification shall be submitted for applying two different analyzers in same application.</i></p> <p><i>CE certificate shall be submitted.</i></p> |
| 19. | <p>M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 14-01-2021</p> | <p>Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Eurotrol B.V,</p> | <p>Brand Name: EPOC Reader & Power Supply & EPOC Host, RX, INT'L Generic Name: N/A Applied as: System</p> | <p>Deferred for following: <i>The scope of submitted ISO certificate does not include the manufacturing site.</i></p> |

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| | CMS tracking ID: LU2-9J7-GZG7 Fee: 5,000/- | Address: Keplerlaan 20 6716BS Ede Netherlands LOA Type: Original Notarization: No Validity date: 16-01-2026 • FSC Type: Original Issued By: HPRA of Ireland Legalization: Apostille Issued: 03-04-2024 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027 CE certificate: N/A | Class: A Models/Code/sizes (as per FSC & application): 10736398 10736420 Shelf Life: N/A | Clarification <i>shall be submitted for the intended product as Class A.</i> <i>The submitted FSC identifies the applied product with different names and product code while the applicant has applied several products in single application. Clarification shall be submitted for applying different</i> <i>The description of each device applied shall be submitted with intended use and role for the accessories.</i> <i>CE certificate shall be submitted.</i> |
| 20. | M/s Hoorra Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 14-01-2021 CMS tracking ID: XEV-5BD-ZJ5V Fee: 5,000/- | Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd Address: Emil-Von -Behring - Str.76 35041 Marburg, Germany LOA Type: Original Notarization: No Validity date: 16-01-2026 • FSC Type: Original | Brand Name: Hematek 3000 Generic Name: N/A Applied as: System Class: A Models/Code/sizes (as per FSC & application): 10805311 System Accessories 10316256 Hematek Cannula Set 10323320 Hematek Under Platen Tubing | <i>Deferred for following:</i> <i>The description and role of the each accessory item shall be submitted. Clarification shall be submitted whether the applied accessories are exclusive for the applied product or not.</i> |

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| | | <p>Issued By: German Authority Legalization: legalized Issued: 27-12-2024</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027</p> <p>CE certificate: N/A</p> | <p>10285244 Hematek PCB AS 10312656 Hematek Pump T 10323320 Hematek Under 10327149 Fan Assy</p> <p>Shelf Life: N/A</p> | <p><i>CE certificate shall be submitted.</i></p> <p><i>Clarification shall be submitted for the intended product as Class A.</i></p> |
| 21. | <p>M/s Hoorra Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 14-01-2021 CMS tracking ID: PUQ-JSY-ABPE Fee: 5,000/-</p> | <p>Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd Address: 62 Flanders-Bartley Road Flanders, NJ, 07836, USA LOA Type: Original Notarization: No Validity date: 16-01-2026</p> <p>• FSC Type: Original Issued By: HPRA of Ireland Legalization: legalized Issued: 22-05-2023</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027</p> <p>CE certificate: N/A</p> | <p>Brand Name: Immulite 2000 Xpi Immunoassay System & Immulite 2000 Immunoassay System Along with accessories Generic Name: N/A Applied as: System</p> <p>Class: A</p> <p>Models/Code/sizes (as per FSC & application): 10373214 10380062</p> <p>System Accessories 10374179 Immulite 2000 Nesting Cups 2mL 10374178 Immulite 2000 Nesting Cups 1mL for 12-mm and 13-mm sample tubes</p> <p>Shelf Life: N/A</p> | <p><i>Deferred for following: The submitted FSC declares that the applied product can be marketed in Ireland till May, hence afresh valid FSC shall be submitted</i></p> <p><i>The submitted FSC identifies each product separately while the applicant has applied two systems in one application.</i></p> <p><i>The description and role of the each accessory item shall be submitted. Clarification shall be submitted whether the applied accessories are exclusive for the applied product or not.</i></p> <p><i>CE certificate shall be submitted.</i></p> |

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| | | | | <i>Clarification shall be submitted for the intended product as Class A.</i> |
| 22. | <p>M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 10-12-2020 CMS tracking ID: REX-36U-GZAD Fee: 5,000/-</p> | <p>Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd Address: Northern Road, Chilton Industrial Sudbury, Suffolk CO10 2XQ, UK LOA Type: Original Notarization: No Validity date: 16-01-2026</p> <p>• FSC Type: Original Issued By: HPRA of Ireland Legalization: legalized Issued: 17-05-2023</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027</p> <p>CE certificate: N/A</p> | <p>Brand Name: RAPID Point® 500e Blood Gas System, RP500 BLOOD GAS ANALYSER, & RAPID Point 500 System & Immolute 2000 Immunoassay System Along with accessories Generic Name: N/A</p> <p>Applied as: System</p> <p>Class: A</p> <p>Models/Code/sizes (as per FSC & application): 11416751 11416752 11416754 11416755 10492730 10696855 10697306</p> <p>System Accessories 11416778 2D Barcode scanner kit 11317626 Holder, barcode scanner 10629576 RAPID Point 500 USB flash drive 10320798 Fuse Pack 10329097 Wash/Waste Cartridge (4) 10341179 Wash/Waste Cartridge (1) 10323407 Sample port/capillary kit 10322638 Air Filter 10702063 CO-ox Lamp</p> <p>Shelf Life:</p> | <p><i>Deferred for following: The submitted FSC identifies each product separately while the applicant has applied two systems in one application.</i></p> <p><i>The description and role of the each accessory item shall be submitted. Clarification shall be submitted whether the applied accessories are exclusive for the applied product or not.</i></p> <p><i>CE certificate shall be submitted.</i></p> <p><i>Clarification shall be submitted for the intended product as Class A.</i></p> |

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| | | | N/A | |
| 23. ` | <p>M/s Hoorra Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 28-04-2021 CMS tracking ID: 61Q-V89-5T8X Fee: 5,000/-</p> | <p>Name of Manufacturer: Legal Manufacturer: Siemens Healthcare Diagnostics Inc. Address: 511 Benedict Ave. Tarrytown, NY 10591, USA Manufacturing Site: Name: Siemens Healthcare Diagnostics Manufacturing Ltd Address: Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ U.K LOA Type: Original Notarization: No Validity date: 16-01-2026</p> <p>• FSC Type: Original Issued By: HPRA of Ireland Legalization: legalized Issued: 17-05-2023</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Validity: 31-12-2027</p> <p>CE certificate: N/A</p> | <p>Brand Name: Rapid lab 348EX Blood Gas Analyzer with its consumables. Generic Name: N/A</p> <p>Applied as: System</p> <p>Class: A</p> <p>Models/Code/sizes (as per FSC & application): 10844678 10697818 System Accessories 10309775 Deproteinizer 10311078 Conditioner 10844682 RAPIDLab 348EX Ca++ Starter Kit 10844683 RAPIDLab 348EX CI-Starter Kit 10844684 RAPIDLab 348EX Starter Kit Blood Gas Only 11046804 RAPID R Lab 348EX Software Upgrade Kit 10311662 Sample & Reagent Pump Tubing Kit Shelf Life: N/A</p> | <p><i>Deferred for following: The submitted FSC identifies each product separately while the applicant has applied two systems in one application.</i></p> <p><i>The description and role of the each accessory item shall be submitted. Clarification shall be submitted whether the applied accessories are exclusive for the applied product or not.</i></p> <p><i>CE certificate shall be submitted.</i></p> <p><i>Clarification shall be submitted for applying the intended product as Class A.</i></p> |
| 24. | <p>M/s Hoorra Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 12-09-2022 CMS tracking ID: 1ET-38B-DQN3 Fee: 50,000/-</p> | <p>Name of Manufacturer: Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado, 80215 USA Manufacturing Site: Name: Terumo BCT Ltd. Address: Old Belfast Road Millbrook Larnie BT40 2SH, United Kingdom LOA Type: Copy Notarization: Yes Issue date: 02-09-2022</p> | <p>Brand Name: Anticoagulant Citrate Dextrose Ph Eur (ACD) Solution A (ACD-A) Generic Name: Anticoagulant Citrate Dextrose Applied as: System</p> <p>Class: A</p> <p>Models/Code/sizes (as per FSC & application): Codes: 40814 40801 Sizes: 12x750ml units/pack</p> | <p>Approved</p> |

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| | | <ul style="list-style-type: none"> • FSC Type: Original Issued By: MHRA of UK Legalization: Apostille Validity: 01-03-2027 • ISO – Certificate: Type: Copy Notarization: Notarized Validity: 04-03-2026 CE certificate: Date of Issue: 04-09 2023 Date OF Expiry 01-03- 2026 | 18x 500ml unis/pack 500ml/pack 750ml/pack Shelf Life: 2 years | |
| 25. | M/s Hoorra Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 12-09-2022 CMS tracking ID: AUE-S1E-TYT1 Fee: 50,000/- | Name of Manufacturer: Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 <ul style="list-style-type: none"> • FSC Type: Original Issued By: US FDA Legalization: Apostille Validity: 19-05-2026 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till 21.04.28 CE certificate: Date of Issue: 04-09 2023 Date OF Expiry 01-03- 2026. | Brand Name: Trima Accel ® Automated Blood collection System Generic Name: utomated Blood collection System Applied as: Single Class: C Models/Code/sizes (as per FSC & application): 81000 Shelf Life: N/A | Approved |
| 26. | M/s Hoorra Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037) R&I Date: 19-08-2024 CMS tracking ID: SPX-D45-NDPB Fee: 50,000/- | Name of Manufacturer: Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado,80215 USA Manufacturing Site: FB Manufacturing SRL Address: Calle 58, Zona Franca la lima, Planta de Terumo BCT Calle Duan y Avendia Turrialba La | Brand Name: Spectra Optia® Collection Set (10120, 12120) Generic Name: Collection Set Applied as: Single Class: C Models/Code/sizes (as per FSC & application): 10120, 12120 | Approved |

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| | | <p>Lima, Guadalupe 3106, Cartago, Costa Ric</p> <p>LOA Type: Copy Notarization: Yes Issue date: 02-09-2022</p> <p>• FSC FSC (APOSTILE) (Australia) Certificate Number: 22/093 Date of issue: 4th- April 2022 Valid for: not provided Country of origin: FSC (APOSTILE) (Costa Rica) Certificate Number: N/a Date of issue: N/a Valid for: 17-02-2027</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Valid till 06-12-2027 Issuance date 07-12-2024 CE certificate: Date of Issue: 04-09- 2023 Date of Expiry: 01-03- 2026</p> | <p>Shelf Life: N/A</p> | |
| 27. | <p>M/s Hoora Pharma (Pvt.) Ltd. WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi. (ELI-00037)</p> <p>R&I Date: 11-07-2023 CMS tracking ID: 5AN-41U-T2QH Fee: 50,000/-</p> | <p>Name of Manufacturer: Legal Manufacturer: Terumo BCT, Inc Address: 10811 West Collins Avenue, Lakewood, Colorado, 80215 USA Manufacturing Site: Terumo BCT Vietnam Co., Ltd, Address: Long Duc Industrial Park, Long Duc Commune, Long Thanh District, Dong Nai Province, Vietnam LOA Type: Copy Notarization: Yes Issue date: 02-09-2022</p> <p>• FSC Issued by: FAMHP of Belgium Date of issue: 22-06-2022 Valid for: not provided Country of origin: FSC (APOSTILE) (Costa Rica) Certificate Number: N/a Date of issue: N/a Valid for: 17-02-2027</p> <p>• ISO – Certificate:</p> | <p>Brand Name: Platelet Pooling Set (41910) and Reveos Platelet Pooling Set (41940)) Generic Name: Blood Transfer Set Applied as: Family Class: C Models/Code/sizes (as per FSC & application): 41910 41940 Shelf Life: 2 years</p> | Approved |

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| | | Type: Copy Notarization: Notarized Valid till 04-03-2026 CE certificate: N/A | | |
| 28. | M/S Medi Health Services Address: 1 st Floor, 16/E, Mehta Street, Temple Road, Lahore (ELI-00180) R&I Date: 26th July, 2022 CMS tracking ID: 52T-J5A-SAZ2 Fee: 25,000/- | Name of Manufacturer: Name: Bioland Technology Ltd. Address: No. A6B7, Block G, Shang Rong Industrial Park, Boalong 5th Road, Long Gang, 518116, Shenzhen, China LOA Type: Copy Notarization: Apostille Issue date: 11-10-2029 • FSC Type: Copy Legalized: Yes Issued by: Provincial Supervision Body Valid for: 02-09-2026 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-01-2027 CE certificate: Valid till 31-12- 2028 | Brand Name: Fast Lab (Model: 2008) Generic Name: Blood Pressure Monitor Applied as: Set Class: B Models/Code/sizes (as per FSC & application: 41910 41940 Shelf Life: 6 years | Approved |
| 29. | M/S Talha Enterprises Address: 67/E, Jami Commercial Street#7, DHA phase VII (ELI-00925) R&I Date: 21-01-2025 CMS tracking ID: E8B-GVU-WP5L Fee: 50,000/- | Name of Manufacturer: Name: Beijing ZKSK Technology Co., Ltd Address: Building 9,6&No.6 yuan Hengye North 7th Street, Yongle Economic Development Zone, Tongzhou District, Beijing 101105, China LOA Type: Copy Notarization: Yes Issue date: 02-09-2022 • FSC Type: Copy Legalized: Apostille Issued by: Provincial Supervision Body Valid for: 31-03-2028 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 05-01-2028 CE certificate: Valid till 31-12- 2028 | Brand Name: ZKSK Generic Name: Disposable Pulse Lavag Applied as: Family Class: B Models/Code/sizes (as per FSC & application: • EP18-01 • EP 18-02 • EP 18-03 Shelf Life: 6 years | Approved |
| 30. | M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, | Name of Manufacturer: Legal Manufacturer: Diagnostic Stago S.A.S. Address: | Brand Name: PTT LA Generic Name: IVD Test Kit (6 x 2ml) Applied as: Kit | Approved |

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| | Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 R&I Date: 04-04-2025 CMS tracking ID: 3HN-QJY-LJGR Fee: 31,000/- | 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. Address: 23-29 Rue Constantin Pecqueur ZAC "Les Châtaigners" 95150 Taverny, France LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Legalized Issued by: France Valid for: 24-05-2024 • ISO – Certificate: Type: Copy Notarization: No Valid till: 23-05-2028 CE certificate: Endorsed in FSC | Class: B Models/Code/sizes (as per FSC & application): 00599 Shelf Life: 2 years (2 - 8°C) | |
| 31. | M/s Martin Dow Specialties (Pvt) Limited 7th Floor, Nice Trade Orbit Building, 44-A&B, Block-6, PECHS, Razi Road, Shahrah-e-Faisal, Karachi ELI-00160 R&I Date: 14-04-2025 CMS tracking ID: JPS-B7D-9E82 Fee: 62,000/- | Name of Manufacturer: Legal Manufacturer: Diagnostic Stago S.A.S. Address: 3 Allée Thérés - 92600 Asnières sur Seine France Manufacturing Site: DIAGNOSTICA STAGO S.A.S. Address: 125, 131 Avenue Louis Roche 92230 Gennevilliers FRANCE LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Legalized Issued by: France Valid for: 24-05-2024 • ISO – Certificate: Type: Copy Notarization: No Valid till: 23-05-2028 CE certificate: Valid till 25-04-2027 | Brand Name: CK Prest 2 Generic Name: 6 x 2-ml Vials of Reagent 1 (C.K. Prest® 2) 6 x 2-ml Vials of Reagent 2 (Activator) Applied as: Kit Class: C Models/Code/sizes (as per FSC & application): 00598 Shelf Life: 2 years (2 - 8°C) | Approved |
| 32. | M/s Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot # | Name of Manufacturer: Legal Manufacturer: Shenzhen Antmed Co., Ltd. | Brand Name: ANTMED Generic Name: | Approved. Firm is advised to |

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| | 5, Block-6, Gulshan-e-Iqbal Karachi ELI-00691 R&I Date: 22-04-2025 CMS tracking ID: 3M5-GJA-UEAS Fee: 62,000/- | Address: 18 Jinhui Ave., Pingshan New District, Shenzhen 518122, China Manufacturing Site: Shenzhen Antmed Co., Ltd Address: No.3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Type: Copy Notarization: Yes Issue date: 16-02-2030 • FSC Type: Copy Legalized: Apostille Issued by: Provincial Supervision Body Valid for: 26-10-2025 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 30-10-2026 CE certificate: Valid till 05-02-2029 | Disposable Pressure Transducer Applied as: Single Class: C Models/Code/sizes (as per FSC & application): PT-01, PT-012, PT013, PT-02, PT-022, PT-023, PT-03, PT032, PT-033 Shelf Life: 5 years | select one model for issuance of enlistment letter. |
| 33. | M/s Royal Medical Office No. 26th, 3rd Floor United Trade Center Plot # 5, Block-6, Gulshan-e-Iqbal Karachi ELI-00691 R&I Date: 22-04-2025 CMS tracking ID: TH7-7PG-DVXV Fee: 31,000/- | Name of Manufacturer: Legal Manufacturer: Shenzhen Antmed Co., Ltd. Address: 18 Jinhui Ave., Pingshan New District, Shenzhen 518122, China Manufacturing Site: Shenzhen Antmed Co., Ltd Address: No.3 Hualian Ave, Songshanhu District 523800 Dongguan LOA Type: Copy Notarization: Yes Issue date: 16-02-2030 • FSC Type: Copy Legalized: Notarized Issued by: Provincial Supervision Body Valid for: 26-10-2025 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 30-10-2026 CE certificate: Valid till 05-02-2029 | Brand Name: ANTMED Generic Name: Manifold Applied as: Single Class: B Models/Code/sizes (as per FSC & application): MD-M-1, MD-M-2, MD-M-3, MD-M4, MD-L-1, MD-L-2, MD-L-3, MD-L-4 Shelf Life: 3 years | Approved. Firm is advised to select one model for issuance of enlistment letter. |
| 34. | M/S POPULAR INTERNATIONAL PVT LTD | Name of Manufacturer: HUMAN Gesellschaft für Biochemica und Diagnostica mbH | Brand Name: HUMASCOPE Generic Name: | Deferred for following: |

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| | ELI-00091 R&I Date: 30-06-2025 CMS tracking ID: 522-W3L-5MZ7 Fee: 6,000/- | Address: Max-PlanckRing 21, 65205 Wiesbaden, Germany LOA Type: Copy Notarization: Yes Issue date: 16-02-2030 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Valid for: N/A • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 11-03-2028 CE certificate: Valid till 26-05-2025 | Microscopic System Applied as: Kit Class: B Models/Code/sizes (as per FSC & application): 14400, 14500, 14600, 14601, 14700, 14701, 14800, 14801, 14802, 14803, 14804, 14900, 14901, 14000/210, 14000/866, 14000/867, 14000/877, 14000/878, 14804 Shelf Life: N/A | <i>The submitted FSC does not include the name of the applied product Clarification shall be submitted for applying different models within same application as a kit.</i> |
| 35. | M/S POPULAR INTERNATIONAL PVT LTD ELI-00091 R&I Date: 30-06-2025 CMS tracking ID: UH2-698-7HW5 Fee: 6,000/- | Name of Manufacturer: HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Address: Max-PlanckRing 21, 65205 Wiesbaden, Germany LOA Type: Copy Notarization: Yes Issue date: 31-12-2029 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Valid for: N/A • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 11-03-2028 CE certificate: Valid till 26-05-2025 | Brand Name: HUMANEX A1C VARIANT Generic Name: Glycated Haemoglobin Monitoring System Applied as: Kit Class: A Models/Code/sizes (as per FSC & application): 16199, 16180, 16185, 16187, 16189, 16195, 16197, 16190, 16190/10 Shelf Life: N/A | <i>Deferred for following: Justification shall be submitted for applying the intended product as Class A Product. Clarification shall be submitted for the list of constituents along with the applied product and their role. Declaration regarding the exclusivity of the constituents with the intended product is required.</i> |
| 36. | M/S POPULAR INTERNATIONAL PVT LTD ELI-00091 R&I Date: 13-06-2025 CMS tracking ID: | Name of Manufacturer: HUMAN Gesellschaft fur Biochemica und Diagnostica mbH Address: Max-PlanckRing 21, 65205 Wiesbaden, Germany LOA | Brand Name: HUMAMETER A1C Generic Name: Glycated Haemoglobin Monitoring System Applied as: Kit | <i>Deferred for following: Justification shall be submitted for applying the intended</i> |

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| | MEX-TRV-U8SL Fee: 6,000/- | Type: Copy Notarization: Yes Issue date: 31-12-2029 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Valid for: N/A • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 11-03-2028 CE certificate: Valid till 26-05-2025 | Class: A Models/Code/sizes (as per FSC & application): 16086, 16085/50, 16080, 16081, 16082 Shelf Life: N/A | <i>product as Class A Product.</i> <i>Clarification shall be submitted for the different codes for applied product and their role.</i> <i>Declaration regarding the exclusivity of the constituents with the intended product is required.</i> <i>The submitted brand name does not clarify whether the applied product is a system or reagent. The generic term of “Glycened Haemoglobin Monitoring system” shall be clarified.</i> | | | | | | |
| 37. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 1NL-9QB-3N63 Fee: 5,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: Yes Issue date: 31-03-2025 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Issued: 13-01-2023 • ISO – Certificate: Type: Copy Notarization: Notarized | Brand Name: IVF LABWARE Generic Name: Labware pipette Applied as: Family Class: A Models/Code/sizes (as per FSC & application): <table border="1"><tr><td>Models</td><td>Ref. no</td></tr><tr><td>V-CENTERWE LL-60</td><td>V-CWD-60</td></tr><tr><td>V-CULTURED ISH-90</td><td>V-CTD-90</td></tr></table> | Models | Ref. no | V-CENTERWE LL-60 | V-CWD-60 | V-CULTURED ISH-90 | V-CTD-90 | <i>Deferred for following:</i> <i>Justification shall be submitted for applying the intended product as Class A Product.</i> <i>Valid LOA, FSC & ISO certificate shall be submitted.</i> |
| Models | Ref. no | | | | | | | | | |
| V-CENTERWE LL-60 | V-CWD-60 | | | | | | | | | |
| V-CULTURED ISH-90 | V-CTD-90 | | | | | | | | | |

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|-----------------------------------|---|--|---|--------------------------|----------|---|----------|--------------------------------|----------|-----------------------------------|----------|-----------------------|---------|------------|------------|-----------|-----------|---|
| | | Valid till: 01-05-2025 CE certificate: Not submitted | <table><tr><td>V- CULTURED ISH-60</td><td>V-CTD-60</td></tr><tr><td>V- CULTURED ISH-35</td><td>V-CTD-35</td></tr><tr><td>V- ICSIDISH— 50</td><td>V-ICD-50</td></tr><tr><td>V- 4WELLDIS H</td><td>V-4WD</td></tr></table> Shelf Life: 3 years | V- CULTURED ISH-60 | V-CTD-60 | V- CULTURED ISH-35 | V-CTD-35 | V- ICSIDISH— 50 | V-ICD-50 | V- 4WELLDIS H | V-4WD | | | | | | | |
| V- CULTURED ISH-60 | V-CTD-60 | | | | | | | | | | | | | | | | | |
| V- CULTURED ISH-35 | V-CTD-35 | | | | | | | | | | | | | | | | | |
| V- ICSIDISH— 50 | V-ICD-50 | | | | | | | | | | | | | | | | | |
| V- 4WELLDIS H | V-4WD | | | | | | | | | | | | | | | | | |
| 38. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 1NL-9QB-3N63 Fee: 5,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: Yes Issue date: 31-03-2025 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Issued: 13-01-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted | Brand Name: IVF LABWARE Generic Name: CULTURE DISH Applied as: Family Class: A Models/Code/sizes (as per FSC & application: <table><tr><td>Models</td><td>Ref. no</td></tr><tr><td>V- Serological Pipette-1</td><td>V-SRO-1</td></tr><tr><td>V- Serological Pipette-5</td><td>V-SRO-5</td></tr><tr><td>V- Serological Pipette-10 V</td><td>V-SRO-10</td></tr><tr><td>V-Transfer Pipet-3</td><td>V-TRP-3</td></tr><tr><td>V-TIP 1000</td><td>V-TIP-1000</td></tr><tr><td>V-TIP 200</td><td>V-TIP-200</td></tr></table> Shelf Life: 3 years | Models | Ref. no | V- Serological Pipette-1 | V-SRO-1 | V- Serological Pipette-5 | V-SRO-5 | V- Serological Pipette-10 V | V-SRO-10 | V-Transfer Pipet-3 | V-TRP-3 | V-TIP 1000 | V-TIP-1000 | V-TIP 200 | V-TIP-200 | <i>Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.</i> |
| Models | Ref. no | | | | | | | | | | | | | | | | | |
| V- Serological Pipette-1 | V-SRO-1 | | | | | | | | | | | | | | | | | |
| V- Serological Pipette-5 | V-SRO-5 | | | | | | | | | | | | | | | | | |
| V- Serological Pipette-10 V | V-SRO-10 | | | | | | | | | | | | | | | | | |
| V-Transfer Pipet-3 | V-TRP-3 | | | | | | | | | | | | | | | | | |
| V-TIP 1000 | V-TIP-1000 | | | | | | | | | | | | | | | | | |
| V-TIP 200 | V-TIP-200 | | | | | | | | | | | | | | | | | |
| 39. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: LET-XA3-MVMN Fee: 5,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: Yes Issue date: 31-03-2025 • FSC Type: Copy Legalized: Legalized | Brand Name: IVF LABWARE Generic Name: Labware tubes Applied as: Family Class: A Models/Code/sizes (as per FSC & application: <table><tr><td>Models</td><td>Ref. no</td></tr></table> | Models | Ref. no | <i>Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.</i> | | | | | | | | | | | | |
| Models | Ref. no | | | | | | | | | | | | | | | | | |

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|-------------------------|--|---|--|---|----------|------------------------|--------------|----------------------|--------------|-----------------|--------------|-----------------|--------------|-----------------|--------------|-----------------|--------------|-----------------|--------------|---|
| | | Issued by: German Authority Issued: 13-01-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted | <table><tr><td>V- ROUND TU BE-14</td><td>V-RTU-14</td></tr><tr><td>V- ROUND TU BE-5</td><td>V-RTU-5</td></tr><tr><td>V-Conical tube-15</td><td>V-CTU-15</td></tr></table> Shelf Life: 3 years | V- ROUND TU BE-14 | V-RTU-14 | V- ROUND TU BE-5 | V-RTU-5 | V-Conical tube-15 | V-CTU-15 | | | | | | | | | | | |
| V- ROUND TU BE-14 | V-RTU-14 | | | | | | | | | | | | | | | | | | | |
| V- ROUND TU BE-5 | V-RTU-5 | | | | | | | | | | | | | | | | | | | |
| V-Conical tube-15 | V-CTU-15 | | | | | | | | | | | | | | | | | | | |
| 40. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: EVJ-B73-PGBR Fee: 5,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: Yes Issue date: 31-03-2025 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Issued: 13-01-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted | Brand Name: IVF LABWARE Generic Name: V CRYOVIAL Applied as: Single Class: A Models/Code/sizes (as per FSC & application): V-CRV-2 Shelf Life: 3 years | <i>Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.</i> | | | | | | | | | | | | | | | | |
| 41. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: P9A-G8B-8NA1 Fee: 25,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: Yes Issue date: 31-03-2025 • FSC Type: Copy Legalized: Legalized Issued by: German Authority Issued: 13-01-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted | Brand Name: V-DENUPET Generic Name: Denudation pipette Applied as: Family Class: B Models/Code/sizes (as per FSC & application): <table><tr><td>Models</td><td>Ref. no</td></tr><tr><td>V DENUPET 125</td><td>V-DEN 125</td></tr><tr><td>VDENUPET 135</td><td>V-DEN 135</td></tr><tr><td>VDENUPET 140</td><td>V-DEN 140</td></tr><tr><td>VDENUPET 150</td><td>V-DEN 150</td></tr><tr><td>VDENUPET 175</td><td>V-DEN 175</td></tr><tr><td>VDENUPET 200</td><td>V-DEN 200</td></tr><tr><td>VDENUPET 275</td><td>V-DEN 275</td></tr></table> | Models | Ref. no | V DENUPET 125 | V-DEN 125 | VDENUPET 135 | V-DEN 135 | VDENUPET 140 | V-DEN 140 | VDENUPET 150 | V-DEN 150 | VDENUPET 175 | V-DEN 175 | VDENUPET 200 | V-DEN 200 | VDENUPET 275 | V-DEN 275 | <i>Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.</i> |
| Models | Ref. no | | | | | | | | | | | | | | | | | | | |
| V DENUPET 125 | V-DEN 125 | | | | | | | | | | | | | | | | | | | |
| VDENUPET 135 | V-DEN 135 | | | | | | | | | | | | | | | | | | | |
| VDENUPET 140 | V-DEN 140 | | | | | | | | | | | | | | | | | | | |
| VDENUPET 150 | V-DEN 150 | | | | | | | | | | | | | | | | | | | |
| VDENUPET 175 | V-DEN 175 | | | | | | | | | | | | | | | | | | | |
| VDENUPET 200 | V-DEN 200 | | | | | | | | | | | | | | | | | | | |
| VDENUPET 275 | V-DEN 275 | | | | | | | | | | | | | | | | | | | |

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| | | | <table><tr><td>VDENUPET 300</td><td>V-DEN 300</td></tr><tr><td>VDENUPET 600</td><td>V-DEN 600</td></tr></table> Shelf Life: 5 years | VDENUPET 300 | V-DEN 300 | VDENUPET 600 | V-DEN 600 | |
| VDENUPET 300 | V-DEN 300 | | | | | | | |
| VDENUPET 600 | V-DEN 600 | | | | | | | |
| 42. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 27-10-2021 CMS tracking ID: 7GJ-QL1-GX39 Fee: 5,000/- | Name of Manufacturer: GYNETICS MEDICAL PRODUCTS NV Address: Rembert Dodoensstraat 51, 3920 Lommel, Belgium LOA Type: Copy Notarization: No Issue date: 31-12-2025 • FSC Type: Copy Legalized: No Issued by: FAMHP of Belgium Issued: 28-04-2021 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 30-01-2023 CE certificate: Not submitted | Brand Name: Gynetics Generic Name: Sterile Endometrial Curette (Sampling) Applied as: Family Class: A Models/Code/sizes (as per FSC & application: #4164 Probet #4164 In/Out #5164 Echosampler Shelf Life: 4 years | <i>Deferred for following: Valid FSC & ISO certificate shall be submitted.</i> <i>The submitted FSC declares that the applied product is not authorized to be placed on the market for use in the exporting country while it also claims that the applied product actually on the market in the exporting country. Clarification shall be submitted for this disparity.</i> | | | | |
| 43. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 2PM-9RT-172J Fee: 5,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: No Issue date: 31-3-2025 • FSC Type: Copy Legalized: Yes Issued by: German Authority Issued: 13-01-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted | Brand Name: IVF LABWARE Generic Name: V SAMPLE CONTAINER Applied as: Single Class: A Models/Code/sizes (as per FSC & application: <table><tr><td>Models</td><td>Ref. no</td></tr><tr><td>V- Sample Container- 100</td><td>V-SAC- 100</td></tr></table> Shelf Life: 3 years | Models | Ref. no | V- Sample Container- 100 | V-SAC- 100 | <i>Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.</i> |
| Models | Ref. no | | | | | | | |
| V- Sample Container- 100 | V-SAC- 100 | | | | | | | |

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| 44. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 11-09-2023 CMS tracking ID: 2PM-9RT-172J Fee: 5,000/- | Name of Manufacturer: VITROMED GmbH Address: Hans-Knoell Strasse. 6 07745 Jena , Germany LOA Type: Copy Notarization: No Issue date: 31-3-2025 • FSC Type: Copy Legalized: Yes Issued by: German Authority Issued: 08-05-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 01-05-2025 CE certificate: Not submitted | Brand Name: V-SPERM MORPHO SLIDE Generic Name: Sperm assessment slide Applied as: Single Class: A Models/Code/sizes (as per FSC & application): V-SMS-01 Shelf Life: 1 year | <i>Deferred for following: Valid LOA, FSC & ISO certificate shall be submitted.</i> |
| 45. | M/S CONCEPT Pharma (Pvt) Ltd Address: 825-E, Johar Town Lahore, Pakistan. ELI-00112 R&I Date: 27-12-2021 CMS tracking ID: Q2J-923-Y1US Fee: 5,000/- | Name of Manufacturer: GYNETICS MEDICAL PRODUCTS NV Address: Rembert Dodoensstraat 51, 3920 Lommel, Belgium LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Yes Issued by: FAMHP of Belgium Issued: 28-04-2021 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 30-01-2023 CE certificate: Not submitted | Brand Name: Gynetics Generic Name: Sterile intra-Uterine Insemination Catheter/Canuula Applied as: Family Class: A Models/Code/sizes (as per FSC & application): Single Lumen Flush Smooze #4225 Smooze Medium #4225 Smooze Long #4225 Smooze Long OM #4220 IUI #4220 IUI Memo #4220 Plus Shelf Life: 4 year | <i>Deferred for following: Valid FSC & ISO certificate shall be submitted.</i> <i>The submitted FSC declares that the applied product is not authorized to be placed on the market for use in the exporting country while it also claims that the applied product actually on the market in the exporting country. Clarification shall be submitted for this disparity.</i> <i>Justification for applying the product as Class A</i> |
| 46. | M/S CONCEPT Pharma (Pvt) Ltd | Name of Manufacturer: GYNETICS MEDICAL PRODUCTS NV | Brand Name: Gynetics Generic Name: | <i>Deferred for following:</i> |

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| | <p>Address: 825-E, Johar Town Lahore, Pakistan.</p> <p>ELI-00112</p> <p>R&I Date: 27-12-2021</p> <p>CMS tracking ID: V35-J9J-XX7S</p> <p>Fee: 5,000/-</p> | <p>Address: Rembert Dodoensstraat 51, 3920 Lommel, Belgium</p> <p>LOA</p> <p>Type: Copy</p> <p>Notarization: Yes</p> <p>Issue date: 31-12-2025</p> <p>• FSC</p> <p>Type: Copy</p> <p>Legalized: No</p> <p>Issued by: FAMHP of Belgium</p> <p>Issued: 28-04-2021</p> <p>• ISO – Certificate:</p> <p>Type: Copy</p> <p>Notarization: Notarized</p> <p>Valid till: 30-01-2023</p> <p>CE certificate: Not submitted</p> | <p>Sterile Embryo transfer catheters</p> <p>Applied as: Family</p> <p>Class: A</p> <p>Models/Code/sizes (as per FSC & application):</p> <p>#2000 Semtrac C</p> <p>#2000 C TIS</p> <p>#2000 Semtrac Set 4.2</p> <p>#2000 Semtrac Set 4.2 SP</p> <p>#2000 Set 4.2 TIS</p> <p>#2000 Set 4.2 TIS SP</p> <p>#2000 Semtrac Set 5</p> <p>#2000 Semtrac Set 5 A</p> <p>#2000 Semtrac Set 5 AB</p> <p>#2000 Semtrac Set CS</p> <p>#2000 Semtrac Set 5 SP</p> <p>#2000 Semtrac Set Short</p> <p>#2000 Semtrac Set 5 Trial</p> <p>#2000 Set 5 TIS</p> <p>#2000 Set 5 TIS SP</p> | <p>Valid FSC & ISO certificate shall be submitted.</p> <p><i>The submitted FSC declares that the applied product is not authorized to be placed on the market for use in the exporting country while it also claims that the applied product actually on the market in the exporting country.</i></p> <p>Clarification shall be submitted for this disparity.</p> <p>Justification for applying the product as Class A</p> |
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| | | | #2000 Semtrac W-180 #2000 Semtrac W-180 SP #2000 Semtrac W-180 Tria #2000 W-180 TIS #2000 W-180 TIS SP #2000 Semtrac W-240 #2000 Semtrac W-240 SP #2000 Semtrac W-240 Tria #2000 W-240 TIS #2000 W-240 TIS SP #4000 The Tulip Memo #4000 The Tulip Memo A #4000 The Tulip #4000 The Tulip A #4000 The Tulip DP #4000 Tulip S #4000 Tulip S TIS #4000 S Memo #4000 S Memo TIS #4000 Tulip S #4000 Tulip L TIS #4000 L Memo #4000 L Memo TIS #4000 Tulip LS #4000 Tulip LS TIS #4000 LS Memo #4000 LS Memo TIS #4219 Emtrac A #4219 Emtrac C-200 #4219 Emtrac C-240 #4219 Emtrac Plus #4219 Emtrac Set #4219 Emtrac Delphin #4219 Delphin TIS #2000 B Set 4.2 #2000 B Set 5 #2000 B W-180 #2000 B W-240 #4000 Memo B L-LS #4000 The Tulip Memo B Shelf Life: 4 year | |
| 47. | M/S MOODY Global Services Address: Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad ELI-00112 R&I Date: 02-09-2024 CMS tracking ID: AZH-7S8-GYZYFee: 5,000/- | Name of Manufacturer: Getein Biotech, Inc. Address: No.9 Bofu Road, Luhe District, Nanjing, 211505, China LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Apostille Issued by: JSMPA, China Validity: 11-07-2025 | Brand Name: Getein Generic Name: Activator Applied as: Kit Class: A Models/Code/sizes (as per FSC & application: 220uL×25, 220uL×50, 220uL×100, 1000mL×2, | Approved. |

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| | | <p>• ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 25-07-2026</p> <p>CE certificate: Copy of Legalized FSC form Spanish Authority has been submitted which endorses the CE status dated 10-11-2022</p> | <p>500mL×2, 250mL×2, 1000mL×4, 500mL×4, 250mL×4</p> <p>Shelf Life: 1 year</p> | |
| 48. | <p>M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: 3AH-A2B-AUHV Fee: 5,000/-</p> | <p>Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025</p> <p>• FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027</p> <p>Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted</p> | <p>Brand Name: Arjo Sara Combilizer and Sara Stedy, Sara Stedy Compact Generic Name: Standing and Raising Aid Applied as: Single Class: A</p> <p>Models/Code/sizes (as per FSC & application): Sara Stedy NTB2000 Sara Stedy Compact NTB 3000 Shelf Life: 10 years</p> | Approved. |
| 49. | <p>M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: 9G4-BM6-RTG1 Fee: 5,000/-</p> | <p>Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025</p> <p>• FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023</p> <p>• ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027</p> <p>Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted</p> | <p>Brand Name: Arjo Concerto Shower Trolley Generic Name: Shower Trolley Applied as: Single Class: A</p> <p>Models/Code/sizes (as per FSC & application): BABxxxx-xx, BAB5000-xx</p> <p>Shelf Life: 10 years</p> | Approved. The firm is advised to select one model for issuance of enlistment certificate. |

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| 50. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: L35-GTZ-6D3S Fee: 5,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted | Brand Name: Arjo Carevo Shower Trolley Generic Name: Shower Trolley Applied as: Single Class: A Models/Code/sizes (as per FSC & application): BAC11xx-xx Shelf Life: 10 years | Approved. |
| 51. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 17-06-2021 CMS tracking ID: EUX-A22-A431 Fee: 5,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted | Brand Name: Arjo Sara Combilizer Generic Name: Standing and Raising Aid Applied as: Single Class: A Models/Code/sizes (as per FSC & application): APA1000xx Shelf Life: 10 years | Approved. |
| 52. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-03-2021 CMS tracking ID: 7AS-N24-6AQL Fee: 5,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 | Brand Name: Arjo Generic Name: Hygiene Lifters Miranti Applied as: Single Class: A Models/Code/sizes (as per FSC & application): | Approved. The firm is advised to select one model for issuance of enlistment certificate. |

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| | | <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 <p>Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted</p> | CEB8xxx-xx, CEB8xxx-xx Shelf Life: 10 years | |
| 53. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-03-2021 CMS tracking ID: BN6-NP1-3JR4 Fee: 5,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 <p>Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted</p> | Brand Name: Arjo Generic Name: Hygiene Lifters Bolero Applied as: Single Class: A Models/Code/sizes (as per FSC & application): CEB6xxx-xx, CEB6x2x-xx Shelf Life: 10 years | Approved. The firm is advised to select one model for issuance of enlistment certificate. |
| 54. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: 123-HEV-9VY7 Fee: 5,000/- | Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretex (China) Medical PLC. Address: Xiguakeng, Guanqiao Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, P.R. China. LOA Type: Copy Notarization: Yes Issue date: 06-02-2026 <ul style="list-style-type: none"> • FSC | Brand Name: Prioma Medical Bed Generic Name: Prioma Medical Bed Applied as: Set Class: A Models/Code/sizes (as per FSC & application): P400, P500, P600 Shelf Life: 10 years | Deferred for submission of valid legalized FSC, issued by the relevant regulatory authority of country of origin. |

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| | | Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 03-03-2026 CE Certificate: N/A | | |
| 55. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: 8L9-NJD-NNZB Fee: 5,000/- | Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretex (China) Medical PLC. Address: Xiguakeng, Guanqiao Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, P.R. China. LOA Type: Copy Notarization: Yes Issue date: 06-02-2026 • FSC Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 03-03-2026 CE Certificate: N/A | Brand Name: Prioma Medical Couches Generic Name: Prioma Medical Couches Applied as: Family Class: A Models/Code/sizes (as per FSC & application): Prioma Semi Electric Couches: HC1, HC2, HC3 Prioma Electric Couches EC1, EC2, EC Shelf Life: 10 years | Deferred for submission of valid legalized FSC, issued by the relevant regulatory authority of country of origin. |
| 56. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 03-01-2023 CMS tracking ID: Z9Z-4LS-VBZ7 Fee: 5,000/- | Legal manufacturer: CARETEK MEDICAL LIMITED Address: UNIT A 10/F,AMTEL BUILDING 144-148 DES VOEUX ROAD CENTRAL,HK Name of Manufacturer: Caretex (China) Medical PLC. Address: Xiguakeng, Guanqiao Village, Shilou Town, Panyu District, Guangzhou City, Guangdong Province, P.R. China. LOA Type: Copy Notarization: Yes Issue date: 06-02-2026 | Brand Name: Prioma Birthing Beds (PBB2) Generic Name: Prioma Birthing Beds (PBB2) Applied as: Single Class: A Models/Code/sizes (as per FSC & application): PBB2 Shelf Life: 10 years | Deferred for submission of valid legalized FSC, issued by the relevant regulatory authority of country of origin. |

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| | | <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Legalized Issued by: China Chamber of Commerce Valid date: 12-03-2025 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 03-03-2026 <p>CE Certificate: N/A</p> | | |
| 57. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-03-2021 CMS tracking ID: HRE-XS6-RTVD Fee: 25,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 <p>Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted</p> | Brand Name: Arjo Skin IQ Generic Name: Skin IQ 365 Applied as: Single Class: B Models/Code/sizes (as per FSC & application): Skin IQ™ 365 Shelf Life: 1 Year or 35 Laundry Cycles | Approved. |
| 58. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 05-10-2021 CMS tracking ID: U1V-SLE-4QZZ Fee: 25,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 | Brand Name: Arjo Flowtron ACS 900 Generic Name: Flowtron ACS900 Applied as: Single Class: B Models/Code/sizes (as per FSC & application): Flowtron ACS900 Pump (526000-xx) Shelf Life: 7 Years | Approved. |

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| | | Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted | | |
| 59. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 05-10-2020 CMS tracking ID: GP2-8L1-Z59Q Fee: 25,000/- | Name of Manufacturer: ARJOHUNTLEIGH AB ADDRESS: Hans Michelsensgatan 10 211 20 Malmo Sweden LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Legalized Issued by: SMPA of Sweden Issue date: 12-07-2023 • ISO – Certificate: Type: Copy Notarization: Notarized Valid till: 05-01-2027 Notarized copy of EU Quality Management System Certificate valid till 10-01-2026 has been submitted | Brand Name: Arjo NINJO Generic Name: Flusher Disinfectors Applied as: Single Class: B Models/Code/sizes (as per FSC & application): FD16xx Shelf Life: 10 Years | Approved. |
| 60. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 21-02-2021 CMS tracking ID: T7B-NJA-8523 Fee: 25,000/- | Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mirandola MO, Italy LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 <ul style="list-style-type: none"> • FSC Type: Copy Legalized: Yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026 | Brand Name: LILLIPUT Generic Name: Infant and neonatal oxygenators Applied as: Family Class: B Models/Code/sizes (as per FSC & application): 597, 050596, 050578, 050598, 050579, 050580 Shelf Life: 3 Years | Approved. Firm is advised to select one model before issuance of enlistment certificate. |
| 61. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 21-02-2021 | Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mirandola MO, Italy LOA Type: Copy | Brand Name: CARDIO ACCESSORIES Generic Name: Auxiliary devices for cardiac surgery Applied as: Set | Deferred for submission of role of each accessory in the applied MD. |

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| | CMS tracking ID: 36M-AWD-84NS Fee: 25,000/- | Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026 | Class: B Models/Code/sizes (as per FSC & application): 05004, 05005, 05006, 05052, 05053, 05055, 05057, 05119, 05200, 05201, 05202, 05203, 05204, 05205, 05206, 05207, 05208, 05209, 05212, 05213, 05214, 05215, 05216, 05217, 05218, 05219, 05220, 05221, 05222, 05223, 05224, 05225, 05226, 05227, 05228, 05229, 05230, 05231, 05234, 05236, 05237, 05238, 05239, 05240, 05241, 05242, 05246, 05247, 05248, 05249, 05250, 05275, 05277, 05278, 05300, 05301, 05303, 05480, 05481, 05483, 05490, 05494, 05495, 05496, 05497, 05498, 050547, 050575, 050660, 050661, BS351-70, BS352-80, BS353-50, BS354-25, BS361-50, BS900-17, S351-70, S352-80, S353-50, S354-25, S361-50, S900-17, 050662. Shelf Life: 3 Years | |
| 62. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-12-2020 CMS tracking ID: EPV-195-BZPY Fee: 25,000/- | Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mirandola MO, Italy LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026 | Brand Name: SORIN Generic Name: Dideco Data Master Applied as: Family Class: B Models/Code/sizes (as per FSC & application): 05170, 05171, 05172, 05173 Shelf Life: 4 Years | Approved. |
| 63. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 | Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mirandola MO, Italy | Brand Name: SORIN Generic Name: Dideco Data Master Applied as: Family | Approved. |

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| | R&I Date: 22-12-2020 CMS tracking ID: 2B3-YSJ-D34P Fee: 25,000/- | LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026 | Class: B Models/Code/sizes (as per FSC & application): 05170, 05171, 05172, 05173 Shelf Life: 4 Years | |
| 64. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 20-11-2020 CMS tracking ID: B3X-GYG-GURL Fee: 25,000/- | Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mirandola MO, Italy LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026 | Brand Name: LIVANOVA Generic Name: Coronary Artery Perfusion Cannula Applied as: Family Class: B Models/Code/sizes (as per FSC & application): CP-11010, CP-11012, CP-11014, CP12010, CP-12012, CP-12014 Shelf Life: 4 Years | Deferred for submission of valid legalized FSC for the applied product. |
| 65. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 22-12-2020 CMS tracking ID: B3X-GYG-GURL Fee: 25,000/- | Name of Manufacturer: Sorin Group Italia S.r.l., ADDRESS: Via Statale Nord 12, 86 41037 Mirandola MO, Italy LOA Type: Copy Notarization: Yes Issue date: 31-12-2025 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Italy Issue date: 26-04-2024 • ISO – Certificate: | Brand Name: SORIN Generic Name: Dideco Micro Applied as: Family Class: B Models/Code/sizes (as per FSC & application): 05340, 05341, 05342, 05343, 05344, 05345, 05367, 05368, 05369 Shelf Life: 4 Years | Deferred for submission of valid legalized FSC for the applied product. |

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| | | Type: Copy Notarization: Apostille Valid till: 14-05-2027 EU MDR Certificate Valid till: 06-04-2026 | | |
| 66. | 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 | Deferred for clarification for applying the intended product as Class A Medical Device. |
| 67. | 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: 9DS-6AD-H53A 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: Stereotactic System Applied as: System Class: A Models/Code/sizes (as per FSC & application): ZD, RM and OSS Shelf Life: 5 Years | Deferred for submission of role of each accessory in MD. |
| 68. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: | Name of Manufacturer: Inomed Medizintechnik GmbH ADDRESS: Im Hausgruen 29 79312 Emmendingen Germany LOA | Brand Name: Inomed Generic Name: ISIS MER System Applied as: System | Deferred for submission of constituents of the system along with their codes. |

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| | 19-05-2020 CMS tracking ID: V2V-XG6-V9YT 25,000/- | Fee: | 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 Extension Valid till: 31-12-2028 | Class: B Models/Code/sizes (as per FSC & application): ISIS MER System Shelf Life: 10 Years | |
| 69. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 08-02-2021 CMS tracking ID: 9DS-5W1-MWJU 25,000/- | Fee: | Name of Manufacturer: TECHNOLOGIE MEDICALE ADDRESS: 101, RUE VAILLANT COUTURIER, 93130 NOISY LE SEC, France LOA Type: Copy Notarization: No Validity: 30-09-2027 • FSC Type: Copy Legalized: No Issued by: Trade Facilitation Department, France Issue date: 23-03-2020 • ISO – Certificate: Type: Copy Notarization: No Valid till: 11-03-2028 EC Certificate Extension Valid till: 31-12-2028 | Brand Name: Venturi TM2 Generic Name: Venturi Ejector Applied as: Single Class: B Models/Code/sizes (as per FSC & application): Venturi TM2 - 20239 Shelf Life: 10 Years | Deferred for submission of valid, legalized FSC |
| 70. | M/s Vertex Medical Pvt. Ltd. Address: 401-402, Block – F, Johar Town, Lahore ELI-00150 R&I Date: 08-02-2021 CMS tracking ID: SS2-UPA-QH2Q 25,000/- | Fee: | Name of Manufacturer: TECHNOLOGIE MEDICALE ADDRESS: 101, RUE VAILLANT COUTURIER, 93130 NOISY LE SEC, France LOA Type: Copy Notarization: No Validity: 30-09-2027 • FSC Type: Copy Legalized: No Issued by: Trade Facilitation Department, France Issue date: 23-03-2020 • ISO – Certificate: Type: Copy | Brand Name: RTM3 Generic Name: Flow meter with floating ball Applied as: Single Class: B Models/Code/sizes (as per FSC & application): Venturi TM2 - 20239 Shelf Life: 10 Years | Deferred for submission of valid, legalized FSC |

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| | | Notarization: No Valid till: 11-03-2028 EC Certificate Extension Valid till: 31-12-2028 | | |
| 71. | M/s ASTO Life Science Pvt. Ltd. Address: Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt. ELI-00103 R&I Date: 21-03-2025 CMS tracking ID: 8VH-5T3-831V Fee: 6,000/- | Name of Manufacturer: Becton, Dickinson and Company ADDRESS: 7 Loveton Circle Sparks, Maryland, 21152 USA LOA Type: Copy Notarization: Yes Validity: 30-09-2025 • FSC Type: Copy Legalized: No Issued by: US FDA Valid date: 26-06-2025 • ISO – Certificate: Type: Copy Notarization: No Valid till: 10-10-2027 EC Certificate: N/A | Brand Name: BD BACTECTM Platelet Aerobic culture media BD BACTECT TM M Platelet Anaerobic culture media Generic Name: Platelet Aerobic culture media & Platelet Anaerobic culture media Applied as: Not mentioned Class: A Models/Code/sizes (as per FSC & application: Venturi TM2 - 20239 Shelf Life: 1 Year | Deferred for following: Valid, legalized FSC shall be submitted. Valid notarized ISO certificate cand LOA shall be submitted Description of the product along with DOC shall be submitted Clarification for applying Anaerobic & Aerobic Culture media in same application, shall be submitted. |
| 72. | M/s ASTO Life Science Pvt. Ltd. Address: Plaza No. 1 Block Orchard 1, Paragon City Barki Road, Lahore Cantt. ELI-00103 R&I Date: 09-04-2025 CMS tracking ID: R6Z-19Q-ENV4 Fee: 25,000/- | Name of Manufacturer: Becton, Dickinson and Company ADDRESS: 7 Loveton Circle Sparks, Maryland, 21152 USA LOA Type: Copy Notarization: Yes Issue date: 29-02-2024 • FSC Type: Copy Legalized: No Issued by: US FDA Valid date: 23-08-2025 • ISO – Certificate: Type: Copy Notarization: Yes Valid till: 17-09-2025 EC Certificate: N/A | Brand Name: | Deferred for following: Valid, legalized FSC shall be submitted. Valid notarized ISO certificate shall be submitted Description of the product along with DOC shall be submitted Clarification for applying different reagents and solutions in one application shall be submitted. |

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| | | | <table><tr><td>349202</td><td>BD FACST™ Lysing Solution</td></tr><tr><td>334224</td><td>BD FACST™ Shutdown Solution</td></tr><tr><td>336911</td><td>BD FACST™ Sheath Solution</td></tr><tr><td>340345</td><td>BD FACST™ Cleaning Solution</td></tr><tr><td>342003</td><td>BD FACST™ Sheath Fluid</td></tr><tr><td>340542</td><td>BD CD3 (SK7) FITC</td></tr><tr><td>349201</td><td>BD CD3 (SK7) FITC</td></tr><tr><td>349209</td><td>BD CD19 (4G7) PE</td></tr><tr><td>340298</td><td>BD Tritest™ CD4/CD8/CD3</td></tr><tr><td>340334</td><td>BD Trucount™ Tubes</td></tr><tr><td>335775</td><td>BD FAGST™ 7-Color Setup Beads</td></tr><tr><td>344563</td><td>Stem Cell Enumeration Kit 50 Tests</td></tr><tr><td>340911</td><td>Multi-check CD4 control (BL)</td></tr><tr><td>340912</td><td>BD Multi-Check Control 2X2.5mL IVD</td></tr><tr><td>340913</td><td>BD Multi-Check Control 5X2.5mL IVD</td></tr><tr><td>340914</td><td>Multi-check CD4 control (BL) 2.5ml</td></tr><tr><td>340915</td><td>BD multi-check CD4 Low Ctrl 2X2.5mL IVD</td></tr></table> <p>Generic Name: Biosciences reagents & IVD Kits</p> <p>Applied as: Not mentioned</p> <p>Class: B</p> <p>Models/Code/sizes (as per FSC & application):</p> <p>Shelf Life: 24 Year</p> | 349202 | BD FACST™ Lysing Solution | 334224 | BD FACST™ Shutdown Solution | 336911 | BD FACST™ Sheath Solution | 340345 | BD FACST™ Cleaning Solution | 342003 | BD FACST™ Sheath Fluid | 340542 | BD CD3 (SK7) FITC | 349201 | BD CD3 (SK7) FITC | 349209 | BD CD19 (4G7) PE | 340298 | BD Tritest™ CD4/CD8/CD3 | 340334 | BD Trucount™ Tubes | 335775 | BD FAGST™ 7-Color Setup Beads | 344563 | Stem Cell Enumeration Kit 50 Tests | 340911 | Multi-check CD4 control (BL) | 340912 | BD Multi-Check Control 2X2.5mL IVD | 340913 | BD Multi-Check Control 5X2.5mL IVD | 340914 | Multi-check CD4 control (BL) 2.5ml | 340915 | BD multi-check CD4 Low Ctrl 2X2.5mL IVD | |
| 349202 | BD FACST™ Lysing Solution | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 334224 | BD FACST™ Shutdown Solution | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 336911 | BD FACST™ Sheath Solution | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340345 | BD FACST™ Cleaning Solution | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 342003 | BD FACST™ Sheath Fluid | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340542 | BD CD3 (SK7) FITC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 349201 | BD CD3 (SK7) FITC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 349209 | BD CD19 (4G7) PE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340298 | BD Tritest™ CD4/CD8/CD3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340334 | BD Trucount™ Tubes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 335775 | BD FAGST™ 7-Color Setup Beads | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 344563 | Stem Cell Enumeration Kit 50 Tests | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340911 | Multi-check CD4 control (BL) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340912 | BD Multi-Check Control 2X2.5mL IVD | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340913 | BD Multi-Check Control 5X2.5mL IVD | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340914 | Multi-check CD4 control (BL) 2.5ml | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 340915 | BD multi-check CD4 Low Ctrl 2X2.5mL IVD | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 73. | M/s EXCEL CORPORATION 435 BYJ Society, Bahadurabad, Karachi. ELI-00110 R&I Date: 13-01-2021 CMS tracking ID: AY5-MGE-BWQ2 Fee: 5,000/- | Name of Manufacturer: Suzhou Suning Underpad Co Ltd ADDRESS: No. 70 Yong An Road Xuguan New district 215151 Suzhou PR China LOA Type: Copy Notarization: No Validity: 14-07-2030 • FSC Not submitted • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2028 EC Certificate: N/A | Brand Name: Star Adult Diapers Generic Name: Adult Diapers Applied as: Not mentioned Class: A Models/Code/sizes (as per FSC & application): Sizes: N/A Shelf Life: N/A | <i>Deferred for submission of Legalized FSC. Notarized ISO certificate and valid LOA.</i> <i>Details of the models or sizes shall be submitted along with product description Details of shelf life required</i> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| 74. | <p>M/s EXCEL CORPORATION 435 BYJ Society, Bahadurabad, Karachi.</p> <p>ELI-00110 R&I Date: 13-01-2021 CMS tracking ID: AY5-MGE-BWQ2 Fee: 5,000/-</p> | <p>Name of Manufacturer: Suzhou Suning Underpad Co Ltd ADDRESS: No. 70 Yong An Road Xuguan New district 215151 Suzhou PR China LOA Type: Copy Notarization: No Validity: 14-07-2030</p> <p>• FSC Type: Copy Legalized: No Issued by: JSMPA Valid date: 14-03-2027</p> <p>• ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2028</p> <p>EC Certificate: N/A</p> | <p>Brand Name: Star Disposable Underpad (Dignity Sheet) Generic Name: Disposable Underpad (Dignity Sheet) Applied as: Not mentioned Class: A</p> <p>Models/Code/sizes (as per FSC & application): Sizes: 24×19, 50×40, 55×40, 55×45, 60×40, 60×50, 60×60, 65×30, 70×70, 85×65, 90×60, 90×75, 120×80, 120×90, 130×70, 140×70, 150×60, 115×105, 150×110, 160×80, 190×70, 200×80, 200×100, 200×120, 200×150, 210×150, 215×75, 220×70, 220×80, 220×90, 220×120, 230×75, 350×190</p> <p>Shelf Life: N/A</p> | <p><i>Deferred for following: Legalized FSC shall be submitted.</i></p> <p><i>Notarized ISO certificate and LOA shall be submitted.</i></p> <p><i>Details of shelf life required</i></p> |
| 75. | <p>M/s MOODY Global Services, Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> <p>ELI-00926 R&I Date: 02-09-2024 CMS tracking ID: TB1-77T-X1X6 Fee: 5,000/-</p> | <p>Name of Manufacturer: Getein Biotech, Inc. ADDRESS: No.9 Bofu Road, Luhe District, Nanjing, 211505, China</p> <p>LOA Type: Copy Notarization: yes Validity: 09-05-2029</p> <p>• FSC Type: Copy Legalized: yes Issued by: JSMPA Valid date: 11-07-2025</p> <p>• ISO – Certificate: Type: Copy Notarization: No Valid till: 25-07-2026</p> <p>EC Certificate: N/A</p> | <p>Brand Name: Getein Generic Name: Cleaning Solution Applied as: Kit Class: A</p> <p>Models/Code/sizes (as per FSC & application): Sizes: 1l×1, 1l×2, 2l×1, 5l×1 7l×1, 10L×1, 20L×1, 1 5ml×25, 1.5ml×50, 1.5ml×100, 500ml×1, 500ml×2, 500mL×4, 10 00mL×1, 1000mL×2, 1000ml×4, 5000mL×1, 5000mL×2, 5000m L×4, 7000ml×1, 7000mL×2, 7000ml×4, 10000mL×1, 10000mL×2, 10000mL×4</p> <p>Shelf Life: 12 months</p> | <p><i>Deferred for following: Legalized valid FSC shall be submitted</i></p> |
| 76. | <p>M/s MOODY Global Services, Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad</p> | <p>Name of Manufacturer: Getein Biotech, Inc. ADDRESS: No.9 Bofu Road, Luhe District, Nanjing, 211505, China</p> | <p>Brand Name: Getein Generic Name: Activator Applied as: Kit</p> | <p><i>Deferred for following: Legalized valid FSC shall be submitted</i></p> |

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| | ELI-00926 R&I Date: 02-09-2024 CMS tracking ID: AZH-7S8-GYZY Fee: 5,000/- | LOA Type: Copy Notarization: yes Validity: 09-05-2029 • FSC Type: Copy Legalized: yes Issued by: JSMPA Valid date: 11-07-2025 • ISO – Certificate: Type: Copy Notarization: No Valid till: 25-07-2026 EC Certificate: N/A | Class: A Models/Code/sizes (as per FSC & application): Sizes: 220uL×25, 220uL×50, 220uL×100, 1000mL×2, 500mL×2, 250mL×2, 1000mL×4, 500mL×4, 250mL×4.4 Shelf Life: 12 months | |
| 77. | M/s MOODY Global Services, Office No. 14, 2nd Floor, Mujahid Plaza, Blue area, Islamabad ELI No:0025 R&I Date: 09-09-2024 CMS tracking ID: R95-J26-6AZY L Fee: 5,000/- | Name of Manufacturer: Getein Biotech, Inc. ADDRESS: No.9 Bofu Road, Luhe District, Nanjing, 211505, China LOA Type: Copy Notarization: yes Validity: 09-05-2029 • FSC Type: Copy Legalized: yes Issued by: JSMPA Valid date: 11-07-2025 • ISO – Certificate: Type: Copy Notarization: No Valid till: 25-07-2026 EC Certificate: N/A | Brand Name: Getein Generic Name: Activator Applied as: Kit Class: A Models/Code/sizes (as per FSC & application): Sizes: 220uL×25, 220uL×50, 220uL×100, 1000mL×2, 500mL×2, 250mL×2, 1000mL×4, 500mL×4, 250mL×4.4 Shelf Life: 12 months | Deferred for following: <i>Legalized valid FSC shall be submitted</i> |
| 78. | MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 23-02-2023 CMS tracking ID: 7RB-L5L-1MSE Fee: 5,000/- | Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: yes Issued by: Germany | Brand Name: Mindray Generic Name: CD-80 Detergent Applied as: Kit Class: A Models/Code/sizes (as per FSC & application): Sizes: 220uL×25, 220uL×50, 220uL×100, 1000mL×2, 500mL×2, 250mL×2, 1000mL×4, 500mL×4, 250mL×4.4 Shelf Life: 12 months | Approved |

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| | | Issue date: 02-02-2021 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A | | |
| 79. | MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 23-02-2023 CMS tracking ID: 1GT-NW9-EABQ Fee: 5,000/- | Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: yes Issued by: Germany Issue date: 02-02-2021 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A | Brand Name: Mindray Generic Name: Chemistry Analyzer-BS2000M Applied as: Kit Class: A Models/Code/sizes (as per FSC & application): Sizes: BS-2000M Shelf Life: 10 years | Approved. |
| 80. | MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 23-02-2023 CMS tracking ID: 99M-RZ2-LZQN Fee: 5,000/- | Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: yes Issued by: Germany Issue date: 02-02-2021 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A | Brand Name: Mindray Generic Name: Reagents of BC-3000 Auto Hematology analyzer Applied as: Single Class: A Models/Code/sizes (as per FSC & application): Sizes: M-30 E(Cleanser) M-30 R(Rinse) M-30P (Probe cleanser) Shelf Life: | Deferred for Clarification for grouping the applied constituents as single product |

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| 81. | MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 22-02-2023 CMS tracking ID: D5A-YR7-UHJW Fee: 5,000/- | Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: No Issued by: Provincial Supervision Body, China Valid : 07-01-2027 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A | Brand Name: Mindray Generic Name: BC-RET Hematology Control Applied as: Kit Class: A Models/Code/sizes (as per FSC & application): Sizes: H: 4.5ml ×1, 4.5ml ×6 N: 4.5ml ×1, 4.5ml ×6 L: 4.5ml ×1, 4.5ml ×6 Shelf Life: 14 days | Deferred for submission of valid legalized FSC. |
| 82. | MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008 R&I Date: 23-02-2023 CMS tracking ID: NPR-D82-DBU6 Fee: 5,000/- | Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: No Issued by: Provincial Supervision Body, China Valid : 26-02-2026 • ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026 EC Certificate: N/A | Brand Name: Mindray Generic Name: ASO/CRP/RF Triple Control Applied as: Kit Class: A Models/Code/sizes (as per FSC & application): Sizes: L:3×1ml H: 3×1ml Shelf Life: 18 months | Deferred for submission of valid legalized FSC. |
| 83. | MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, | Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. | Brand Name: Mindray Generic Name: | Approved. |

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| | <p>Blue Area, Islamabad, Pakistan. ELI No:01008</p> <p>R&I Date: 20-12-2022 CMS tracking ID: 2X4-XMW-U82X Fee: 5,000/-</p> | <p>ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA Type: Copy Notarization: yes Validity: 14-04-2027</p> <p>• FSC Type: Copy Legalized: Apostille Issued by: Provincial Supervision Body, China Valid : 01-04-2026</p> <p>• ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026</p> <p>EC Certificate: N/A</p> | <p>Total β Human Chorionic Gonadotropin (CLIA) Applied as: Kit Class: A</p> <p>Models/Code/sizes (as per FSC & application): Sizes: 2×50 test 2×100 test Shelf Life: 18 months</p> | |
| 84. | <p>MR Medical Pakistan Private Limited Office no: 1101, 11th floor, ISE Tower, Jinnah Avenue, Blue Area, Islamabad, Pakistan. ELI No:01008</p> <p>R&I Date: 22-02-2023 CMS tracking ID: 7VG-Q6Q-RYNH Fee: 5,000/-</p> | <p>Name of Manufacturer: M/s Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ADDRESS: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA</p> <p>LOA Type: Copy Notarization: yes Validity: 14-04-2027</p> <p>• FSC Type: Copy Legalized: No Issued by: Provincial Supervision Body, China Valid : 02-11-2022</p> <p>• ISO – Certificate: Type: Copy Notarization: No Valid till: 31-08-2026</p> <p>EC Certificate: N/A</p> | <p>Brand Name: Mindray Generic Name: Chemistry Analyzer BS-200 Applied as: Kit Class: A</p> <p>Models/Code/sizes (as per FSC & application): Sizes: 2×50 test 2×100 test Shelf Life: 10 years</p> | Deferred for submission of valid legalized FSC. |
| 85. | <p>M/s. A.Feroz & Co., Medicine Street No. 1, Marriot Road, Karachi ELI No:00066</p> <p>R&I Date:</p> | <p>Name of Manufacturer: M/s Supermax Gloves Manufacturing SDN BHD (SGM), ADDRESS: Lot 38, Putra Industrial Park, Bukit Rahman Putra, 47000 Sungai Buloh, Selangor, MALAYSIA</p> | <p>Brand Name: Supermax-Non-Sterile Latex Examination Gloves, Powdered Generic Name: NonSterile Latex Examination Gloves, Powdered Applied as: Family</p> | Approved. |

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| | 13-03-2020 CMS tracking ID: NL1-LWH-ZEZG Fee: 5,000/- | LOA Type: Copy Notarization: yes Validity: 14-04-2027 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Malaysia Valid : 06-07-2027 • ISO – Certificate: Type: Copy Notarization: yes Valid till: 06-02-2026 EC Certificate: N/A | Class: A Models/Code/sizes (as per FSC & application): Sizes: XS, S, M, L, XL Shelf Life: 05 years | |
| 86. | M/s. A.Feroz & Co., Medicine Street No. 1, Marriot Road, Karachi ELI No:00066 R&I Date: 13-03-2020 CMS tracking ID: NL1-LWH-ZEZG Fee: 5,000/- | Name of Manufacturer: M/s Supermax Gloves Manufacturing SDN BHD (SGM), ADDRESS: Lot 38, Putra Industrial Park, Bukit Rahman Putra, 47000 Sungai Buloh, Selangor, MALAYSIA LOA Type: Copy Notarization: yes Validity: 25-08-2029 • FSC Type: Copy Legalized: yes Issued by: Ministry of Health Malaysia Valid : 06-07-2027 • ISO – Certificate: Type: Copy Notarization: yes Valid till: 06-02-2026 EC Certificate: N/A | Brand Name: Supermax-Non-Sterile Latex Examination Gloves, Powder free Generic Name: NonSterile Latex Examination Gloves, Powder free Applied as: Family Class: A Models/Code/sizes (as per FSC & application): Sizes: XS, S, M, L, XL Shelf Life: 05 years | Approved. |

Evaluator: Rana Ahsan-ul-Haq Athar

Agenda Item II (g) DEFERRED CASES IMPORT

| S# | Importer Name | Manufacturer Details | Name of MD / Class / Codes / Shelf life / etc. | Decision |
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| 1. | M/s Ferozs Laboratories Limited, P.O. Ferozs, Amangarh, Nowshera-KPK, Pakistan. | Legal Manufacturer: Boston Scientific Corporation, 300, Boston Scientific Way, Marlborough, MA 01752 USA. | Brand Name: Wallflex™ Esophageal Fully Covered RMV Stent System | Approved <i>Wallflex™ Esophageal Fully Covered</i> |

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| | <p>(ELI-00120)</p> <p>Date of R& I 14-07-2025</p> <p>Fee: PKR100,000/- Slip # 9830837763</p> | <p>Manufacturing Site: Boston Scientific Limited, Ballybrit Business Park, Ireland.</p> <p>• LOA Type: Copy of Notarized Notarization: Notarized Validity: 30-06-2025</p> <p>• FSC Type: Copy of apostilled Issued By: HPRA Legalization: Apostilled Issue Date: 20-11-2024 Validity: Not mentioned.</p> <p>• ISO – Certificate: Type: Copy of notarized Notarization: Notarized Validity: 23-03-2027</p> | <p>Generic Name: Polymer-Metal Oesophageal Stent.</p> <p>Applied as: Family</p> <p>Class: C</p> <p>Models/Code/sizes (As per FSC & Application): Fully Covered RMV Stent System</p> <ul style="list-style-type: none"> • M00516210 (18/23-25X103) • M00516220 (18/23-25X123) • M00516230 (18/23-25X153) • M00516240 (23/28X105) • M00516250 (23/28X125) • M00516260 (23/28X155) <p>Fully Covered RMV Stent System Longer Loop</p> <ul style="list-style-type: none"> • M00516270 (18/23-25X103) • M00516280 (18/23-25X123) • M00516290 (18/23-25X153) • M00516300 (23/28X105) • M00516310 (23/28X125) • M00516320 (23/28X155) • M00516920 (18/23X153) • M00516930 (23/28X105) • M00516940 (23/28X125) • M00516950 (23/28X155) <p>Service Life: 19 Months</p> | <p><i>RMV Stent System only. Firm will apply separately for Fully Covered RMV Stent System Longer Loop.</i></p> |
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| 2. | U.M. Enterprises 3 Boulevard Raymond Poincare, 92430 Marnes-la-Coquette, France Plot No. 12, Sector No. 15, Korangi Industrial Area, Karachi | BIO-RAD Laboratories 3 Boulevard Raymond Poincare, 92430 Marnes-la-Conquette, France FSC Original France Copy of LOA expiry 31.12.2020 | Platelia Rabbies II Class A Shel life 12 months 2-8°C Fee 5000 | Approved in class C subject to submission of valid, notarized LOA. |
| 3. | M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R& I 27-06-2025 Fee: 6,000/- Slip # 386760094 | Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostilled Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 | Brand name: BRUN Ballon Inflation Device Set Generic Name: Balloon Inflation Device Set Applied as: Single Class: A Code/sizes (as per FSC & Application): BR-BID-130A, BR-BID-130AL, BR-BID-II26A, BR-BID-II30A, BR-BID-III30A, BR-BID-130B, BR-BID-130BL, BR-BID-II2BA, BR-BID-II30B, BR-BID-III30B, BR-BID-130C, BR-BID-130CL, BR-BID-II26C, BR-BID-II30C, BR-BID-III30C, BR-BID-130D, BR-BID-130DL, BR-BID-II26D, BR-BID-II30D, BR-BID-III30D, BR-BID-130E, BR-BID-130EL, BR-BID-II26E, BR-BID-II30E, BR-BID-III30E, BR-BID-130F, BR-BID-130FL, BR-BID-II26F, BR-BID-II30F, BR-BID-III30F, BR-BID-130, BR-BID-130L, BR-BID-II26, BR-BID-III30, BR-BID-140, BR-BID-140L, BR-BID-II30, BR-BID-IV30 Service Life: 3 Years | Deferred (last opportunity) for the following: 1. submission of original legalized/apost ille FSC and original, notarized LOA and ISO 13485 certificate. 2. Clarification of the components of Balloon Inhalation Device Sets. 3. submission of the fee for the family and codes. 4. submission of Brochure/catal ogue. |
| 4. | M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R& I | Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China | Brand name: BRUN Manifolds Generic Name: Manifolds Applied as: Single | Deferred (last opportunity) for the following: 1. submission of original legalized/apost |

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| | <p>27-06-2025</p> <p>Fee: 31,000/- Slip # 3467162744</p> | <p>• LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027</p> <p>• FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028</p> <p>• ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026</p> <p>• CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028</p> | <p>Class: B</p> <p>Code/sizes (as per FSC & Application): BR-GW018-45S, BR-GW018-45J, BR-GW021-45S, BR-GW021-45J, BR-GW025-45S, BR-GW025-45J, BR-GW018-60S, BR-GW018-60J, BR-GW021-60S, BR-GW021-60J, BR-GW025-60S, BR-GW025-60J, BR-GW018-80S, BR-GW018-80J, BR-GW021-80S, BR-GW021-80J, BR-GW025-80S, BR-GW025-80J, BR-GW018-120S, BR-GW018-120J, BR-GW021-120S, BR-GW021-120J, BR-GW025-120S, BR-GW025-120J, BR-GW018-150S, BR-GW018-150J, BR-GW021-150S, BR-GW021-150J, BR-GW025-150S, BR-GW025-150J, BR-GW018-180S, BR-GW018-180J, BR-GW021-180S, BR-GW021-180J, BR-GW025-180S, BR-GW025-180J, BR-GW018-260S, BR-GW018-260J, BR-GW021-260S, BR-GW021-260J, BR-GW025-260S, BR-GW025-260J, BR-GW032-45S, BR-GW032-45J, BR-GW035-45S, BR-GW035-45J, BR-GW038-45S, BR-GW038-45J, BR-GW032-60S, BR-GW032-60J, BR-GW035-60S, BR-GW035-60J, BR-GW038-60S, BR-GW038-60J, BR-GW032-80S, BR-GW032-80J, BR-GW035-80S, BR-GW035-80J, BR-GW038-80S, BR-GW038-80J, BR-GW032-120S, BR-GW032-120J, BR-GW035-120S, BR-GW035-120J, BR-GW038-120S, BR-GW038-120J, BR-GW032-150S, BR-GW032-150J, BR-</p> | <p>ille FSC and original, notarized LOA and ISO 13485 certificate.</p> <p>2. submission of the fee for the family and codes.</p> <p>3. submission of Brochure/ catalogue.</p> |
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| | | | GW035-150S, BR-GW035-150J, BR- | |
| | | | GW038-150S, BR-GW038-150J, BR- | |
| | | | GW032-180S, BR-GW032-180J, BR- | |
| | | | GW035-180S, BR-GW035-180J, BR- | |
| | | | GW038-180S, BR-GW038-180J, BR- | |
| | | | GW032-260S, BR-GW032-260J, BR- | |
| | | | GW035-260S, BR-GW035-260J, BR- | |
| | | | GW038-260S, BR-GW038-260J, BR- | |
| | | | GWC018-45S, BR- GWC018-45J, BR- | |
| | | | GWC021-45S, BR- GWC021-45J, BR- | |
| | | | GWC025-45S, BR- GWC025-45J, BR- | |
| | | | GWC018-60S, BR- GWC018-60J, BR- | |
| | | | GWC021-60S, BR- GWC021-60J, BR- | |
| | | | GWC025-60S, BR- GWC025-60J, BR- | |
| | | | GWC018-80S, BR- GWC018-80J, BR- | |
| | | | GWC021-80S, BR- GWC021-80J, BR- | |
| | | | GWC025-80S, BR- GWC025-80J, BR- | |
| | | | GWC018-120S, BR- GWC018-120J, BR- | |

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| | | | GWC021-120S, GWC021-120J, BR- | BR- | |
| | | | GWC025-120S, GWC025-120J, BR- | BR- | |
| | | | GWC018-150S, GWC018-150J, BR- | BR- | |
| | | | GWC021-150S, GWC021-150J, BR- | BR- | |
| | | | GWC025-150S, GWC025-150J, BR- | BR- | |
| | | | GWC018-180S, GWC018-180J, BR- | BR- | |
| | | | GWC021-180S, GWC021-180J, BR- | BR- | |
| | | | GWC025-180S, GWC025-180J, BR- | BR- | |
| | | | GWC018-260S, GWC018-260J, BR- | BR- | |
| | | | GWC021-260S, GWC021-260J, BR- | BR- | |
| | | | GWC025-260S, GWC025-260J, BR- | BR- | |
| | | | GWC032-45S, GWC032-45J, BR- | BR- | |
| | | | GWC035-45S, GWC035-45J, BR- | BR- | |
| | | | GWC038-45S, GWC038-45J, BR- | BR- | |
| | | | GWC032-60S, GWC032-60J, BR- | BR- | |
| | | | GWC035-60S, GWC035-60J, BR- | BR- | |
| | | | GWC038-60S, GWC038-60J, BR- | BR- | |
| | | | GWC032-80S, GWC032-80J, BR- | BR- | |
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| | | | GWC038-80S, GWC038-80J, BR- | BR- | |
| | | | GWC032-120S, GWC032-120J, BR- | BR- | |
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| | | | GWC038-120S, GWC038-120J, BR- | BR- | |
| | | | GWC032-150S, GWC032-150J, BR- | BR- | |
| | | | GWC035-150S, GWC035-150J, BR- | BR- | |
| | | | GWC038-150S, GWC038-150J, BR- | BR- | |
| | | | GWC032-180S, GWC032-180J, BR- | BR- | |
| | | | GWC035-180S, GWC035-180J, BR- | BR- | |
| | | | GWC038-180S, GWC038-180J, BR- | BR- | |
| | | | GWC032-260S, GWC032-260J, BR- | BR- | |
| | | | GWC035-260S, GWC035-260J, BR- | BR- | |
| | | | GWC038-260S, GWC038-260J, BR- | BR- | |
| | | | NGW018-45S, NGW018-45J, BR- | BR- | |
| | | | NGW021-45S, NGW021-45J, BR- | BR- | |
| | | | NGW025-45S, NGW025-45J, BR- | BR- | |
| | | | NGW018-60S, NGW018-60J, BR- | BR- | |
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| | | | NGW025-80S, NGW025-80J, BR- | BR- | |
| | | | NGW018-120S, NGW018-120J, BR- | BR- | |
| | | | NGW021-120S, NGW021-120J, BR- | BR- | |
| | | | NGW025-120S, NGW025-120J, BR- | BR- | |
| | | | NGW018-150S, NGW018-150J, BR- | BR- | |
| | | | NGW021-150S, NGW021-150J, BR- | BR- | |
| | | | NGW025-150S, NGW025-150J, BR- | BR- | |
| | | | NGW018-180S, NGW018-180J, BR- | BR- | |
| | | | NGW021-180S, NGW021-180J, BR- | BR- | |
| | | | NGW025-180S, NGW025-180J, BR- | BR- | |
| | | | NGW018-260S, NGW018-260J, BR- | BR- | |
| | | | NGW021-260S, NGW021-260J, BR- | BR- | |
| | | | NGW025-260S, NGW025-260J, BR- | BR- | |
| | | | NGW032-45S, NGW032-45J, BR- | BR- | |
| | | | NGW035-45S, NGW035-45J, BR- | BR- | |
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| | | | NGW032-80S, NGW032-80J, BR- | BR- | |
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| | | | NGW038-80S, NGW038-80J, BR- | BR- | |
| | | | NGW032-120S, NGW032-120J, BR- | BR- | |
| | | | NGW035-120S, NGW035-120J, BR- | BR- | |
| | | | NGW038-120S, NGW038-120J, BR- | BR- | |
| | | | NGW032-150S, NGW032-150J, BR- | BR- | |
| | | | NGW035-150S, NGW035-150J, BR- | BR- | |
| | | | NGW038-150S, NGW038-150J, BR- | BR- | |
| | | | NGW032-180S, NGW032-180J, BR- | BR- | |
| | | | NGW035-180S, NGW035-180J, BR- | BR- | |
| | | | NGW038-180S, NGW038-180J, BR- | BR- | |
| | | | NGW032-260S, NGW032-260J, BR- | BR- | |
| | | | NGW035-260S, NGW035-260J, BR- | BR- | |
| | | | NGW038-260S, NGW038-260J, BR- | BR- | |
| | | | NGWC018-45S, NGWC018-45J, BR- | BR- | |

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| | | | NGWC021-45S, BR- NGWC021-45J, BR- NGWC025-45S, BR- NGWC025-45J, BR- NGWC018-60S, BR- NGWC018-60J, BR- NGWC021-60S, BR- NGWC021-60J, BR- NGWC025-60S, BR- NGWC025-60J, BR- NGWC018-80S, BR- NGWC018-80J, NGWC021- 80S, BR-NGWC021-80J, BR-NGWC025-80S, BR- NGWC025-80J, BR- NGWC018-120S, BR- NGWC018-120J, BR- NGWC021-120S, BR- NGWC021-120J, BR-NGWC025-120S, BR- NGWC025-120J, BR-NGWC018-150S, BR- NGWC018-150J, BR-NGWC021-150S, BR- NGWC021-150J, BR-NGWC025-150S, BR- NGWC025-150J, BR-NGWC018-180S, BR- NGWC018-180J, BR-NGWC021-180S, BR- NGWC021-180J, BR-NGWC025-180S, BR- NGWC025-180J, BR-NGWC018-260S, BR- NGWC018-260J, BR-NGWC021-260S, BR- NGWC021-260J, BR-NGWC025-260S, BR- NGWC025-260J, | |
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| | | | <p>BR-NGWC032-45S, BR-NGWC032-45J,</p> <p>BR-NGWC035-45S, BR-NGWC035-45J,</p> <p>BR-NGWC038-45S, BR-NGWC038-45J,</p> <p>BR-NGWC032-60S, BR-NGWC032-60J,</p> <p>BR-NGWC035-60S, BR-NGWC035-60J,</p> <p>BR-NGWC038-60S, BR-NGWC038-60J,</p> <p>BR-NGWC032-80S, BR-NGWC032-80J,</p> <p>BR-NGWC035-80S, BR-NGWC035-80J,</p> <p>BR-NGWC038-80S, BR-NGWC038-80J,</p> <p>BR-NGWC032-120S, BR-NGWC032-120J,</p> <p>BR-NGWC035-120S, BR-NGWC035-120J,</p> <p>BR-NGWC038-120S, BR-NGWC038-120J,</p> <p>BR-NGWC032-150S, BR-NGWC032-150J,</p> <p>BR-NGWC035-150S, BR-NGWC035-150J,</p> <p>BR-NGWC038-150S, BR-NGWC038-150J,</p> <p>BR-NGWC032-180S, BR-NGWC032-180J,</p> <p>BR-NGWC035-180S, BR-NGWC035-180J,</p> <p>BR-NGWC038-180S, BR-NGWC038-180J,</p> | |
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| | | | BR-NGWC032-260S, BR-NGWC032-260J, BR-NGWC035-260S, BR-NGWC035-260J, BR-NGWC038-260S, BR-NGWC038-260J Service Life: 3 Years | |
| 5. | M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R& I 27-06-2025 Fee: 31,000/- Slip # 98205538650 | Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 | Brand name: BRUN Guidewires Generic Name: Guidewires Applied as: Single Class: B Code/sizes (as per FSC & Application): BR MF1 ON, BR MF2 ON, BR MF3 ON, BR MF1 OFF, BR MF2 OFF, BR MF3 OFF Firm has submitted the following codes BR-GWC025-150J, BR-GWC025-150S, BR-GWC025-260S, BR-GWC025-260J, BR-GWC032-150S, BR-GWC032-150J, BR-GWC035-150S, BR-GWC035-150J, BR-GWC038-150S, BR-GWC038-150J, BR-GWC035-260S, BR-GWC035-260J, BR-GWC038-260S, BR-GWC038-260J, BR-NGW018-45J, BR-NGW021-45J, BR-NGW025-45J, BR-NGW018-60J, BR-NGW021-60J, BR-NGW025-60J, BR-NGW021-150S, BR-NGW021-150J, BR-NGW025-150S, BR-NGW025-150J, BR-NGW032-45J, | Deferred (last opportunity) for the following: 1. submission of original legalized/apostille FSC and original, notarized LOA and ISO 13485 certificate. 2. submission of the fee for the family and codes. 3. submission of Brochure/catalogue. |

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| | | | BR-NGW035-45J, BR-NGW038-45J, BR-NGW032-60J, BR-NGW035-60J, BR-NGW038-60J, BR-NGW032-150J, BR-NGW035-150J, BR-NGW038-150J. Service Life: 3 Years | |
| 6. | M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R& I 27-06-2025 Fee: 31,000/- Slip # 5905805985 | Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 | Brand name: BRUN Connecting Tubings (Pressuere Extension Line) Generic Name: Connecting Tubes Applied as: Single Class: B Code/sizes (as per FSC & Application): BR CT1.80 10, BR CT1.80 20, BR CT1.80 30, BR CT1.80 60, BR CT1.80 90, BR CT1.80 120, BR CT1.80 150, BR CT2.00 10, BR CT2.00 20, BR CT2.00 30, BR CT2.00 60, BR CT2.00 90, BR CT2.00 120, BR CT2.00 150, BR CT2.70 10, BR CT2.70 20, BR CT2.70 30, BR CT2.70 60, BR CT2.70 90, BR CT2.70 120, BR CT2.70 150, BR CT3.00 10, BR CT3.00 20, BR CT3.00 30, BR CT3.00 60, BR CT3.00 90, BR CT3.00 120, BR CT3.00 150, BR CT3.20 10, BR CT3.20 20, BR CT3.20 30, BR CT3.20 60, BR CT3.20 90, BR CT3.20 120, BR CT3.20 150, BR CT3.65 10, BR CT3.65 20, BR CT3.65 30, BR CT3.65 60, BR CT3.65 90, BR CT3.65 120, BR CT3.65 150, BR CT4.00 10, BR CT4.00 20, BR CT4.00 30, BR CT4.00 60, BR CT4.00 90, BR CT4.00 120, BR CT4.00 150, BR CT3.20 | Deferred (last opportunity) for the following: 1. submission of original legalized/apostille FSC and original, notarized LOA and ISO 13485 certificate. 2. submission of the fee for the family and codes. 3. submission of Brochure/catalogue. |

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| | | | <p>20A, BR-CT3.20-60A, BR-CT3.20-90A, BR-CT3.20-120A, BR-CT3.20-150A, BR-CT3.20-180A, BR-CT3.20-200A, BR-CT3.65-20B, BR-CT3.65-60B, BR-CT3.65-90B, BR-CT3.65-120B, BR-CT3.65-150B, BR-CT3.65-180B, BR-CT3.65-200B, BR-CT4.00-150S, BR-CT4.00-150D.</p> <p>Now firm has applied following codes only. BR-CT1.80-90, BR-CT1.80-120, BR-CT1.80-150, BR-CT2.00-90, BR-CT2.00-120, BR-CT2.00-150, BR-CT2.70-90, BR-CT2.70-120, BR-CT2.70-150, BR-CT3.00-90, BR-CT3.00-120, BR-CT3.00-150, BR-CT3.65-90, BR-CT3.65-120, BR-CT3.65-150, BR-CT3.20-90A, BR-CT3.20-120A, BR-CT3.20-150A, BR-CT3.20-180A, BR-CT3.20-200A, BR-CT3.65-90B, BR-CT3.65-120B, BR-CT3.65-150B, BR-CT3.65-180B, BR-CT3.65-200B,</p> <p>Service Life: 3 Years</p> | |
| 7. | <p>M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore</p> <p>ELI-00147</p> <p>Date of R& I 27-06-2025</p> <p>Fee: 31,000/- Slip # 54732192</p> | <p>Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China</p> <p>• LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027</p> <p>• FSC: Netherlands</p> | <p>Brand name: BRUN Introducer Sheath Set</p> <p>Generic Name: Introducer Sheath</p> <p>Applied as: Single</p> <p>Class: B</p> <p>Code/sizes (as per FSC & Application): BR-RA0407, BR-RA0507, BR-RA0607 BR-RA0707,</p> | <p>Deferred (last opportunity) for the following:</p> <ol style="list-style-type: none"> 1. submission of original legalized/apostille FSC and original, notarized LOA and ISO 13485 certificate. 2. submission of the fee for |

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| | | Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 | BR-RA0411, BR-RA0511 BR-RA0611, BR-RA0711, BR-RA0416 BR-RA0516, BR-RA0616, BR-RA0716 BR-RA0423, BR-RA0523, BR-RA0623 BR-RA0723, BR-FA0409, BR-FA0511 BR-FA0611, BR-FA0711, BR-FA0811 BR-FA0911, BR-FA1011, BR-FA1211 BR-FA0419, BR-FA0523, BR-FA0623 BR-FA0723, BR-FA0823, BR-FA0923 BR-FA1023, BR-FA1223. Service Life: 3 Years | the family and codes. 3. submission of Brochure/catalogue. |
| 8. | M/s Alliance Medical, 12-B, 1 st Floor, Agro Flats, Shadman, Lahore ELI-00147 Date of R& I 27-06-2025 Fee: 31,000/- Slip # 871539410213 | Name of Manufacturer: Brun Medical Co., Ltd., Building B8, Entrepreneurship and Innovation Park, 88 Changtang Road, Yunlong Demonstration Zone, Zhuzhou City 412000, China • LOA: Type: Copy Notarization: By CCPIT Issue Date: 29-07-2024 Validity: 28-07-2027 • FSC: Netherlands Type: Copy Legalization: Apostille Issue Date: 22-07-2024 Validity: 12-09-2028 • ISO – Certificate: Type: Copy Notarization: By CCPIT | Brand name: BRUN Angiography Syringes and Accessories Generic Name: Angiography Syringes and Accessories Applied as: Single Class: B Code/sizes (as per FSC & Application): BR-AS-CT-200-A01, BR-AS-CT-200/200-A02, BR-AS-CT-200-A03, BR-AS-CT-200/200-A04, BR-AS-CT-190-A05, BR-AS-CT-200-B01, BR-AS-CT-200/200-B02, BR-AS-CT-200-C01, BR-AS-CT-100/200-D02, BR-AS-CT-100-D01, BR-AS-CT-200-D03, | Deferred (last opportunity) for the following: 1. submission of original legalized/apostille FSC and original, notarized LOA and ISO 13485 certificate. 2. submission of the fee for the family and codes. 3. submission of Brochure/catalogue. |

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| | | Validity: 14-10-2026 • CE - EU Certificate: Type: Copy Notarization: By CCPIT Validity: 12-09-2028 | BR-AS-CT-200-E01, BR-AS-CT-200/200-E02, BR-AS-CT-190/190-A06, BR-AS-CT-200/200-A08, BR-AS-DSA-150-A01, BR-AS-DSA-200-A03, BR-AS-DSA-60-A05, BR-AS-DSA-150-B01, BR-AS-DSA-150-B03, BR-AS-CT-200/200-C02, BR-AS-CT-100/100-D04, BR-AS-CT-200/200-D06, BR-AS-CT-60/200-D08, BR-AS-MRI-65-E01, BR-AS-MRI-65/65-E02, BR-AS-DSA-130-A07, BR-AS-DSA-150-A09, BR-AS-MRI-65/65-A02, BR-AS-MRI-115/115-A04, BR-AS-MRI-65/115-A06, BR-AS-MRI-60-B01, BR-AS-MRI-60/60-B02, BR-AS-DSA-120-D01, BR-AS-MRI-60-D01, BR-AS-MRI-60/60-D02, BR-AS-MRI-65/200-E04. | |
| | | | Service Life: 3 Years | |
| 9. | Mubarak Vision, 32-A Usman Center, Shah Alam Market, Lahore. ELI-00045 5152-P | <u>Legal Manufacturer:</u> M/s Henan Simedice Biotechnologies Co., Ltd, No. 28, Floor 7, Unit A, Building 1, No. 8, Guohuai Ave., Hi-Tech Industries Development Zone, Zhengzhou, Henan 450001, P.R. China. FSC China validity 06-07-2025 FSC: Germany. Issuance 27-10-2021 | Simedice Hydrophobic Aspheric Foldable IOL's (Hydrophobic Aspheric Foldable IOL's) Class-C Shelf Life: 5 years Models: SM60AS SM60AS1 SM60AS2 SM60AS3 | Rejected due to following reasons: 1. Fee for the family has not been submitted. 2. The name of the device at cover note of the Form 7A is Henan Simedice Aspheric Foldable IOL's and as section 4 of the Form 7A is Simedice Aspheric Foldable IOL's. 3. Firm has not submitted EU technical documentation certificate. 4. DoC not mentioned. 5. copy of the apostille FSC China valid till |

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| | | | | <p>26.02.2027. as per FSC the applied codes belong to different devices. Floodable IOLs not mentioned in the FSC.</p> <p>7. In none of the submitted document Foldable Intraocular Lens mentioned.</p> <p>8. Firm has applied intraocular lens, Preloaded Aspheric Intraocular lens, Toric Lens, Preloaded Toric Lens in single application.</p> <p>9. Firm has not submitted revised LOA.</p> |
| 10. | <p>M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore.</p> <p>(ELI- 00087)</p> <p>R&I detail 08-07-2025 Fee: 25,000/- Slip: 75267236</p> | <p>Legal Manufacturer: Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany.</p> <p>Manufacturing Sites: 1. Richard Wolf GmbH, DE-75438 Knittlingen, Pforzheimer Strabe 32, Germany. 2. Merz tronic GmbH, DE-78054 Villingen-Schwenningen, Siederstr. 50 Germany. 3. Kogel GmbH, DE-75038 Oberderdingen, Hagenfeldstrasse 4, Germany.</p> <p>• LOA Type: Original Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 26-06-2024</p> | <p>Brand name: Camera Head, Controller, Remote Control USB & Perforated Basket for Camera Head</p> <p>Generic Name: Camera Head, Controller, Remote Control USB & Perforated Basket for Camera Head</p> <p>Applied as: System</p> <p>Class: A</p> <p>Model/Codes/Sizes (as per application & FSC):</p> <ul style="list-style-type: none"> • Camera Head 85525942 85525902 5525933 • Lens 85261504 85261.501 5261504 | <p>MDB approved LOGIC 4K CAMERA HEAD (code 85525942) only subject to submission of brand name. Firm will apply others devices in separate application.</p> |

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| | | <ul style="list-style-type: none"> • ISO Certificate Type: Original Notarization: Notarized Validity: 28-11-2027 | 85261144 85261244 85261272 85261.322 5257141 5257171 5257.271 <ul style="list-style-type: none"> • Camera Controller 5525301 5525201 5525105 5525833 85525812 • Manual Remote Control USB 5525401 • Perorated Basket for Camera Head 38002 Service life: Not mentioned. | |
| 11. | M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore. (ELI- 00087) R&I detail 08-07-2025 Fee: 50,000/- Slip: 75175126850 | Legal Manufacturer: Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany. Manufacturing Site: 1.Richard Wolf GmbH, DE- 75438 Knittlingen, Pforzheimer Strabe 32, Germany. <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 31-12-2025 • FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 26-06-2024 • ISO Certificate Type: Original Notarization: Notarized Validity: 28-11-2027 | Brand Name: Insufflator 45 Basic FR 45L/Min & Insufflation Tube System Generic Name: Insufflator & Insufflation Tube System Applied as: System Class: B Model/Codes/Sizes (as per application & FSC): <ul style="list-style-type: none"> • 2235021 (Insufflator 45 Heat FR 45L/Min) • 2235001 (Insufflator 45 Basic FR 45L/Min) • 2235031 (Insufflator 45 EVAC+ Heat FR 45L/Min) • 2235011 (Insufflator 45 EVAC FR 45L/Min) • 8170.101 (Insufflation Tube Set L 2.5M) Service life: Not mentioned. | MDB approved Insufflator 45 Heat FR 45L/Min (code 2235021) only subject to submission of brand name. Firm will apply others devices in separate application. |

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| 12. | <p>M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore.</p> <p>(ELI- 00087)</p> <p>R&I detail 08-07-2025 Fee: 50,000/- Slip: 61802386</p> | <p>Legal Manufacturer: Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany.</p> <p>Manufacturing Site: 1. Richard Wolf GmbH, DE-75438 Knittlingen, Pforzheimer Strabe 32, Germany. 2. Henke-Sass, Wolf GmbH, DE-78532 Tuttlingen, Keltenstrabe 1, Germany. 3. Richard Wolf, Betriebsstatte Berlin, DE-10553 Berlin Reuchlinstr. 11, Germany.</p> <p>• LOA Type: Original Notarization: Notarized Validity: 31-12-2025</p> <p>• FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 26-06-2024</p> <p>• ISO Certificate Type: Original Notarization: Notarized Validity: 28-11-2027</p> | <p>Brand Name: Panoview Telescope Blue</p> <p>Generic Name: Medical endoscope</p> <p>Applied as: Family</p> <p>Class: B</p> <p>Model/Codes/Sizes (as per application & FSC):</p> <ul style="list-style-type: none"> • 8654.531 (Telescope Blue 12° Ø 4MM WL 298MM) • 8654.522 (Telescope Blue 30° Ø 4MM WL 299MM) • 8650.515 (Telescope Blue 70° Ø 4MM WL 303MM) • 8650.514 (Telescope Blue 0° Ø 4MM WL 298MM) • 8934462 (Telescope 30° Ø 10MM WL 305MM) • 89344416 (Telescope 0° Ø 10MM WL 440MM) • 89344436 (Telescope 50° Ø 10MM WL 440MM) • 8934461 (Telescope 0° Ø 10MM WL 305MM) • 89344426 (Telescope 30° Ø 10MM WL 440MM) • 8934463 (Telescope 50° Ø 10MM WL 305MM) • 8935462 (Telescope Ø 5.5MM WL 300MM) • 8935461 (Telescope Ø 5.5MM WL 300MM) <p>Service life: Not mentioned.</p> | <p>MDB approved the Panoview Telescope Blue with following codes:</p> <ul style="list-style-type: none"> • Telescope Blue 0° Ø 4mm WL 298mm. • Telescope Blue 12° Ø 4mm WL 298mm. • Telescope Blue 30° Ø 4mm WL 299mm. <p>Telescope Blue 70° Ø 4mm WL 303mm.</p> <p>Firm will apply other in separate application.</p> |
| 13. | <p>M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore.</p> <p>(ELI- 00087)</p> <p>R&I detail 08-07-2025 Fee: 50,000/- Slip: 49008141332</p> | <p>Legal Manufacturer: Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany.</p> <p>Manufacturing Sites: 1. Kurt Semrau GmbH, DE-78532 Tuttlingen, Gansacker 64, Germany. 2. Richard Wolf GmbH, DE-75438 Knittlingen, Pforzheimer Strabe 32, Germany.</p> | <p>Brand name: Suction tube, irrigation tube set & Irrigation pump system</p> <p>Generic Name: Suction tube, irrigation tube set & Irrigation pump system</p> <p>Applied as: System</p> <p>Class: B</p> | <p>Deferred (last opportunity) for the followings:</p> <ol style="list-style-type: none"> 1. submission of the Brand name. 2. Justification of the grouping. 3. submission of the |

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| | | <p>3.W.O.M. World of Medicine GmbH, DE-10587 Berlin, Salzufer 8, Germany</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 31-12-2025 • FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 26-06-2024 • ISO Certificate Type: Original Notarization: Notarized Validity: 28-11-2027 | <p>Model/Codes/Sizes (as per application & FSC):</p> <ul style="list-style-type: none"> • 8171402 (Suction Tube) • 2216001 (LAP Suction/Irrigation Pump) • 817123 (Irrigation Tube) • 8385.901 (Suction Irrigation Handle) • 4171223 (Irrigation Tube Set Spike L 3M) • 4171225 (Suction/Irrigation Tube Set L 3M) • 8171223 (Irrigation Tube Set Spike) <p>Service life: Not mentioned.</p> | brochure/catalogue. |
| 14. | <p>M/s. Verizon, 60-D, F.C.C. Zahoor Elahi Road, Gulberg-4, Lahore.</p> <p>(ELI- 00087)</p> <p>R&I detail 08-07-2025 Fee: 25,000/- Slip: 78805408660</p> | <p>Legal Manufacturer: Richard Wolf GmbH, Pforzheimer Strabe 32 75438 Knittlingen, Germany.</p> <p>Manufacturing Site: 1.Richard Wolf GmbH, DE-75438 Knittlingen, Pforzheimer Strabe 32, Germany 2.ITD GmbH Office Neubiberg, DE-85579 Neubiberg, Lilienthalstr. 19, Germany.</p> <ul style="list-style-type: none"> • LOA Type: Original Notarization: Notarized Validity: 31-12-2025 • FSC Type: Original Issued By: Govt. Body Legalization: Legalized Issue Date: 26-06-2024 • ISO Certificate Type: Original Notarization: Notarized Validity: 28-11-2027 | <p>Brand Name: Unit Cart, Unit Cart Base & Flexon Port System</p> <p>Generic Name: Unit Cart, Unit Cart Base & Flexon Port System</p> <p>Applied as: System</p> <p>Class: A</p> <p>Model/Codes/Sizes (as per application & FSC):</p> <ul style="list-style-type: none"> • Unit Cart 32116011 (Unit Cart) 82116015 (Unit Cart Premium Electr. 220-230 V AC) • Unit Cart Base Electr. 220-240V AC 32116014 • Flexon-Port 32116103 (Flexon-Port 350+400 (103CM)) 32116058 (Flexon-Port 300 (58CM)) 32116068 (Flexon-Port 400 (68CM)) 32116093 (Flexon-Port 350+300 (93CM)) | <p>Deferred (last opportunity) for the followings:</p> <ol style="list-style-type: none"> 1. submission of the Brand name. 2. Justification of the grouping. 3. submission of the brochure/catalogue and FSC. |

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| | | | Service life: Not mentioned. | |
| 15. | <p>Applicant Name:</p> <p>Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi</p> <p>ELI-01304</p> <p>Date of R&I 26-06-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 25496997</p> | <p>Name of Manufacturer:</p> <p>M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD 20878, USA</p> <p>LOA Validity: 30-04-2027 (Copy)</p> <p>FSC: USA Validity: 18-03-2027(Copy)</p> <p>ISO Validity: 28-11-2027 (Copy)</p> <p>EU QA/ EC Certificate</p> | <p>Brand name:</p> <p>Medifil II Particles Medifill II Collagen Particle</p> <p>Generic Name: Collagen Particles Collagen Based Wound Care Dressing</p> <p>Class-D</p> <p>Shelf life: 5 Years</p> <p>Models/ Specification</p> <p>Applied as Single</p> | Approved. |
| 16. | <p>Applicant Name:</p> <p>Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi</p> <p>ELI-01304</p> <p>Date of R&I 26-06-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 6371025106</p> | <p>Name of Manufacturer:</p> <p>M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD 20878, USA</p> <p>LOA Validity: 30-04-2027 (Copy)</p> <p>FSC: USA Validity: 18-03-2027(Copy)</p> <p>ISO Validity: 28-11-2027 (Copy)</p> <p>EU QA/ EC Certificate</p> | <p>Brand name:</p> <p>SkinTemp II</p> <p>Generic Name: Collagen Sheets</p> <p>Class-D</p> <p>Shelf life: 5 Years</p> <p>Models/ Specification</p> | Approved. |
| 17. | <p>Applicant Name:</p> <p>Akbar Biotech, Plot No. 5-C, Mezzanine Floor, Bukhari Commercial, Lane No. 06, Phase 06, DHA, Karachi</p> <p>ELI-01304</p> <p>Date of R&I 26-06-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 24443048499</p> | <p>Name of Manufacturer:</p> <p>M/s Human Biosciences Inc. 940 Clopper Road, Gaithersburg, MD 20878, USA</p> <p>LOA Validity: 30-04-2027 (Copy)</p> <p>FSC: USA Validity: 18-03-2027(Copy)</p> <p>ISO Validity: 28-11-2027 (Copy)</p> <p>EU QA/ EC Certificate</p> | <p>Brand name:</p> <p>Collatek Collagen Gel</p> <p>Generic Name: Collagen Wound Dressing</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification</p> | Approved subject to submission of shelf life studies. |

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| 18. | <p>Iqbal and Company,</p> <p>Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector, E-11/4, Islamabad, Pakistan.</p> <p>ELI-00117</p> <p>Date of R&I 28-04-2025</p> <p>Fee Details: Paid Fee: 62030/- Fee Challan No: 0349520396</p> | <p>Legal Manufacturer:</p> <p>MEDICAL COMPONENTS INC DBA-Medcomp</p> <p>Address: 1499 DELP DRIVE HARLEYSVILLE, PA 19438, USA.</p> <p>LOA Validity: 31-12-2025 (Copy)</p> <p>FSC: USA Validity: 27-05-2026 (notarized)</p> <p>ISO Validity: 28-09-2025</p> <p>EC validity: 26-05-2024 (Copy)</p> | <p>Brand Name:</p> <p>Duo-Flow Soft-line Catheter Set T73M - 7F X 7CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T73MGL - 7F X 7CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T74M - 7F X 10CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T74MGL - 7F X 10CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T94M - 9F X 12CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T94MGL - 9F X 12CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T96M - 9F X 15CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET T96MGL - 9F X 15CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER.</p> <p>Double Lumen Hemodialysis Catheter Set</p> <p>Class D</p> <p>Shelf Life : 5 Years</p> | <p>Approved Duo-Flow Soft-line Catheter Set T73M - 7F X 7CM DUO-FLOW® SOFT-LINE® DOUBLE LUMEN HEMODIALYSIS CATHETER BASIC SET only. Firm will apply other in separate application.</p> <p>MDB constituted the following sub- committee for evaluation of the devices that require registration of devices as family of the sets.</p> <p>1. Ms. Tazeen Saeed Bukhari, Biomedical Engineer (Chairperson). 2. Ms. Sadaf Ahmad (coordinator). 3. Muhammad Ashfaq (Member).</p> |
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| | | | Applied as: Family | |
| | | | Models/ Specification | |
| 19. | <p>M/s AMB HK Enterprises (Pvt.) Ltd., 2nd Floor Plaza 60, Commercial Block-K Phase-1, DHA, Lahore.</p> <p>ELI-00863</p> <p>Date of R& I 27-06-2025</p> <p>Fee: 31,000/- Slip # 5218031569</p> | <p>Name of Manufacturer: Guangdong Zhongai Medical Technology Co. Ltd., No.1 Shaping Village, Baidu Town, Meixian District 514700 Meizhou, Guangdong, China.</p> <p>• LOA: Not submitted.</p> <p>• FSC Type: Copy Issued By: MPA Legalization: Not Legalized Validity: 17-11-2025</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 31-08-2026</p> <p>• EU QMS Certificate: Type: Copy Notarization: Not Notarized Validity: 27-09-2028</p> | <p>Brand name: Sure-Guard</p> <p>Generic Name: Sterile Hollow Fiber Dialyzer (Low Flux)</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Code/sizes (as per FSC & Application): V-16L V-17L V-18L V-19L V-20L</p> <p>Shelf Life: 3 Years</p> | Approved |
| 20. | <p>M/s AMB HK Enterprises (Pvt.) Ltd., 2nd Floor Plaza 60, Commercial Block-K Phase-1, DHA, Lahore.</p> <p>ELI-00863</p> <p>Date of R& I 27-06-2025</p> <p>Fee: 31,000/- Slip # 94194435</p> | <p>Name of Manufacturer: Guangdong Zhongai Medical Technology Co. Ltd., No.1 Shaping Village, Baidu Town, Meixian District 514700 Meizhou, Guangdong, China.</p> <p>• LOA: Not submitted.</p> <p>• FSC Type: Copy Issued By: MPA Legalization: Not Legalized Validity: 17-11-2025</p> <p>• ISO – Certificate: Type: Copy Notarization: Not Notarized Validity: 31-08-2026</p> <p>• EU QMS Certificate: Type: Copy Notarization: Not Notarized Validity: 27-09-2028</p> | <p>Brand name: Sure-Guard</p> <p>Generic Name: Sterile Hollow Fiber Dialyzer (High Flux)</p> <p>Applied as: Single</p> <p>Class: C</p> <p>Code/sizes (as per FSC & Application): V-16H V-17H V-18H V-19H V-20H</p> <p>Shelf Life: 3 Years</p> | Approved. |

DEFERRED CASES (LOCAL MANUFACTURING)

| Name & Address of Establishment | Name of Medical Devices With Size | Decision |
|--|--|---|
| <p>21. Caraway Diagnostics, Plot No. 12, Street N-3, National industrial Zone Rawat, Rawalpindi (ELM-0092) [958-6L]</p> <p>License permits the manufacture of following medical devices in Liquid Section for IVD Products;</p> <ol style="list-style-type: none"> 1. Diluent for Hematology Analyzer, 2. Cleaning Solution for hematology analyzer 3. Lyse (IVD) 4. Reagent for quantitative determination of Hemoglobin (Hb) 5. -Reagent for quantitative determination of Total Protein 6. Reagent for quantitative determination of Creatinine 7. Reagent for quantitative determination for Bilirubin. <p>D. No. 13158 dated 15-05-2025.</p> | <p>Cleaner -CA</p> <p>Analyzer System Cleaner "Probe / Flow Cell Cleaner" "Maintenance Wash Solution"</p> <p>Ingredients: Detergents...<1.0 % Buffers.... <1.0% Preservatives.... <0.5% Stabilizers.... <0.5% in ion free water.</p> <p>Class: A Shelf Life: 3 Years Fee: 6000 Fee Slip No. 7408981643</p> | <p>Approved subject to verification of the formulation/ composition of approved Analyzer System Cleaner "Probe / Flow Cell Cleaner" "Maintenance Wash Solution"</p> |

DEFERRED CASES OF IMPORT

| Importer Name | Manufacturer Details | Name of MD / Class / Codes / Shelf life / etc. | Decision |
|--|--|--|---|
| <p>Kokab Enterprises No. G-56, Billys Shoppers Galleria, Gulistan-e-jauhar, Block 18, Karachi</p> <p>(ELI-00544)</p> <p>Evaluator: AD-IV [3599]</p> | <p>Manufacturer: Preservation Solutions Inc. 1099 Proctor Drive, Elkhorn, WI 53121 USA</p> <p>Carnamedica Sp. ZO. O. ul. Olszynki Grochowskiej 21 lok. U6, 04-281 Warsaw, Poland</p> <p>Exported by: Bridge to Life Limited 1 Filament Walk LU 311 (The Light Bulb) Wandsworth, England SW 18 4GQ United Kingdom.</p> | <p>Belzer UW Cold Storage Solution</p> <p>Generic Name: (University of Wisconsin Solution)</p> <p>Class D</p> <p>Shelf life 24 months</p> | <p>Board approved the Belzer UW Cold Storage Solution (University of Wisconsin Solution). The Board Authorized Chairman MDB to give personal hearing to the M/s Healthline Pharmaceuticals currently known as Diligent Health Solution for de- registration of his product, before issuance of Registration letter.</p> |

| | |
|---|--|
| Name | Name : Shams Scientific Traders, |
| Address of Importer | Address of Importer: 22-Y-J Madina Town, Faisalabad |
| Detail of ELM/ELI | ELI: 00459 |
| Name Address of Manufacturer | (LEGAL MANUFACTUREUR) Healgen Scientific LLC, 3818 Fuqua Street, Houston, TX 77047, USA. Manufacturing site: Zhejiang Orient Gene Biotech Co., Ltd., 3787, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou Zhejiang, China. |
| Brand Name | Healgen (H. Pylori Ab Rapid Test Cassette (Feces)) Firm has submitted that correct name of the device is Healgen (H. Pylori Ag Rapid Test Cassette (Feces)) |
| Country of origin FSC | FSC Spain Date of issue 03-11-2023 (Original and attested, already submitted) |
| Class of medical device | B |
| Stability data/ service life | Shelf Life: 24 Months |
| Documents submitted | Marketing Authorization Letter: LOA valid till 18-02-2024 (Original and notarized, already submitted) |
| Marketing Authorization Letter: | Production Quality Management System Certificate (ISO 13485) valid till 08-02-2025 |
| Production Quality Management System Certificate (ISO 13485) | Full Quality Assurance Certificate or Equivalent: N/A |
| Full Quality Assurance Certificate or Equivalent: | Design Examination: N/A |
| Design Examination | Declaration of Conformity (Doc): Provided |
| Declaration of Conformity (Doc): | |
| Codes/ sizes/models | GCHP-602a (DoC) |
| Decision | Approved |

POST LICENSE VARIATION (CHANGE OF MANAGEMENT)

| Importer name | Existing Management | Proposed Management | Decision |
|--|---|---|---|
| M/s Gulf Marketing International, 11B/2 Mohallah Satellite town, Abdullah Jan Masjid Street Near Kali Tanki, Said Pur Road Rawalpindi. ELI-00194, dated 18-10-2018 Change of Management | 1. Muhammad Shafiq, Gulf House 11B/2, Mohallah Satel.lite Town, Saidpur Road, Rawalpindi. CNIC:61101-2035270-1 2. Mr. Muhammad Shabbir P/O khas Bhola Mosa Tehsil Sumbrial Distt. Sialkot CNIC No. 61101-2026893-1 | Muhammad Shafiq, Gulf House 11B/2, Mohallah Satel.lite Town, Saidpur Road, Rawalpindi. CNIC:61101-2035270-1 Akifa Batool, House No.11-B/2, Block-B, Satellite Town, Saidpur Road, Rawalpindi. CNIC:33100-9963420 | The MDB deferred the case and decided that current management will submit the succession or transfer of shares to the legal heirs and from the legal heirs to the proposed management from the civil court, magistrate/civil judge. Till the approval of the management, all other application of the firm will not be entertained. |

Deferred Cases for Import

| S. No | Company Name | Name of Manufacturer and Documents details | Name of Medical Device | Decision. |
|-------|---|--|--|--|
| 1. | Global Clinical Cura 18, Mian Iqbal Road Westridge 1, Rawalpindi ELI: 00196 [3724] Evaluator: DD-1 | Legal Manufacturer: M/s Beijing Wantai Biological Pharmacy Enterprises Co., Ltd, No. 31 Kexueyuan Road Changping District Beijing P.R China FSC: China Valid till: 2023/03/22. ISO 13485 valid upon 18-01- 2025 | Diagnostic kit for T cell infected with Mycobacterium Tuberculosis (TB-IGRA) Codes & sizes: Class-C Shelf Life: 12 months Fee: 50000 Date of Application:02-02- 2023 | Deferred Final opportunity of submission of documents. • Justification for not submission of reply since 2024. • The validity of FSC & Notarized CE has been expired so the case cannot be approved for the subject kits the decision of 65 th meeting held on 25-26 th January, 2024 is reiterated. |

ADDITIONAL AGENDA

Item No. 1: DEFERRED CASES AGENDA FOR ENLISTMENT OF IMPORTED MEDICAL DEVICES

DEFERRED CASES IMPORT

Rana Ahsan-ul-Haq Athar – Deputy Director

| S# | Importer Name | Manufacturer Details | Name of MD / Class / Codes / Shelf life / etc. | Decision |
|-----|---|--|---|----------|
| 22. | <p>Applicant Name:</p> <p>Global Marketing Services, 111, Hali Road, Westridge 1, Rawalpindi</p> <p>ELI-00109</p> <p>Date of R&I 04-07-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 3683919435</p> | <p>Name of Manufacturer:</p> <p>M/s GreatBatch Medical, 2300 Berkshire Lane North, Minneapolis, MN 55441 USA</p> <p>LOA Validity: 31-12-2026 (Copy)</p> <p>FSC: USA Validity: validity 04.2026</p> <p>ISO 13485 Validity: 10.12.2027</p> <p>EU QA/ EC Certificate 28-02-2026</p> <p>Design examination certificate notarized 15.09.2029</p> | <p>Brand name:</p> <p>Myopore</p> <p>Generic Name: Sutureless Pacing Lead</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification 511210 (25cm), 511211 (35mm), 511212 (54 cm)</p> | Approved |
| 23. | <p>Applicant Name:</p> <p>Global Marketing Services, 111, Hali Road, Westridge 1, Rawalpindi</p> <p>ELI-00109</p> <p>Date of R&I 10-06-2025</p> <p>Fee Details: Paid Fee: 62,000/- Fee Challan No: 401504968</p> | <p>Name of Manufacturer:</p> <p>Abbott Medical 15900 Valley View Court, Sylmar, California-91342, USA</p> <p>Manufacturing site: Abbott Medical (Also Known as ST, Jude Medical) 15900 Valley View Court, Sylmar, California, USA</p> <p>Abbott Medical (Also Known as ST, Jude Medical) Plot No. 102, Lebuhraya Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia, Country, Malaysia</p> | <p>Brand name:</p> <p>Allure RF</p> <p>Generic Name: Cardiac Resynchronization Therapy Pacemaker</p> <p>Class-D</p> <p>Shelf life: 18 months</p> <p>Models/ Specification PM 3222</p> | Approved |

| | | | | |
|-----|--|--|--|-----------------|
| | | <p>Abbott Medical (Also know as ST Jude Medical) Puerto Rico, LLC Lot a Interior No. 2 RD Km 67.5 Santana Industrial Park, Arecibo, PR USA</p> <p>LOA Validity: 31-12-2026 (Copy)</p> <p>FSC: USA Validity: 31-03-2027 (Copy)</p> <p>ISO Validity: 31-03-2028 (Copy)</p> <p>EU QA/ EC Certificate Validity: 14-08-2027</p> | | |
| 24. | <p>Applicant Name:</p> <p>Global Marketing Services, 111, Hali Road, Westridge 1, Rawalpindi</p> <p>ELI-00109</p> <p>Date of R&I 10-06-2025</p> <p>Fee Details: Paid Fee: 100000/- Fee Challan No: 15622816060</p> | <p>Name of Manufacturer:</p> <p>Abbott Medical 15900 Valley View Court, Sylmar, California-91342, USA</p> <p>Manufacturing site: Abbott Medical (Also Known as ST, Jude Medical) 15900 Valley View Court, Sylmar, California, USA</p> <p>Abbott Medical (Also Know as ST, Jude Medical) Plot No. 102, Lebuhraya Kampung Jawa, Bayan Lepas, Industrial Zone, 11900 Penang, Malaysia, Country, Malaysia</p> <p>Abbott Medical (Also know as ST Jude Medical) Puerto Rico, LLC Lot a Interior No. 2 RD Km 67.5 Santana Industrial Park, Arecibo, PR USA</p> <p>LOA Validity: 31-12-2026 (Copy)</p> <p>FSC: USA Validity: 05-09-2026 (Copy)</p> <p>ISO Validity: 31-03-2028 (Copy)</p> <p>EU QA/ EC Certificate Validity: 14-08-2027</p> <p>DE Validity: 23-05-2029</p> | <p>Brand name:</p> <p>Optisure</p> <p>Generic Name: Defibrillation Leads</p> <p>Class-D</p> <p>Shelf life: 3 Years</p> <p>Models/ Specification</p> | Approved |

| | | | | |
|-----|--|---|--|---|
| 25. | <p>Muslim Scientific Corporation, 3 Syed Moj Darya Road 3rd Floor of Building</p> <p><u>Warehouse Address:</u> House # 57 PAF Colony Zarar Shaheed Road, Lahore</p> <p>ELI: 00431 3036-P 13-06-2022</p> | <p><u>Legal Manufacturer:</u> Taidoc Technology Corporation 127, Wugong 2nd Road, Wugu District, New Taipei City, Taiwan 248</p> | <p>CC TD-4116 (CC Advance Glucometer+ strips) Class-C Shelf life: AS per stability study</p> | <p>The board deliberated on the matter and decided to put a hold on the renewal application and shall grant the firm 06 months time for shifting of premises to a new location. The board shall conduct the inspection and shall decide renewal application in the light of new findings at new location.</p> |
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