**Government of Pakistan**

**Ministry of National Health Services, Regulation & Coordination**

**Drug Regulatory Authority of Pakistan**

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**MINUTES OF THE 12TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 13-05-2019**

12th meeting of the Medical Device Board (MDB) was held in the office of Drug Regulatory Authority of Pakistan, TF Complex, G-9/4, Islamabad on 13th May, 2019. The Secretary MDB referred to Sub-rule (9) Rule (59) of Medical Devices Rules, 2017 where in the absence of Chairman MDB members may elect one of the members to preside over the meeting. The members unanimously elected Dr. Prof. Saqib Shafi Sheikh, member MDB to preside over the meeting as Chairman. Subsequently meeting was chaired by Dr. Prof. Saqib Shafi Sheikh, Interventional Cardiologist, Mayo Hospital, Lahore and was attended by the following:-

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| --- | --- | --- |
| **S.No**. | **Name and Designation / Department** | **Position in the MDB** |
|  | Dr. Prof. Saqib Shafi Sheikh, Interventional Cardiologist, Mayo Hospital, Lahore. | Member / Chairman |
|  | Dr. Abdul Haleem Khan, Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore. | Member |
|  | Mr. Muhammad Alamgir Rao, Director Procurement, Director General Health Services, Lahore. (Nominee of Director General Health, Punjab). | Member |
|  | Mr. Imranullah, Chief Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa). | Member |
|  | Dr. Prof. Sajid Bashir, Professor of Pharmaceutics, University of Sargodha, Sargodha. | Member |
|  | Brig. ® Dr. Waqar Azim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Islamabad. | Member |
|  | Mr. Muhammad Asghar, CEO, Cyber Soft Technologies, Lahore. | Member |
|  | Mrs. Tazeen S. Bukhari, Biomedical Equipment Planner, Saleem Memorial Trust Hospital, Lahore. | Member |
|  | Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad. | Secretary / Member |

The meeting started with the recitation of the Holy Quran. The Secretary MDB welcomed all the participants and presented the agenda of the meeting.

**Item No.I**. **CONFIRMATION OF MINUTES OF 11TH MEDICAL DEVICE BOARD MEETING**.

**Decision:** The Board confirmed the minutes of the 11th meeting of MDB.

**Item No. II**. **APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO IMPORT MEDICAL DEVICES.**

The following firms have applied for grant of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The recommendations of the panels areas mentioned against each is submitted for consideration of MDB please:-

**Decision:- The MDB decided as mentioned against each:-**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr. No.** | **Name of Establishment** | **Director/ Proprietor / Partners** | **Name of Panel of Inspector(s)** | **Cold Chain**  **(Yes/No)** | **Decisions** |
|  | M/s Dolitso Pakistan Pvt Ltd. Suit No 3, Building 13C, 5th commercial Lane, Sehar commercial Area, DHA Phase 7, Karachi.  **Godown address:**  Same as above | Mr Habib Ahmed Navaid  Mrs. Iffat Fatima Navaid | Ms. Hira Bhutto, AD-I (MD&MC), DRAP, Islamabad.  Hafiz Muhammad Asif Iqbal, AD-V (MD&MC), DRAP, Islamabad | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Hakimsons Pvt ltd.A-58/B, SITE, Mangophir Road, Karachi.  **Godown address:**  Same as above | Nawazish Ali Hakim.  Nayyar Jahan Hakim.  Naveed Hakim. | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Marie Stopes Society, 21 C- Commercial Area, Old Sunset Boulevard, DHA Phase 2, Karachi.  **Godown address:**  P.No.B-93, Sector 31-A, Korangi Township K.I.A, Karachi. | Ms. Asma Balal  Muhammad Shaiq Usmani  Ronaq Iqbal Lakhani  Arjumand Ahmed Minai | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility subject to provision of DSL |
|  | M/s Creative Network Solution., G-170, G-199 Naz Plaza M.A Jinnah Road, Karachi.  **Godown address:**  Same as above | Jawaid Hussain. | -do- | No | **Approved** for warm range (above 30°C) medical devices with limited storage without cold chain facility. |
|  | M/s V-Care International, Maznine Floor, Flat No 02, Plot No 8-C, 6th Sunset Commercial Lane, 24th Commercial Street, Phase II, Extension DHA, Karachi.  **Godown address:**  Plot No. 23, D/1, Khayaban-e-Jami, Phase-II Extension DHA, Karachi. | Abdul Hameed Khan  Sikandar Khan | -do- | No. | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Analytical Measuring System (Pvt) Ltd, AMS House 14-C, Main Sehar Commercial Avenue, Lane No 4, Khayaban e Sehar, DHA Phase VII, Karachi.  **Godown address:**  Same as above | Zahid Mustafa  Syed Saad Mustafa | -do- | Yes | **Approved** for storage of cold chain and warm range (above 30°C) medical devices. |
|  | M/s Sapphire International, Room No 903, 9th Floor Uni Center, I.I. Chundrigar Road Karachi.  **Godown address:**  Same as above | Muhammad Nadeem Malik | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Bench Mark Corporation, A-706, 7th Floor, Saima Trade Tower, I.I Chundrigar Road, Karachi.  **Godown address:**  M-12, Mezzanine Floor, Saima Trade Tower, I.I.Chundrigar Road, Karachi. | Faraz Ahmed | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Mehran Dental Supplies,  Headoffice:  Office No. 207 SF14, 2nd Floor , Apwa Complex opposite IBA & AMP. Ankle Saria Hospital Karachi.  Godown:  F-12, 2nd Floor, Apwa Complex Opp. Ankle Saria Hospital, Karachi. | Dhanraj Assnani | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s S.S. Surgical Point, Building No 111-C, Mezzanine Floor, Phase II Ext DHA, Karachi.  **Godown address:**  Same as above. | Sardar Humayun Rizwan.  Shahan Humayun. | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Organs Pharma, Office No 2, 2nd Floor Plot No. 50-D Khyaban e Ittehad Muslim Commercial, Phase VI, DHA, Karachi.  **Godown address:**  Same as above | Saif Ur Rehman.  Atiq Ur Rehman  Kashif Rehman | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Galaxy Pharma (Pvt) Ltd., D-180, Rojhan Street, Block 5, Clifton Karachi.  **Godown address:**  Same as above | Kashif Rehman | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s CSM Pakistan (Gurantee) Ltd.,23-C/ Commercial Area,Old Sunset Boulevard, DHA Phase 2, Karachi  **Godown address:**  P.No.C-21, Sector 31-A, Mehran Extension, Korangi Industrial Area, Karachi. | Amos Nadeem.  Mohsina Ahsan Bilgrami  Naheed Khuhro | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Bios, Building 2C, 12 Commercial Phase II Ext DHA, Karachi.  **Godown address:**  Same as above. | Munir Ahmed | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s IHI Integrated Human Initiatives, Elaaf Center 1, First Floor, C-5/C-1, Lane-3, Khyaban e Nishat, Phase 6 DHA,Karachi. | Khalid Qureshi | -do- |  | **Rejected** due to outsource storage facility. |
|  | M/s Kaf Surgical & Disposable Equipment, Shop No 20, Medicine Corner, Mezzanine Floor, Medicine Market Denso Hall, Karachi.  **Godown address:**  Shop No.10, 3rd Floor, Medicine Corner, Medicine Market, Denso Hall, Karachi. | Kausar Parveen | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Kingston Health Crafts (Pvt) Ltd, Mezzanine Floor Building No 5C, Lane No 10, Commercial Area, Khayaban- e- Sehar Phase 7, DHA,Karachi.  **Godown address:**  Same as above. | Arshad Nawab  Omar Nawab | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Bayer Pakistan (Pvt) Ltd C-21, SITE, Karachi. | Imran Ahmad Khan  Muhammad shafiq | -do- | No | **Approved** for limited stoarage facility for medical devices without cold chain fcility. |
|  | M/s Elegant Health Services, Suit No.123-124, 1st Floor, SP Chamber, SITE, Karachi.  **Godown address:**  House NO.80, Mussarrat Colony, Near Rehmania Masjid, Nazimabad No.1, Karachi. | Sahibzada Adeel Ahmed | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Zam Zam Corporation, Suit No.205-206, 2nd Floor, 6-CL-10 Beaumont Plaza, Beaumont Road, Karachi.  **Godown address:**  Suit No.10, Ground Floor, 6-CL-10 Beaumont Plaza, Beaumont Road, Karachi. | Muhammad Iqbal. | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Lab Line, 98, National Medicine Market, Arambagh Road, Karachi.  **Godown address:**  Same as above. | Jahnagir Chishty | -do- | Yes | **Approved** for storage of cold chain medical devices. |
|  | M/s Bio Medical Technologies, 407, 4th Floor Madina City Mall, Abdullah Haroon Road, Karachi.  **Godown address:**  408, 4th Floor Madina City Mall, Abdullah Haroon Road, Karachi. | Joaquim Alvares | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Melamine Emporium, 814, Star City Mall, Saddar, Karachi.  **Godown address:**  Same as above. | Abdul Munim Akif | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Technology Links (Pvt) Ltd, 4/18 Rimpa Plaza, 4th Floor, M.A Jinah Road, Karachi.  **Godown address:**  Room No.4/4, Rimpa Plaza, 4th Floor, M.A Jinah Road, Karachi. | Zubair Farooqui | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s SK Surgical, 60 C, Mezzanine Floor, 11th Commercial Street, DHA Phase-II, Karachi.  **Godown address:**  Same as above. | Muhammad Kaleem | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Sy,AH Impex  Head Office:  1-6/15 Sector 5, Korangi Industrial Area, Karachi.  Godown address: Same as above | Syed Omer Ahmed | Mr. Muhammad Ayub Naveed, AD-II (MD&MC), DRAP, Islamabad.  Mrs. Unum Zia Shamsi, AD-IV (MD&MC), DRAP, Islamabad. | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Diabetapak (Pvt) Ltd  Head Office:  Showroom No 3 Ground Floor, Dadabhoy Centre, Plot ST-11 Shahrah- e- Faisal Karachi.  Godown address: Same as above | Mr. Shakaib Ahmed Qureshi  Farah Mumtaz | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Battla Brothers  Head Office:  Shop No:12 H.J Centre, Kutchi Gali No 2. Marriot Road Karachi.  Godown address: C/16, 3rd floor H.J Centre, Kutchi Gali No 2. Marriot Road Karachi. | Naseem Akhtar Battla | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Biomadics  Head Office:  No 4, Ground Floor, Happy Heights, Modern Housing Society, Shaheed-e- Millat Road, Karachi.  Godown address: No 5, Ground Floor, Happy Heights, Modern Housing Society, Shaheed-e- Millat Road, Karachi. | Baqi Bullah | -do- | Yes | **Approved** for storage of temperature sensitive and room temperature (limited capacity) medical devices. |
|  | M/s Euronano Diagnostics (Pvt) Ltd  Head Office:  Plot No 225/1/F, Block-2, PECHS Society, Jamshed Town, Karachi. **Godown address:**  Same as above | Alper Akyuz.  Elif Akyuz  Abdullah Abdul Waheed | -do- | Yes | **Approved** for storage of temperature sensitive and room temperature (limited capacity) medical devices subjecdt to provision of DSL. |
|  | M/s Sanoptech  Head Office:  Second Floor, D-22, Block D, North Nazimabad, Karachi.  **Godown address:**First Floor, D-22, Block D, North Nazimabad, Karachi. | Amar Furquan Butt | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Samerian's Enterprises  Head Office:  Shop No 4, First Floor, H.J Centre, Kutchi Gali No.2, Marriot Road, Karachi.  **Godown address:**  Suite # 1, Ground Floor, Cambel Street, SR-7, Shahrah-e-Liaquat, Karachi | Muhammad Hanif Soomro | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Ameer Din Instruments  Head Office:  Office No 1, Mono Garden 3, N.K.C.H.S, Shaheed-e-Millat Road, Karachi. **Godown address:**  Office No 5, Mono Garden 3, N.K.C.H.S, Shaheed-e-Millat Road, Karachi. | Salman-Ul-Arshad  Fasih Ud Din | -do- | No | **Approved** for storage of warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Rehman Medicine Co. Head Office:  Shop No. 1 & 2, First Floor, H.J Centre, Kutchi Gali No.2, Karachi  **Godown address:**Suite # 2, Ground Floor, Cambel Street, SR-7, Shahrah-e-Liaquat, Karachi | Abdul Rehman Soomro | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s K.S Agencies  Head Office:  Office No, 210, Business Arcade, Main University Road, Karachi.  **Godown address:**  33 & 34 Business Arcade, Main University Road, Karachi. | Muhammad Idrees Memon | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Unique Visual System  Head Office:  L-18, Block-17, Gulshan-e-Iqbal Karachi  **Godown address:**  Same as above | Muhammad Javed Jabbar  Muhammad Raees  Abdul Samad | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Hospital Supply Corporation  Head Office:  42 Darul Aman Housing Society, Block 7 & 8, Karachi.  Godown address:  Same as above **(Inspection for inclusion of cold chain and room temperature medical devices storage facility in ELI-00005).** | Mehtabuddin Feroz.  Muhammad Yahya Feroz  Sohail Feroz. | -do- | Yes | **Approved** for storage of temperature sensitive and room temperature medical devices. |
|  | M/s Martin Dow Marker Specialities (Pvt) Ltd.  Head Office:  D-7 Shaheed-e-Millat Road, Karachi.  Godown address:  Plot No.130, Sector 15,  Korangi Industrial Area, Karachi. (**Inspection for inclusion of room temperature medical devices storage facility in ELI-00160).** | Mr Amjad  Ali Amir  Anis Ahmad Shah. | -do- | Yes | **Approved** for storage of room temperature medical devices. Cold chain facility already approved. |
|  | M/s Jasani Scientifics,  Head Office: Office No. 1, SC-45, Marium Square Chandni Chowk Stadium Road, Karachi.  **Godown Address:**  1. Shop No.2, C-A-34, Karim Palace, Chandni Chowk, Stadium Road, Karachi.  2. Office No. 2, SC-45, Marium Square Chandni Chowk Stadium Road, Karachi. | Arshad Ali Jasani | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Burraq Enterprises  Head Office:  Kishwer House 1/7-B, 2nd Floor, Muhammad Ali Cooperative Housing Society, Karachi.  **Godown Address**: C2, Block N, North Nazimabad, Karachi. | Muhammad Tufail Khanzada | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M./s Green Top Pharma, Head Office:  B-137, Block-D, Five Star Chowrangi, North Nazimabad, Karachi.  **Godown Address:**  Plot No.E-415, Metro Cinema, Orangi Town, Karachi. | Ghulam Akbar | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Kantech Medical System Head Office:  Office No. R-820 Ground Floor, Block-1, Federal B Area, Opposite Delhi College, Karachi.  **Godown Address:**  Same as above | Anwer Baig | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Combined Engineers  Head Office: H.No.246, St. No.17, BMCHS, Sharfabad, Karachi.  Godown Address:  Same as above | Muhammad Altash Butt  Choudhry Muhammad Nadeem  Muhammad Saleem Anwar | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Dentsco International  Head Office:  Suit No M-14 Dada Terrace, Main Shaheed-e-Millat Road, Karachi.  **Godown Address:**  Suit No M-15 Dada Terrace, Main Shaheed-e-Millat Road, Karachi. | Zesheen idrees Daar  Nauman Idrees Dar | -do- | No | **Approved** for storage of room temperature (limited capacity) medical devices without cold chain facility. |
|  | M/s Ethos Healthcare (Pvt) Ltd  **Head Office:**  1st Floor, Plot No 18, Sector 47, Survey 86, Off main Korangi Creek Road, Karachi.  **Godown Address**:  Same as above | Saeed Rasheed  Muhammad Ali Saya | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Ruella Medical,  **Head Office:**  Suit No 1002, 10th Floor, Kawish Crown Plaza, Shahra-e-Faisal,Karachi.  **Godown address:**  same as above. | Kamran Muhammad Khan | -do- | No | **Approved** for storage of room temperature (limited capacity) medical devices without cold chain facility. |
|  | M/s Lucky Lab International  Head Office:  F-6 Usmania Center, Muhammad Ali Housing Society, Commercial Market, Karachi.  **Godown address:**same as above | Muhammad Jawad Akhter | -do- | Yes | **Approved** for storage of temperature sensitive and room temperature medical devices. |
|  | M/s M.N. Enterprise,  Head Office:  Plot No 65/3, B.Y. J.C.H.S., Near Portia Fabric, Bahadurabad, Karachi.  **Godown address:**same as above | Abdul Wahab | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Mydent International  Head Office:  A-16, 4th Floor, Block 13-C, Dashtiyaar Chambers, SB 32, Gulshan-e-Iqbal, Karachi.  **Godown address:**same as above | Sohail Rasheed | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s United Brothers  Head Office:  Office No 301, Mehrab Market Medicine Street No 1, Marriot Road, Karachi.  **Godown address:**Plot No SA: 05-06, Sector 31-B, Shah Muhammad Road, Korangi Industrial Area, Karachi | Khalid Rashid | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Medi Impex  Head Office:  Room No 109 Rehmani Chamber, Altaf Hussain Road, New Challi Karachi.  **Godown address:**Room No 103 Rehmani Chamber, Altaf Hussain Road, New Challi Karachi. | Shahzad Malik  Farrukh Naseem | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Surgical World  **Head Office:**  Office No 105, 1st Floor, Rehmani Chambers, Altaf Hussain Road New Challi, Karachi.  **Godown address:**Office No 104, 1st Floor, Rehmani Chambers, Altaf Hussain Road New Challi, Karachi. | Fahad Anis | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Biotech Pakistan  Head Office:  Suit No. 302 & 303, 3rd Floor,  Tahir Plaza, KCHS., Shahrah-e-Faisal,  Karachi.  **Godown address**: H.No 3626, TP II, Street III, Mehmoodabad, Karachi | Kashif Latif | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Leven Medical Care  Head Office:  8-C Ground Floor, St No. 3, Shah Jamal, Lahore.  Godown address:  Same as above | Adeel Ur Rehman | Ms. Hira Bhutto, AD-I (MD&MC), DRAP, Islamabad.  Mrs. Unum Zia Shamsi, AD-IV (MD&MC), DRAP, Islamabad | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Pharm Canada Pakistan  Head Office:  391 -B, Faisal Town, Lahore. **Godown address**:  Same as above | Asadullah Khan  Assad Maqbool | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Forcare  Head Office:  788, Block J-2 M.A, Johar Town Lahore.  **Godown address**:  Same as above | Shaikh Naeem Ahmad  Shoukat Ali  Talat Mehmood Qureshi. | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s 3N- Lifemed Head Office:  18/20N, Gulberg-II, Lahore.  **Godown address**:  Same as above | Nazir Ahmad | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Basic Pharmaceuticals (Pvt) Ltd  Head Office:  14-A, Babar Block, New Garden Town Lahore.  **Godown address:**  Same as above | Jaleel ur Rehman (CEO)  Rafiq-ur-Rehman | -do- | Yes | **Approved** for storage of temperature sensitive and room temperature medical devices |
|  | M/s Martin Dow Marker Specialties (Pvt) Ltd.  Head Office:  D-7 Shaheed-e-Millat Road, Karachi.  **Godown Address:**  75/1-M, Quaid-e-Azam Industrial Estate, Township Kot Lakhpat Lahore.  **(For inclusion of Warehouse in ELI-00160).** | Mr Amjad  Ali Amir  Anis Ahmad Shah. | -do- | Yes | **Approved**  for inclusion of Warehouse in existing ELI-00160 for storage of temperature sensitive and room temperature medical devices. |
|  | M/s Accu Sight  Head Office:  131, Nasheman e Iqbal Housing Society Phase 1, Jinnah Avenue Lahore.  **Godown Address**:  Same as above | Mr. Zaigham Mansoor Khan | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s McPharm International (Pvt) Ltd  Head Office:  219-A Lalazar Commercial Market, Raiwind Road Lahore.  **Godown Address**:  Same as above | Azhar Farooq  Tahir Imtiaz  Aasim Farooq | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Votex Pharma (Pvt) Ltd  Head Office:  60-A, Faisal Town Lahore.  **Godown Address**:  Same as above | Aasim Shahzad  Shala Aasim (CEO) | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Al Waali Care Concepts  Head Office:  86-Allama Iqbal Road, Chah Baba Shadiwal Street, Garhi Shahu, District Lahore.  **Godown Address**:  Same as above | Abdul Waheed.  Abu Baker Siddique. | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Jet Services International,  Head Office:  231- Block B2, Johar Town Lahore.  **Godown Address**:  Same as above | Muhammad Anas Ali Kasuri.  Syed Imran Arif  Kalim Shuja | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Muslim Scientific Corporation  Head Office:  3-Syed Moj Darya Road, Lahore.  **Godown Address**:  57-B, PAF Colony, Zarar Shaheed Road, Lahore Cantt, Lahore | Sami Ullah Sheikh | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Forward Solutions  Head Office:  Plot No 19-B Qazalbash Chowk, Abdul Sattar Edhi Road Distt, Lahore.  **Godown Address:**  Same as above | Asim Mahmood Khan  Sajid Ali Khan  Muhammad Naeem Khalid | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s KASBN International  Head Office:  422-A-1, Ghalib Market, Gulberg-III, Lahore.  **Godown Address**:  Same as above | Babar Waseem Kayani | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Remington Pharmaceutical Industries (Pvt) Ltd.,  **Head Office:**  18 Km Multan Road, Lahore.  **Godown Address:**  Same as above | Abdul Qadeer Khokhar  Shaheena Qadeer Khokhar  Faisal Qadeer Khokhar  Shahab Qadeer Khokhar | -do- | Yes | **Approved** for storage of temperature sensitive and room temperature medical devices. |
|  | M/s Lens House **Head Office:**  3rd Floor, Musarat Plaza, Ainak Market, Shah Alam Market, Lahore.  **Godown Address:**  Same as above | Muhammad Shahid Alam.  Mrs.Aqsa Shahid. | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Technoware **Head Office:**  PS-65, 2nd floor, UBL Bank, Al-Jannat Building, Robert Road, Nila Gumbad, Lahore  **Godown Address**:  Same as above | Azhar Mehmood Khan | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Heartec  **Head Office:**  1st Floor, 734, Shadman 1, inside Alam Audiology Clinic, District Lahore.  **Godown Address:**  Same as above | Saima Fazal | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Ahmad Medix Pvt Ltd  **Head Office:**  129/6 Quaid-e- Azam Industrial Estate, Township, Lahore.  **Godown Address:**  Same as above | Dr. Sohail Mukhtar Ahmad  Mrs.Kausar Sohail  Mr. Adeel Ahmad | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s HSB Innovation in Health  **Head Office:**  Suite No C-3A, Third Floor, First City Tower, More Samanabad, Lahore.  **Godown Address:**  Same as above | Sarfaraz Ali Shah | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Surgi Vision, Head Office:  Plot No.7-A, Model Town, Lahore.  **Godown Address:**  Same as above | Babar Abbas | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Medilink Trading And Maintenance (Pvt) Ltd  Head Office:  654-D Canal View, Distt Lahore.  **Godown Address:**  Same as above | Rana Amjad Hanif  Mrs Nadia Amjad | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Womas International, Saadat House, Aqsa Street, Capital Road, Nia Miana Pura, Sialkot. | Shees Haider Zaidi | Mr. Muhammad Ayub Naveed, AD-II (MD&MC), DRAP, Islamabad.  Hafiz Muhammad Asif Iqbal, AD-V (MD&MC), DRAP, Islamabad. | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | Mian Scientific Corporation Pvt Ltd., Office No. 534, Jinnah Colony Faisalabad.  **Godown Address:**  273 Rehman Garden, Near City Housing , Chak No.5/J-B, Kamal Pur, Sargodha Road, Faisalabad. | Muhammad Tahir Yaqooq.  Muhammad Abid Yaqoob | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s Shams Scientific Traders, Office No 7, First Floor Sadiq Plaza, P-481-Jinnah Colony, Faisalabad.  **Godown Address:**  22-Y-J, Madina Tower,Faisalabad | Irfan Ayaz | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s Dia Scient International, Room No.11, 12, 13, 14, Emaan Arcade, Iqbal Stadium Road New Civil Line Faisalabad. | Muhammad Ehsan | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s Novatek Pakistan, P-20, 1st Floor, Office No.1, Channab Market, Susan Road, Madina Town, Faisalabad. | Munawwar Hussain Zahid | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Shaheer Pharma Enterprises, House No. 443/2, Bahar Shah Zafar Road, Near Chema Heart Center, Sargodha.  **Godown Address:**  Same as above. | Rana Khalid Ghaffar | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Mukhtar A. Sheikh Memorial Welfere Hospital-Workwers Welfare Board, Jahangirabad, Near Pakarab Fertilizers Limited, Main Khanewal Road, Multan.  **Godown Address:**  Same as above. | Mr. Faisal Ahmad Mukhtar  Mrs Atifa Riffat  Mr. Muhammad Qasim Samad Khan  Mr. Muhammad Bilal  Rehman Naseem  Mukhtar Ahmad Khan  Qamoos Gul Khattak  Maqbool Khan  Zaheer Khan  Mr. Amir Shahnshah Athar | -do- | No | **Rejected.** Establishment Licence to Import (ELI) medical devices are for commercial imports. Since hospitals are exempted from Sales Tax and Customs Duty, therefore, misuse potential exists where a hospital may import medical devices under ELI and sale it commercially. The provision for import of medical devices for hospitals are given under Rule 24 of Medical Device Rules, 2017. |
|  | M/s Abdullah Traders, 3 Green Town, Ghous-ul- Azam Road, Multan.  **Godown Address:**  Same as above. | Fayyaz Ali | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s Nimra Farma, 223/4, Abdul Habib Khan Road, Tariqabad, Rawalpindi | Sabir Sohail Mir  Babar Mir | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Cabbot Surgicals, Ho No CB 6060 Rose Lane 3-A New Lalazar Rawalpindi | Muhammad Attique Shahid | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Amir Enterprises, 1st Floor Plaza No 55, Opp. Security Chekpoint Gate No 1, Gulshan Abad, Adyala Road, Rawalpindi. | Muhammad Asim Khan | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Cent Dix Curative Smc-Pvt ltd, Office No 201-03, 2nd Floor, Platinum Arcade, 11/1 Civic North Commercial, Soan Garden, Islamabad. | Syed Muhammad Zeeshan Haidar | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Life Elements Pvt Ltd, Office No 5 Ground Floor, Nawab Plaza, Shallay Valley, Range Road, Rawalpindi. | Muhammad Irfan Azam  Shazia Irfan | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Swera Phama Distributers, House No 687, Street No 3, Ch Walayat Khan Road, Chaklala Scheme 111, Rawalpindi | Iftikhar Ahmed | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Platinum Corporation,  F-10/7/6 Near Arfeen Masjid Barrage Colony,  Sukkur. | Shoukat Rafique | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s Friends Traders,  Head Office:  Ground Floor, Peshawar Medical Centre, Hussain Plaza, Shoba Chowk, Khyber Bazar, Peshawar.  **Godown Address:**  Lodhi Katrage, Old Bara Road, University Town, Peshawar. | Asadullah Khan Lodhi. | Mr. Muhammad Ayub Naveed, AD-II (MD&MC), DRAP, Islamabad.  Mrs. Unum Zia Shamsi, AD-IV (MD&MC), DRAP, Islamabad. | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | M/s Haris Enterprises,  Head Office:  10A Karachi Market Khyber Bazar Peshawar.  **Godown Address:**  35A Karachi Market Khyber Bazar Peshawar. | Nasrullah.  Sajjad Ullah.  Shamsher Ali Safi. | -do- | Yes | **Approved** for storage of cold chain and room temperature medical devices. |
|  | M/s Medilink International,  S-8 2nd Floor, Alfarid Center Eidgah Road,  Peshawar.  **Godown Address:**  H.No.57, St. No. 2, Zintara Town New Ring Road, Near Charsadda Road, Peshawar. | Muhammad Islam  Abdullah Shah | -do- | No | **Approved** for storage of room temperature medical devices without cold chain facility. |
|  | **Previous Address:**  M/s Asto Life Sciences (Pvt) Limited, 44/1 K-Block, Model Town, Lahore.  **For Change of Establishment Address (New Address) as mentioned below:**  M/s Asto Life Sciences (Pvt) Limited, Plaza No.1, Block Orchard 1, Paragon City, Barki Road, Lahore Cantt. |  | Mr. Asim Rauf,  Additional Director (E&M) DRAP, Lahore. |  | **Approved.** |

**Item No.III. APPLICATIONS FOR GRANT OF ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.**

Secretary MDB informed the Board that the following applications for grant of enlistment of medical devices for import on prescribed form 6-A under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. No** | **Name and Addresses of Establishment** | **Manufacture Details** | **Name of Medical Device with sizes/Class/Shelf Life** | **Brief Description** | **Decisions** |
|  | M/s Scilife Pharma (Pvt) Ltd., 16, KOCHS Amir Khusro Road, Karachi  Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi  (ELI-00187)  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:**  M/s Taian Dalu Medical Instrument Co., Ltd., West Part of Yitianmen Street, Hi-tech Zone Taian, Shandong  (FSC China Valid Till  12-03-2020) | Sci Air Dry Powder Inhaler  Class A  Shelf Life: 5 Years  DL-D01, DL-D02, DL-D03,  DL-D04, DL-D05, DL-D06,  DL-D07, DL-D08  Fee submitted: Rs, 5000/- | Dry Powder Inhaler Device | **Approved** subject to registration of drug by the Registration Board. |
|  | M/s Hashir Surgicals  1. Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar.  2. Office No.05, 2nd Floor, Syed’s Tower, University Road, Peshawar.  3. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar  Evaluator: Muhammad Ayub Naveed | **Legal Manufacturer:**  Jiangsu Kangjin Medical Instruments Co., Ltd.,  Address: Zhenglu Town, Changzhou City, China 213111  FSC China  Valid till 14.12.2019 | Bio Bag  (Urine Bag)  750ml, 2000ml  Class A  Shelf Life: 05 years  Fee submitted: Rs, 5000/- | The Products are clinically used for educing and storing the body fluid or urine with the emiction tube and preventing the cross infection of an infection or other complication of treatment effectively. | **Approved.** |
|  | M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051)  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Jiaxing Meson Medical Material Co., Ltd.,  1F, Building 5, 1880 Renmin Road, Wutong Street, Tongxiang, Jiaxing, ZheJiang Province, China  (FSC China Valid Till 10-05-2020) | Biotape  (Microporous surgical tape)  Class A  Shelf Life: 2 Years  1.25cm x 450cm, 2.5cm x 450cm  5cm x 450cm, 7.5cm x 450cm,  10cm x 450cm,  1.25 cm x 274.32 cm  2.5 cm x 274.32 cm  5 cm x 274.32 cm  7.5 cm x 274.32 cm  10 cm x 274.32 cm  Fee submitted: Rs, 5000/- | Disposable Surgical Tape, Non-sterile | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Jiaxing Meson Medical Material Co., Ltd., 1F, Building 5, 1880 Renmin Road, Wutong Street, Tongxiang, Jiaxing, ZheJiang Provice, China  (FSC China Valid Till 10-05-2020) | Meson  (Adhesive wound dressing tape)  Class A  Shelf Life: 2 Years  10cm x 10m  Ref: MS6506  Fee submitted: Rs, 5000/- | Disposable Surgical Tape Roll, Non-sterile. | **Approved**. |

**Item No.IV. APPLICATIONS FOR RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

Secretary MDB informed the Board that the following applications for grant of renewal of registration of medical devices for import on prescribed form 7-A under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. No** | **Name and Addresses of Establishment** | **Manufacture Details** | **Name of Medical Device with sizes/Class/Shelf Life** | **Brief Description** | **Decisions** |
|  | M/s Anthro Pharmaceuticals (Pvt) Ltd., C19D, Badar Commercial Lane 5, Phase 5 Ext, DHA, Karachi  (ELI-00127) | **Manufacture By:** M/s Shengguang Medical Instrument Co., Ltd., Weiwu Road, Xincheng District, Pingdingshan City, Henan Province.  (FSC China Valid Till 30-11-2023)  **Fee submitted Rs.100,000/-** | AB Disposable Infusion Set (IV Set)  (Reg No. 074654)  Class B  Shelf Life: 3Years  A1, A3, A5, A6, A7, A8, A9 | AB Disposable Infusion Set | The Board approved the renewal of product subject to foreign inspection under Rule 71 of Medical Device Rules, 2017. |
|  | M/s Anthro Pharmaceuticals (Pvt) Ltd., C19D, Badar Commercial Lane 5, Phase 5 Ext, DHA, Karachi  (ELI-00127) | **Manufacture By:** M/s Shengguang Medical Instrument Co., Ltd., Weiwu Road, Xincheng District, Pingdingshan City, Henan Province.  (FSC China Valid Till 30-11-2023)  **Fee submitted Rs.100,000/-** | AB Disposable Cannula (Pen Type)  (Reg No. 074653)  Class B  Shelf Life: 3Years  18G, 20G, 22G, 24G | AB Disposable Cannula (Pen Type) | The Board approved the renewal of product subject to foreign inspection under Rule 71 of Medical Device Rules, 2017. |
|  | M/s Anthro Pharmaceuticals (Pvt) Ltd., C19D, Badar Commercial Lane 5, Phase 5 Ext, DHA, Karachi  (ELI-00127) | **Manufacture By:** M/s Shengguang Medical Instrument Co., Ltd., Weiwu Road, Xincheng District, Pingdingshan City, Henan Province.  (FSC China Valid Till 30-11-2023)  **Fee submitted Rs.100,000/-** | AB Disposable Syringe (Luer Lock and Luer Slip): Conventional Syringe. Safety-Syringe, AD Syringe, Insulin Syringe  (Reg No. 074655)  Class B  Shelf Life: 5Years  0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml | Disposable Syringe | The Board approved the renewal of product subject to foreign inspection under Rule 71 of Medical Device Rules, 2017. |
|  | M/s B.Braun Pakistan (Pvt) Ltd.,  The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi  (ELI-00006) | **Manufacturer:**  M/s B. Braun Melsungen AG Carl-Braun-Strabe 1 34212 Melsungen, Germany  **Manufacturing Site:**  M/s Almo Erzeugnisse Erwin Busch GmbH Grobe Allee 84 34454 Bad Arolsen, Germany  (FSC Germany Issue Date 05-05-2017) | Omnican® 100 (Insulin Syringe)  Class B  Shelf Life: 5 Years  Code:- 9151133S  Fee submitted: Rs.12,500/- | Sterile, Single use Insulin syringe for subcutaneous injection of insulin. | Approved. |

**Item No.V. CHANGE OF HEAD OFFICE ADDRESS**

M/s Roche Pakistan Limited, Karachi have requested for change of their Head Office address on their Establishment License as per details given below:-

|  |  |
| --- | --- |
| **Existing Address as per Establishment License.** | **Proposed / New Address** |
| 37-C, Block-6, P.E.C.H.S, Karachi 75400. | 1st Floor, 37-B, Block-6, P.E.C.H.S, Karachi East 75400. |

They have informed that the address of Warehouse will remain the same and the said change does not have any impact on their Warehouse. The firm has submitted following documents:-

1. Application on Form-2.
2. SECP Form-21 having new office address.
3. Copy of Certificate of Incorporation.
4. Declaration and Undertaking on stamp paper.
5. Copy of Establishment License (ELI-00009) dated 03-08-2018.
6. Copy of DSL having new address.
7. Fee of Rs.10,000/-

Submitted for consideration of MDB please.

**Decision: The Board acceeded to the request of the firm /company and approved their new Head Office address.**

**Item No.VI**. **EXTENSION IN SHELF LIFE.**

M/s Otsuka Pakistan Limited, Karachi has requested for extension in shelf life from 12 months to 2 years of their already registered following imported medical device (registered as drug):-

|  |  |  |  |
| --- | --- | --- | --- |
| **S.No.** | **Regn. No.** | **Name of Medical Device** | **Approved Shelf Life** |
| (i) | 081738 | Firehawk Rapamycin Target Eluting Coronary Stent System | 12 months |

The firm has submitted following documents:-

1. Fee of Rs.5000/-.
2. DEKRA report.
3. Long term stability study of 24 months at 30ºC + 2ºC / 65% RH + 5% along with the relevant attachments of the said medical device.
4. Legalized copy of approval of shelf life of the subject medical device by SFDA China.
5. Original, valid and legalized Free Sale Certificate of the Netherlands.
6. Legalized CE marking documents

The case was placed before the MDB in its 11th meeting held on 1st February, 2019 and the MDB decided as follows:-

*"The Board decided to refer the matter to two Interventional Cardiologist for their opinion before extension of shelf life of product."*

Accordingly the matter was referred to Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist/Cardiovascular Surgeon, Mayo Hospital, Lahore and Maj. (Gen) (R) Dr. Azhar Mahmood Kayani, Executive Director, Rawalpindi Institute of Cardiology, Rawalpindi for their opinion / comments in the matter within 15 days.

In response to our letter, Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist/Cardiovascular Surgeon, Mayo Hospital, Lahore has stated ***that the shelf life of next supply of the above stent can be increased to two years. However this cannot be applied to already existing stock in Pakistan imported and stamped as one year shelf life***. The response from Maj. (Gen) (R) Dr. Azhar Mahmood Kayani, Executive Director, Rawalpindi Institute of Cardiology, Rawalpindi has not yet been received.

Submitted for consideration of MDB please.

**Decision: The Board decided to refer the matter to Prof. Dr. Ejaz Ahmed, Interventional Cardiologist, Multan Institute of Cardiology, Multan for opinion on extension of shelf life of Firehawk Rapamycin Target Eluting Coronory Stent System. The Board also asked the firm to deposit Rs. 20000-/ differential fee for change in particulars. If an opinion is received in favour of extension in shelf life, the approval shall be accorded accordingly.**

**Item No. VII.** **REGISTRATION OF MEDICAL DEVICES PREVIOUSLY REGISTERED AS DRUG.**

**Case No.01.**

M/s Searle Company Limited, Karachi has applied for registration of the following medical devices, previously registered as drug in the name of M/s Vertex Enterprises, Lahore.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.#** | **Regn.No.** | **Brand Name of Medical Device** | **Packing** | **Shelf Life** | **Name of Manufacturer** |
| (i) | 059232 | Medeco I.V. Cannula  14G, 16G, 18G, 20G, 22G &24G. | 100 per box | 5 years | M/s Abu Dhabi Medical Devices Co., Limited, United Arab Eminates. |

The firm has submitted following documents:-

1. Application dossier alongwith Form 7-A for each product.
2. Copy of NOC from M/s Verrtex Enterprises, Lahore regarding transfer of registration of above products.
3. Fee of Rs.100, 000/- for each product.
4. Letters of Authorization regarding above products from the foreign manufacturer wherein it has also been mentioned that M/s Serale Company Limited, Karachi is their Exclusive Agent/Distributor in the territory of Pakistan.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sr No.** | **Name of Importer** | **Name of Manufacturer** | **Name of Medical Device** | **Brief Description** | **Remarks** | **Evaluated by** |
|  | M/s Searle Company Limited,1st Floor, N.I.C.L Building, Abbasi Shaheed Road, Karachi.  (ELI-00057) | **Manufacturer:** M/s Abu Dhabi Medical Devices Co. L.L.C, Mussafah City M43-Block 124, P.O.Box 30485, Abu Dhabi, U.A.E.  (FSC valid till 27-12-2020) | Medeco I.V. Cannula  Class B  Shelf Life: 5 years  Fee submitted: Rs 100,000/- | For the intravenous administration of medication and fluids. |  | Mr.M.Ayub Naveed, AD-II |

It is submitted that M/s Searle Company Limited, Karachi has been issued Establishment Licence to import Medical Devices under MDR, 2017 vide Licence No. ELI-00057, dated 3rd August, 2018.

**Decision: The Board approved the product subject to inspection of the manufacturer abroad under Rule 71 of Medical Device Rules, 2017. The Board also authorized the Secretary, MDB to issue registration of the product if the manufacturing plant is approved by the panel of experts.**

**Item No. VIII.** **CORRECTION OF BRAND NAME.**

M/S Royal Enterprises, Karachi have informed that their following medical device manufactured by M/s Foshan Tpmghe Medical Technology Co., Ltd, China has been enlisted as per detailed below:-

|  |  |  |
| --- | --- | --- |
| S.No. | Reg.No. | Medical Device Name |
| 1 | MDIE-0000023 | Wheel Chair (All Sizes)  Class-A |

The firm has submitted that brand name of medical device is **UNIKA Wheel Chair** while in the enlistment letter the word "UNIKA" has not been mentioned. The firm has requested for issuance of Corrigendum with complete brand name i.e. **UNIKA Wheel Chair.**

It is subitted that the brand name "UNIKA" was inadvertantly missed in agenda as well as in the minutes of the 11th meeting of MDB.

**Decision: The Board acceeded to the request of the firm /company and approved the brand name "UNIKA Wheel Chair".**

**Item No. IX.** **CHANGE OF MANUFACTURER NAME**

M/s Zenith International, Karachi have requested to approve the change of manufacturer name of their following registered imported medical devices from **M/s Sutures India Pvt Ltd, Plot No.13-16 KIADB Industrial Area, Kalanayakkanahalli, Kunigal Taluk, Tumkar District, Karnataka, India** to **M/s Healthium Medtech Private Limited, Plot No.13-16 KIADB Industrial Area, Kalanayakkanahalli, Kunigal Taluk, Tumkar District, Karnataka, India**. The address of the manufacturer will remain same:-

|  |  |  |
| --- | --- | --- |
| S.No. | Reg. No. | Name of Medical Device (s) |
| 1. | 081439 | Trucath Foley Balloon Catheter |

The firm has deposited the fee of Rs.25, 000/- for that purpose (pages 50 & 55/Corr) and submitted following documents:-

1. Copy of registration letter (pages 59-61/Corr)
2. Copy of Establishment Licence to import medical devices (page 62/corr).
3. Approval letter for change of company name isued by Drug Control Department, Government of Karnataka (pages 63-89/Corr) attested by Embassy.
4. Free Sale Certificate of the product issued by Drug Control Department, Government of Karnataka with the new company name i.e. M/s Healthium Medtech Private Limited, Plot No.13-16 KIADB Industiral Area, Kalanayakkanahalli, Kunigal Taluk, Tumkar District, Karnataka, India (Embassy attested) (pages 64-65/Corr).
5. Certificate of Incorporation pursuant to change of name issued by Ministry of Corporate Affairs, Government of India (page 66 /Corr).
6. EC Certificate (Production Quality Assurance) with the new company name (pages 67-70/Corr).
7. ISO 13485 certificates with the new company name (page 71/Corr).
8. Authorization letter (page 72/Corr).
9. Copy of G.M.P Certificate with the new company name (page 73/Corr).

**Decision: The Board acceeded to the request of the firm /company and approved change in name of the firm to M/s Healthium Medtech Private Limited, Plot No.13-16 KIADB Industrial Area, Kalanayakkanahalli, Kunigal Taluk, Tumkar District, Karnataka, India.**

**Item No. X**. **REDUCTION OF SHELF LIFE OF COROFLEX ISAR NEO SIROLIMUS-ELUTING CORONARY STENT SYSTEM" REGISTRATION NO.083394**

M/s B.Braun Pakistan (Pvt) Limited, Karachi has requested for reduction of shelf life of already registered medical device (registered as drug) namely "Coroflex ISAR NeoSirolimus-eluting Coronary Stent System" Registration No.083394 dated 10-03-2017 **from 03 years to 02 years**. The firm has submitted following documents for perusal:-

1. Form 7-A on the prescribed format dully filled and signed.
2. Copy of Establishment License.
3. Stability studies supporting shelf life claim of 24 months (2 years).
4. Fee of Rs.25000/-.
5. Undetaking on stamp paper.

The case is being placed before the MDB with following details for its consideration please:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr No.** | **Name of Importer** | **Name of Manufacturer** | **Name of Medical Device** | **Brief Description** | **Remarks** |
|  | M/s B.Braun Pakistan (Pvt) Limited,  The Forum Suite # 216,  Khayaban-e-Jami, Clifton Block-9,  Karachi  (ELI-00006) | **Manufacturer:** B.Braun Melsungen AG Carl-Braun –Stabe 1 34212 Melsungen, Germany.  **Manufacturing Site:** B.Braun Melsungen AG Vascular Systems Sieversufer 8, 12359 Berlin, Germany.  FSC Germany. Date of issue 18-10-2016. | Coroflex ISAR NEO  Sirolimus-eluting Coronary Stent System   |  |  | | --- | --- | | Dia (mm) | Length (mm) | | 2.0 | 9,12,16,19,24,28,32,38. | | 2.25 | 9,12,16,19,24,28,32,38. | | 2.5 | 9,12,16,19,24,28,32,38. | | 2.75 | 9,12,16,19,24,28,32,38. | | 3.0 | 9,12,16,19,24,28,32,38. | | 3.5 | 9,12,16,19,24,28,32,38. | | 4.0 | 9,12,16,19,24,28,32,38. |   Class-D  Shelf Life: 2 years | Drug Eluting Stent Delivery System |  |

**Decision: The Board acceeded to the request of the firm /company and approved the reduction in shelf-life of their product Coroflex Isar Neo Sirolimus- Eluting Coronory Stent System from three to two years.**

**Agenda Item XI** : **CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR CONTRACT MANUFACTURING.**

Under rule 67 of Medical Devices Rules, 2017, manufacturing of medical devices may be outsourced to contract acceptor having valid establishment licence issued by MDB under these rules. For this purpose, MDB may determine conditions for such contract manufacturing. Furthermore, the contract acceptor shall also possess establishment licence issued by the MDB. Under Rule 63(3) of MDR, 2017, The Authority may, on the recommendation of MDB, amend Schedules A,B and D and the Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein.

Therefore, a Form namely, **“Form-8B” Certificate of Enlistment or Registration of a medical device or accessory or component for contract manufacturing** as mentioned below is placed before the MDB for consideration:-

**DRUG REGULATORY AUTHORITY OF PAKISTAN**

**FORM-8B**

***[****See rule 15(5), 67(1)****]***

**CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR CONTRACT MANUFACTURING**

**Licence No**. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Islamabad, Date of issue:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**F.No : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

M/s ………………..

The medical device as per details given below has been registered/enlisted on contract manufacturing basis under the DRAP Act and the rules made there-under subject to the conditions appearing hereinafter:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Enlistment or Registration No.** | **Name of medical device or accessory or component** | **Brief description** | **Class** | **Shelf life** |
| (1) | (2) | (3) | (4) | (5) |
|  |  |  |  |  |

|  |  |
| --- | --- |
| **Name of Contract Giver** |  |
| **Address of Contract Giver** |  |
| **Name of Contract Acceptor** |  |
| **Address of Contract Acceptor** |  |
| **Licence No. Contract Acceptor** |  |

2. This enlistment/registration shall be valid for a period of five years from the date mentioned above unless earlier suspended or cancelled.

3. The name shall be changed in case it has resemblance with already enlisted/registered medical device.

4. This enlistment/registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Secretary

Medical Device Board

Seal:

**Decision: The Board recommended the FORM-8B, namely, Certificte of Enlistment or Registration of a Medical Device or Accessory or Component for Contract Manufacturing for the approval of the Authority.**

**Item No.XII. PENDING CASES OF M/S UDL DISTRIBUTION (PVT) LIMITED, KARACHI.**

In the last meeting i.e., 11th MDB the following agenda was discussed and resultantly decision was made by the MDB:

*“M/s UDL Distribution (Pvt) Limited, Karachi has applied on Form-7A for registration of the following medical devices manufactured by M/s Arrow International, Inc (Subsidiary of Teleflex, Incorporated) 2400 Bernville Road, Reading PA 19605, USA under Medical Devices Rules, 2017:-*

1. *Ultra-8 Intra Aortic Balloon Catheters.*
2. *Rediguard Intra Aortic Balloon Catheters.*
3. *Arrow Two-Lumen Hemodialysis Catheterization Set*
4. *Arrow Multi-Lumen Central Venous Catheterization Set*
5. *Arrow Central Venous Catheterization Set*
6. *Ultra Intra Aortic Balloon Catheters.*
7. *Arrow Balloon Wedge Pressure Catheter.*
8. *Arrow Berman Angiographic Balloon Catheter.*

*It is submitted that the following medical devices including the above mentioned medical devices of the same manufacturer have already been registered as drug with M/s Iqbal & Company, Islamabad on 21-02-2013.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***S.No*** | ***Reg.No.*** | ***Name of drug (s) & Composition*** | ***Packing*** | ***M R P*** | ***Approved***  ***Shelf Life*** |
| *1* | *074635* | *Arrow Central Venous Catheterization Set* | *1’s* | *Decontrolled till policy decision by the Federal Government.* | *05 Years* |
| *2.* | *074636* | *Arrow Intra Aortic Balloon Catheters.* | *1’s* | *-do-* | *2 years* |
| *3.* | *074637* | *Arrow Two Lumen Haemodialysis Catheterization Set.* | *1’s* | *-do-* | *5 years* |
| *4.* | *074638* | *Arrow Balloon Wedge Pressure Catheters.* | *1’s* | *-do-* | *2 years* |
| *5.* | *074639* | *Arrow Arterial Catheterization Set.* | *1’s* | *-do-* | *5 years* |
| *6.* | *074640* | *Arrow Berman Angiographic Balloon Catheters* | *1’s* | *-do-* | *18 months* |
| *7.* | *074641* | *Arrow Multi Lumen Access Catheters.* | *1’s* | *-do-* | *5 years* |

*Letter of Authorization issued to M/s Iqbal & Company, Islamabad has expired on 31-12-2017 and the manufacturer has not renewed the agreement. The manufacturer has appointed M/s UDL Distribution (Pvt) Limited, Karachi as their distributor in Pakistan for their above products:-*

*Letters for personal hearing to M/s Iqbal & Company, Islamabad and M/s UDL Distribution (Pvt) Limited, Karachi has been issued to clarify their status of Letter of Authorization.*

*Submitted for consideration of MDB please.*

***Decision:*** *The Board heard both the importers, namely, M/s UDL (Pvt) Limited, Karachi and M/s Iqbal & Company, Islamabad at length. Mr. Arshad Abdullah, Director Sales and Mr. Arshad Malik, CEO made their appearance on behalf of M/s UDL (Pvt) Limited, Karachi and M/s Iqbal & Company, Islamabad respectively.*

*It was noticed by the Board that the same principal, namely, M/s Arrow International, Inc (Subsidiary of Teleflex, Incorporated) 2400 Bernville Road, Reading PA 19605, USA has given their same products to both the importers. M/s Iqbal & Company was of the opinion that they have a stock of products under consideration for cancellation and has to fulfill tender supply commitments at various institutions / hospitals, and requested M/s UDL (Pvt) Limited, Karachi to take their stock in order to settle the matter. The representative from M/s UDL (Pvt) Limited, Karachi has agreed in front of the Board to take the stock of M/s Iqbal & Company, Islamabad.*

*The Agency Agreement in the name of M/s Iqbal & Company, Islamabad has not been renewed by the principal, while M/s UDL (Pvt) Limited, Karachi has the Agency Agreement therefore the above mentioned products were cancelled in the name of M/s Iqbal & Company, Islamabad and were registered in the name of M/s UDL (Pvt) Limited, Karachi for which application on Form 7A are submitted.”*

Mr Arshad Abdullah, Director M/S UDL Distribution (Pvt) Limited has written a letter to Chairman, MDB on 18-04-2018. The contents of the letter are reproduced below:

“ *We would like to refer to our cases of product registration pending with Medical Devices Board since October, 2018. In this respect the board meeting was held on 01st Feb, 2019 in Islamabad. The previous distributor M/S Iqbal & Company & UDL were represented in the meeting by Mr. Arshad Malik (owner) and myself respectively. After hearing from both side, the board decided as follows;*

* *The product registration previously held by Iqbal &co. would be cancelled as their distribution agreement with Teleflex was terminated in Feb.2018.*
* *Products registration would be transferred to M\S UDL Distribution (Pvt) Ltd. being the authorized distributer for M\S Teleflex in Pakistan.*
* *In order to facilitate M\S Iqbal &Co., the board gave directives to UDL to support in terms of purchasing unsold stock lying with M\S Iqbal & and Co. & provide stocks to M\S Ibal & Co. in order for Iqbal & Co. to fulfill contractual obligations pertaining to year 2018.*

*The board meeting was headed by Mr. Dr. Abdul Aleem Khan. The board instructed UDL to confirm the same in writing to Iqbal & Co. with copy to board and UDL’s case products registration would be processed accordingly. UDL acted upon the directives of board in good gesture and confirmed the same twice in writing to Iqbal & Co. on dated 13th Feb, 2019 and 27th Mar, 2019 with copy to board (copies enclosed).*

*However, during the period of Seventy two days, M\S Iqbal & Co. responded four times (copies enclosed) and each time with different stance and unreasonable claims and very through their correspondence, you would endorse our view point.*

*Based on the developments so far, we are of the opinion;*

* *The M/S Iqbal & Co is using unlawful tactics and their sole intension is to delay UDL’s product registration to their own benefits. We understand that their other brand in direct competition with UDL’s is in registration process and they intend to take advantage by complicating the matters.*
* *They are trying to indulge UDL in matters that are solely associated with M/S Iqbal & Co and M/S Teleflex. They are also involving MDB in matters which are beyond the domain of MDB.*
* *UDL has already suffered heavy losses due to delay in issuance of product registration and several government and private institutions are in dire need of the products. MDB has also been approached by several institutions in this regards.*
* *Last but not the least, the goodwill gesture by MDB and UDL to support Iqbal & Co had been misunderstood as our weakness without realizing the spirit behind our gesture.*

*We very strongly request you to kindly issue directivesfor issuance of product registration to UDL and oblige.*

**Decision: The Board deliberated the matter at length and decided that M/S UDL Distribution (Pvt) Limited shall fulfill the liabilities at the consumer end in terms of warranty/services or replacement of defective or short expiry medical devices. The Board observed that any replacement of expired stock lying with the M/s Iqbal & Co. or any financial liability is a matter related to the importer and its principal abroad. The Board permitted to issue the registration certificates of products of M/s UDL Distribution (Pvt) Limited.**

**Item No.XIII. APPLICATIONS FOR GRANT OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT.**

Secretary MDB informed the Board that the following applications for grant of registration of medical devices for import on prescribed form 7-A under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. No** | **Name and Addresses of Establishment** | **Manufacture Details** | **Name of Medical Device with sizes/Class/Shelf Life** | **Brief Description** | **Decisions** |
|  | M/s Apsta International,  38-A Johar Town, Lahore  (ELI-00042)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Laboratorium Dr. Deppe GmbH Hooghe Weg 35, 47906 Kempen, Germany  (FSC Germany Issuance Date 31-10-2016)  **Fee submitted Rs.50,000/-** | Endomat Plus Viruguard  Composition:  100 gm contains:  Glutaraldehyde 20 gm  Pack Size:  50ml,500ml, 1000ml, 5000ml  Class C  Shelf Life: 3 Years | For Disinfection and Cold Sterilization of Medical Devices | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Laboratorium Dr. Deppe GmbH Hooghe Weg 35, 47906 Kempen, Germany  (FSC Germany Issuance Date 31-10-2016)  **Fee submitted Rs.50,000/-** | Endo Star NEU  Composition:  Alkyldimethylethyl ammonium methyl sulfate……. 5 % (w/w)  Polyhexamethyl enbiguanid hydrochloride…… 1 % (w/w)  Cocospropylenguanidium diacetate ………..1.8 % (w/w)  Pack Size:  50ml,500ml, 1000ml, 5000ml  Class C  Shelf Life: 3 Years | Instrument Disinfectant | **Approved**. |
|  | M/s PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi  (ELI-00055)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Bionime Corporation Daoing Factory, No. 100, Sec 2, Daqing St. Taichung City 40242, Taiwan  (FSC China Issuance Date 02-11-2021)  **Fee submitted Rs.50,000/-** | EvoCheck Blood Glucose Monitoring System  Class C  Shelf Life: 2 Years | Blood Glucose Meter | **Deferred.** The Board referred the matter to Foreign Office for seeking clarification of foreign inspection in Taiwan. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Bionime Corporation Daoing Factory, No. 100, Sec 2, Daqing St. Taichung City 40242, Taiwan  (FSC China Issuance Date 02-11-2021)  **Fee submitted Rs.50,000/-** | EvoCheck Blood Glucose Test Strips  Class C  Shelf Life: 24 Months | Blood Glucose Test Strip | **Deferred.** The Board referred the matter to Foreign Office for seeking clarification of foreign inspection in Taiwan. |
|  | M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi  (ELI-00030)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerland  (FSC SwitzerlandValid Till 19-03-2020)  **Fee submitted Rs.50,000/-** | Contour Plus Blood Monitoring System  Class C  Shelf Life: 24 Months | Blood Glucose Monitoring system | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerland  (FSC SwitzerlandValid Till 19-03-2020)  **Fee submitted Rs.50,000/-** | ContourTM TS Blood Glucose Monitoring System  Class C  Shelf Life: 5 Years | Blood Glucose Monitoring system | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerland  (FSC SwitzerlandValid Till 19-03-2020)  **Fee submitted Rs.50,000/-** | ContourTM Plus Blood Glucose Test Strips  Class C  Shelf Life: 24 Months  Pack size:  10 Counts Test Strips  25 Counts Test Strips  2x25 CountsTest Strips  50 Counts Test Strips  2x50 Counts Test Strips | Blood Glucose Test Strips | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerland  (FSC SwitzerlandValid Till 19-03-2020)  **Fee submitted Rs.50,000/-** | Contour TS Test Strips  Pack size:  10 Counts Test Strips  25 Counts Test Strips  2x25 CountsTest Strips  50 Counts Test Strips  2x50 Counts Test Strips  Class C  Shelf Life: 24 Months | Contour TS Blood Glucose Test Strips | **Approved subject to audit report.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerland  (FSC SwitzerlandValid Till 19-03-2020)  Fee submitted Rs.50,000/- | ContourTM TS Blood Glucose Monitoring System  Class C  Shelf Life: 5 Years | The ContourTM TS Blood Glucose Monitoring System utilizes amperometic biosensor technology to quantitatively measure the glucose concentration in whole blood or in Contour TS Control Solutions. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ascensia Diabetes Care Holdings AG, Peter Merian-Strasse 90, 4052 Basel, Switzerland  (FSC Switzerland Valid Till 19-03-2020)  **Fee submitted Rs.50,000/-** | ContourTM Plus Blood Glucose Test Strips  Class C  Shelf Life: 24 Months | The ContourTM Plus Blood Glucose Test Strips is designed for use with the Contour Plus Blood Glucose Meter. The test provides a quantitative measurement of glucose in blood from 10 to 600mg/ dL (0.6 to 33.3mmol/L) | **Approved**. |
|  | M/s 4S International, Suite No. 205, 2nd Floor Al-Fiza Glass Tower Rashid Minhas Road, Block 10-A Gulshan e Iqbal Road, Karachi  (ELI-00290)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China  (FSC Germany Issuance Date 14-08-2018)  **Fee submitted Rs.50,000/-** | Sterile Hemostasis Introducer  Class D  Shelf Life: 3 years  Codes & Sizes as per German FSC No. 0362/2018 dated 21st August, 2018 | Sterile Hemostasis Introducer | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China  (FSC Germany Issuance Date 14-08-2018)  **Fee submitted Rs.50,000/-** | ConquerorTM PTCA Balloon Catheter  Class D  Shelf Life: 3 years  Codes & Sizes as per German FSC No. 0362/2018 dated 21st August, 2018 | ConquerorTM PTCA Balloon Catheter | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Mediquip Pty Ltd 3 Henry Street Loganholme QLD 4129, Australia  **Manufacturer:**  M/s Medima Ltd., 200 Al Jerozolimskie Warsaw 02-486, Poland  (FSC Australia Issuance Date18-04-2018) | Infusion Pump, General Purpose (Volumetric)  Class C  Shelf Life: 3 Years  ARTG:287600  **Fee submitted Rs.50,000/-** | Vloumetric Infusion Pump | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Mediquip Pty Ltd 3 Henry Street Loganholme QLD 4129, Australia  **Manufacturer:**  M/s Medima Ltd., 200 Al Jerozolimskie Warsaw 02-486, Poland  (FSC Australia Issuance Date 18-04-2018) | Syringe Infusion Pump  Class C  Shelf Life: 3 Years  ARTG:287596  **Fee submitted Rs.50,000/-** | Syringe Infusion Pump | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China  **Authorized Representative:**  M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20357 Hamburg, Germany  (FSC Germany Issuance Date 14-08-2018)  **Fee submitted Rs.50,000/-** | APT Medical Hydrophilic Guidewire  Class D  Shelf Life: 3 years  Codes and sizes as per FSC. | Guidewire | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China  **Authorized Representative:**  M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20357 Hamburg, Germany  (FSC Germany Issuance Date 14-08-2018)  **Fee submitted Rs.50,000/-** | ExpressmanTM Guiding Extension Catheter  Class D  Shelf Life: 3 years  Codes and sizes as per FSC | Catheter | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China  **Authorized Representative:**  M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20357 Hamburg, Germany  (FSC Germany Issuance Date 14-08-2018)  **Fee submitted Rs.50,000/-** | APT Medical Microcatheter  Class D  Shelf Life: 3 years  Codes and sizes as per FSC | Microcatheter | **Approved.** |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China  **Authorized Representative:**  M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20357 Hamburg, Germany  (FSC Germany Issuance Date 14-08-2018) | MarchTM Guiding Catheter  Class D  Shelf Life: 3 years  Codes and sizes as per FSC  **Fee submitted Rs.50,000/-** | Guiding Catheter | **Approved.** |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s APT Medical Inc., No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone, Xiangxiang City Hunan, 411400, PR China.  **Authorized Representative:**  M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20357 Hamburg, Germany  (FSC Germany Issuance Date 14-08-2018) | APT Medical Hydrophilic Angiographic Catheter  Class D  Shelf Life: 3 years  Codes and sizes as per FSC  **Fee submitted Rs.50,000/-** | Hydrophilic Angiographic Catheter | **Approved**. |
|  | M/s Mana & Co., Office No. 401, 4th Floor, Masood Chamber, Shahrah-e-Liaquat, Karachi  (ELI-00098)  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Jiangxi Huali Medical Instrument Co Ltd., Yudu Industrial Zone, Jiangxi, China  (FSC China Valid Till  03-11-2017) | Medicare Sterile IV Catheter  Class B  Shelf Life: 3 Years | Sterile IV Catheter for single use. | **Approved** subject to provision of stability data. |
|  | **A.H Distributors:**  House No. CB-708, Lane No. 5, Peshawar Road, Rawalpindi  (ELI-00225)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. Curatia Medical Limited Address:198 Xiangjiang Road, New  District, Suzhou 215011, China.  FSC USFDA valid till 25-11-2020 | URSA Angiographic Catheter  Class D  Shelf Life: Three years  Codes and sizes as per USFDA FSC No. 2043-11-2018  **Fee submitted Rs.50,000/-** | Angiographic Coronary Catheter | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  Micro Science Medical AG  Meisenweg 5, D-75443 Oetisheim, Germany  FSC Germany issue date 16-10-2018  Codes and sizes as per USFDA FSC No. 2043-11-2018  **Fee submitted Rs.50,000/-** | MSM DES Sirolimus Eluting Stent System  Class D  Shelf Life 36 months  Codes and sizes:  2,25x8mm; 2,25x10mm; 2,25x13mm; 2,25x16mm; 2,25x18mm; 2,25x23mm; 2,25x28mm; 2,50x8mm; 2,50x10mm; 2,50x13mm; 2,50x16mm; 2,50x18mm; 2,50x23mm; 2,50x28mm; 2,50x33mm; 2,50x38mm; 2,75x8mm; 2,75x10mm; 2,75x13mm; 2,75x16mm; 2,75x18mm; 2,75x23mm; 2,75x28mm; 2,75x33mm; 2,75x38mm; 3,00x8mm; 3,00x10mm; 3,00x13mm; 3,00x16mm; 3,00x18mm; 3,00x23mm; 3,00x28mm; 3,00x33mm; 3,00x38mm; 3,25x8mm; 3,25x10mm; 3,25x13mm; 3,25x16mm; 3,25x18mm; 3,25x23mm; 3,25x28mm; 3,25x33mm; 3,25x38mm; 3,50x8mm; 3,50x10mm; 3,50x13mm; 3,50x16mm; 3,50x18mm; 3,50x23mm; 3,50x28mm; 3,50x33mm; 3,50x38mm; 4,00x8mm; 4,00x10mm; 4,00x13mm; 4,00x16mm; 4,00x18mm; 4,00x23mm; 4,00x28mm; 4,00x33mm; 4,00x38mm |  | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  Micro Science Medical AG  Meisenweg 5, D-75443,  Oetisheim, Germany  FSC Germany issue date 16-10-2018  Codes and sizes as per USFDA FSC No. 2043-11-2018  **Fee submitted Rs.50,000/-** | MSM PTCA SC Balloon Catheter  Class D  Shelf Life 36 Months  1.5x10/15/20/25/30/35/40  1.75x10/15/20/25/30/35/40  2.0x10/15/20/25/30/35/40  2.25x10/15/20/25/30/35/40  2.5x10/15/20/25/30/35/40  2.75x10/15/20/25/30/35/40  3.0x10/15/20/25/30/35/40  3.5x10/15/20/25/30/35/40  4.0x10/15/20/25/30/35/40 | Semi-Compliant Coronary Balloon Catheter | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  Micro Science Medical AG  Meisenweg 5, D-75443,  Oetisheim, Germany  FSC Germany issue date 16-10-2018  **Fee submitted Rs.50,000/-** | MSM CIS Cobalt Chromium Bare Metal Coronary Stent System  2.25x8/13/18/23/28,  2.5x8/13/18/23/28/33/38,  2.75x8/13/18/23/28/33/38,  3.0x8/13/18/23/28/33/38,  3.5x8/13/8/23/28/33/38,  4.0x8/13/18/23/28/33/38 | Bare Metal Cobalt Chromium Cardiac Stent | **Approved.** The shelf life of the product is 3 years. |
|  | **M/s Nasir Brothers,** 22B, 2nd Floor, Zeenat Medicine Market, North Napire Road, Karachi  (ELI-00036)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Nanchang Biotek Medical Technology Company Limited., No. 738, Youkou Road, High-Tech Development Zone, Nanchang, Jiangxi, China  (FSC China Valid Till  25-09-2019)  **Fee Submitted Rs.25,000/-** | V. Cath I.V Cannula  Class B  Shelf Life: 3 Years  Sizes: 26G, 24G, 20G, 18G, 16G, 14G | IV Cannula for single use. | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ningbo MFLAB Medical Instruments Co., Ltd., No.508, Yindong Road(N) Yinzhou Economic Development Zone315145 Ningbo, China  (FSC China Valid Till  22-05-2020)  **Fee Submitted Rs.25,000/-** | Vcare Connecting Tube with Yankauer Handle  Class B  Shelf Life: Not Mentioned  X01-PY, X01-PW, …………..  Codes & sizes as per FSC. | Connecting Tube with Yankauer Handle | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ningbo MFLAB Medical Instruments Co., Ltd., No.508, Yindong Road(N) Yinzhou Economic Development Zone315145 Ningbo, China  (FSC China Valid Till  22-05-2020)  **Fee Submitted Rs.25,000/-** | Vcare Nasal Oxygen Cannula  Class B  Shelf Life: Not Mentioned  B01-L, B01-S, B01-XS,  B01-XXS, B02-L, B02-S,  B02-XS, B02-XXS | Nasal Oxygen Cannula | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ningbo MFLAB Medical Instruments Co. Ltd., No. 508, Yindong (N) Yinzhou Economic Development Zone 315145 Ningbo, China  (FSC China Valid Till  22-05-2020)  **Fee Submitted Rs.25,000/-** | VCARE Nebulizer Mask for Single Use  Class B  Shelf Life: 5 Years  S04-XL, S04-L, S04-L2, S04-L3, S04-M, S04-M2, S04-S, S04-XS | Nebulizer Mask for Single Use | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Longfian Scitech Co. Ltd., 2F & 3F, East Section, Building 12, Power Valley PioneerPark, No.369, Huiyang Street, 071051, Baoding, Hebei Province, China  (FSC China Valid Till  02-09-2020)  **Fee Submitted Rs.25,000/-** | LONGFIANG Medical Oxygen Concentrator  Class B  Shelf Life: 5 Years or 20000Hrs  Model: JAY-5 (20172540088) | Medical Oxygen Concentrator | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.  Also subject to provision of Stability study. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Shangai Yuechen Medical Supply Co. Ltd., 8th Building No. 776 Huhang Road, Fengxian District, Shanghai City, China  (FSC China Valid Till  02-05-2020)  **Fee Submitted Rs.25,000/-** | VCARE Disposable ECG Electrodes  Class B  Shelf Life: 5 Years  HS07, HS08, HS09, HS10, HS11, HS12, HS13; HW01, HW02, HW03, HW04, HW05, HW06, HW07, HW08, HW09, HW10, HW11, HW12, HW13, HW14; HA01, HA02, HA03, HA04, HA05, HA06, HA07, HA08, HA09, HA10, HA11, HA12, HA13 | Disposable ECG Electrodes | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.  Also subject to provision of Stability study.  Also subject to provision of Stability study. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Changzhou Jinlong Medical Plastic Appliance Co. Ltd., Zhennan Road, Zhenglu Town, Changzhou City, Diangsu Province, China  (FSC China Valid Till  22-05-2020)  Copy of FSC of UK is provided .  **Rs.100,000/-**  **Already submitted against slip no. 0560700 dated 16-11-2016** | VCARE Sterile Syringes for single use (with needle)  Class B  Shelf Life: 5 Years  1mL, 2mL, 3mL, 5mL, 10mL, 20mL | Sterile Syringes for single use (with needle) | **Approved** subject to provision of Stability study and Embassy Attested Free Sale Certificate from Pakistan Embassy in UK. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Ningbo MFLAB Medical Instruments Co. Ltd., No. 508, Yindong (N) Yinzhou Economic Development Zone 315145 Ningbo, China  Copy of FSC of UK is provided .  (FSC China Valid Till  22-05-2020)  **Rs.25,000/-** | VCARE Oxygen masks for single use  Class B  Shelf Life: 5 Years  S01-XL, S01-L, S01-L2, S01-L3, S01-M, S01-M2, S01-S, S01-XS | Oxygen masks for single use | **Approved** subject to provision of Stability study and Embassy Attested Free Sale Certificate from Pakistan Embassy in UK. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Changzhou Jinlong Medical Plastic Appliance Co. Ltd., Zhennan Road, Zhenglu Town, Changzhou City, Diangsu Province, China  (FSC China Valid Till  22-05-2020)  **Rs.100,000/-**  **Already submitted against slip no. 0560700 dated 16-11-2016** | VCARE Sterile Infusion Sets for SingleUse (with needle)  Class B  Shelf Life: 5 Years  ISI-G-Z, IS2-G-Z, IS3-G-Z, IS4-G-Z, IS5-G-Z, IS6-G-Z, IS7-G-Z, IS8-G-Z, IS9-G-Z, IS10-G-Z  (0.45, 0.5, 0.55, 0.6, 0.7, 0.8, 0.9, 1.1, 1.2) | Sterile Infusion Sets for SingleUse (with needle) | **Approved** subject to provision of Stability study and Embassy Attested Free Sale Certificate from Pakistan Embassy in UK. |
|  | M/s S. Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078)  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s JMS Singapore PTE Ltd., 440 ANG MO Kio Industrial Park 1, 569620 Singapore  (FSC Singapore Valid Till  15-08-2019)  Fee Submitted Rs.50,000/- | JMS Transfer Pack  Class C  Shelf Life: 3Years  300ml | Blood Transfer Pack intended for separating blood components from whole blood. | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s JMS Singapore PTE Ltd., 440 ANG MO Kio Industrial Park 1, 569620 Singapore  (FSC Singapore Valid Till  15-08-2019)  Fee Submitted Rs.50,000/- | JMS Extension Tube  Class C  Shelf Life: 3Years  ET 2 500MM CE,  ET 2 825MM CE,  ET 2 1000MM CE,  ET 2 1500MM CE  ET 2 2000MM W/LUER SLIP CE  M.V.E.T 500MM W/LUER SLIP CE | Extension Tube intended for extending fluid pathway lines, connecting with infusion set, syringe or other infusion devices in a way that allow IV tubing to be changed away from insertion site, thereby reducing risk of contamination. | **Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant. |
|  | M/s Timax Life Sciences (Pvt) Ltd., M-1, FL-37, Block B, Gulshan-e-Jamal, Karachi  (ELI-00309)  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Flen Pharma NV-Blauwesteenstraat 87-2550 Kontich, Belgium  (FSC Belgium Issuance Date  08-05-2018)  Fee Submitted Rs.50,000/- | Flaminal Hydro  (Enzyme Alginogel)  Class C  Shelf Life: 2 Years  10g tube,15g tube, 25g tube, 30g tube, 40g tube,50g tube, 500g jar | Wound healing hydrogel(with less conc. of alginate Fluminal Fort)  keeps the wound clean and moist and leads to continuous debridement of the wound. | **Approved.** |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Flen Pharma NV-Blauwesteenstraat 87-2550 Kontich, Belgium  (FSC Belgium Issuance Date  08-05-2018)  Fee Submitted Rs.50,000/- | Flaminal Forte  Class C  Shelf Life: 2 Years  10g tube,15g tube, 25g tube, 30g tube, 40g tube,50g tube, 500g jar | Wound healing hydrogel.  Keeps the wound clean and moist and leads to continuous debridement of the wound.. | **Approved**. |
|  | do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:**  M/s B. Braun Melsungen AG Carl-Braun-Strabe 1 34212 Melsungen, Germany  **Manufacturing Site:**  M/s Braun Medical Industries Sdn. Bhd., Bayan Lepas Free Industrial Zone 11900 Penang, Malaysia  (FSC Germany Issuance Date  10-01-2019) | Perifix® (Set for Continuos epidural anaesthesia)  Class D  Shelf Life: 5 Years  4514017, 4514025  Fee Submitted Rs.50,000/- | Set for Continuos Epidural Anaesthesia | **Approved**. |
|  | **M/s Hoora Pharma (Pvt) Ltd.,** WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Immulite 1000 Rubella IGM Assay  i) Immulite 1000 Rubella IGM Assay  SMN 10381282 REF LKRM1  ii) Immulite 1000 IGG/IGM (ID1) Sample Diluent Module  SMN 10387608 REF L1KIGW1  Class C  Shelf Life: 12 Months | IgG Antibodies to the Rubella Virus Group | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Immulite 1000 CMV IGG Assay  i) Immulite 1000 CMV IGG Assay  SMN 10381289 REF LKCV1  ii) Immulite 1000 IGG/IGM (ID1) Sample Diluent Module  SMN 10387608 REF L1KIGW1  Class C  Shelf Life: 12 Months | IgG Antibodies to Cytomegalovirus Assay | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Immulite 2000 PSA Assay  i) Immulite 2000 PSA Assay  SMN 10380986 REF L2KPS2 (200 Tests)  SMN 10380996 REF L2KPS6 (600 Tests)  ii) Immulite PSA Sample Diluent  SMN 10386994 REF LPSZ  Class C  Shelf Life: 12 Months | Prostate-Specific Antigen Assay | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Immulite 1000 PSA Assay  i) Immulite 1000 PSA Assay  SMN 10380960 REF LKPS1 (100 Tests)  SMN 10380949 REF LKPS5 (500 Test)  ii) Immulite PSA Sample Diluent  SMN 10386994 REF LPSZ  Class C  Shelf Life: 12 Months | Prostate-Specific Antigen Assay | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Atellica IM Toxoplasma IgM (Toxo M) Assay  i) Atellica IM Toxoplasma IgM (Toxo M)  SMN 10995701  ii) Atellica IM Toxoplasma IgM Quality Contorl (Toxo M QC)  SMN 10995702  Class C  Shelf Life: 8 Months | IgM Antibodies to Toxoplasma gondii Assay Group | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Advia Centaur PSA Assay  i) Advia Centaur PSA Assay  SMN 10310295 REF 02484801 P/N 118220  SMN 10310296 REF 04847308 P/N 118221  ii) Advia Centaur Calibrator Q  SMN 10310292 REF 06574155 P/N 118156  SMN 10310293 REF 02676506 P/N 118157  iii) ADVIA Centaur Multi-Diluent 2  SMN 10309943 REF 07948423 P/N 110314  SMN 10311601 REF 04855629 P/N 672260000  Class C  Shelf Life: 12 Months | Prostate-Specific Antigen Assay | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Advia Centaur Rubella M Assay  i) Advia Centaur Rubella M Assay  SMN 10310285 REF 02633319 P/N 117733  ii) Advia Centaur Rubella IgM QC  SMN 10310286 REF 00347629 P/N 117734  Class C  Shelf Life: 12 Months | IgM Antibodies to the Rubella Virus Group | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Advia Centaur Rubella G Assay  i) Advia Centaur Rubella G Assay  SMN 10310283 REF 08666235 P/N 117710  ii) Advia Centaur Rubella G Quality Control Material  SMN 10310284 REF 01549403 P/N 117711  Class C  Shelf Life: 12 Months | IgM Antibodies to the Rubella Virus Group | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Advia Centaur Toxoplasma M Assay  i) Advia Centaur Toxoplasma M Assay  SMN 10310320 REF 05303018 P/N 120153  ii) Advia Centaur Toxoplasma M Quality Control Material  SMN 10310326 REF  03089388 P/N 120383  Class C  Shelf Life: 8 Months | IgM Antibodies to the Toxoplasma gondii Assay Group | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Atellica IM Rubella IgG (Rub G) Assay  i) Atellica IM Rubella IgG (Rub G) Assay  SMN 10995670  ii) Atellica IM Rubella IgG Quality Control (Rub G QC)  SMN 10995671  Class C  Shelf Life: 12 Months | IgM Antibodies to the Rubella Virus Group | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Atellica IM Toxoplasma IgG (Toxo G)  i) Atellica IM Toxoplasma IgG (Toxo G)  SMN 10995699  ii) Atellica IM Toxoplasma IgM Quality Contorl (Toxo M QC)  SMN 10995702  Class C  Shelf Life: 12 Months | IgM Antibodies to Toxoplasma gondii Assay Group | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** Siemens Healthcare Diagnostics Inc. located at 511 Benedict Ave. Tarrytown, NY 10591, USA  (FSC UK Valid Till  16-10-2020)  Fee Submitted Rs.50,000/- | Atellica IM Rubella IgM Assay  i) Atellica IM Rubella IgM Assay  SMN 10995668  ii) Atellica IM Rubella IgM Quality Control (Rub M QC)  SMN 10995669  Class C  Shelf Life: 12 Months | IgM Antibodies to the Rubella Virus Group | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/** M/s Siemens Healthcare Diagnostics Inc.  511 Benedict Ave. Tarrytown, NY 10591, USA.  **Manufacturing Site:** Siemens Healthcare Diagnostics Inc.  333 Coney Street E. Walpole, MA, 02032-1597 USA.  (FSC UK Valid Till 31-12-2020)  Fee Submitted Rs.50,000/- | Siemens Advia Centaur Toxoplasma G Assay Kit  1. Advia Centaur Toxoplasma G  SMN 10310321 REF 04520287 P/N 120154  2. Advia Centaur Toxoplasma G Quality Control Material  SMN 10310325 REF 06317233 P/N 120382  Class C  Shelf Life: 12 Months | An IVD immuno assay intended for the quantitative and qualitative detection of IgG antibodies to Toxoplasma gondi in serum or plasma using ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur XPT systems. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/** M/s Siemens Healthcare Diagnostics Inc.  511 Benedict Ave. Tarrytown, NY 10591, USA.  **Manufacturing Site:** Siemens Healthcare Diagnostics Inc.  333 Coney Street E. Walpole, MA, 02032-1597 USA.  (FSC UK Valid Till 31-12-2020)  Fee Submitted Rs.50,000/- | Siemens Atellica IM PSA Assay Kit  1. Siemens Atellica IM Prostate-Specific Antigen (PSA)  SMN10995662 (100 tests)  2. Siemens Atellica IM Prostate-Specific Antigen (PSA)  SMN10995663 (500 tests)  3. Siemens Atellica IM Calibrator (Cal Q)  SMN10995517 ( 2 Packs)  4. Siemens Atellica IM Calibrator (Cal Q)  SNM 10995518 (6 Packs)  5. Siemsens Atellica IM Multi-Diluent 2  SMN 10995644  Class C  Shelf Life: 12 Months | In vitro diagnostic assay intended to quantitatively measure PSA in Human Serum using the Atellica IM systems. | **Approved**. |
|  | **M/s Cardiac Care**  848-C, Shadman 1, Lahore  (ELI-00070)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s VYGON 5 rue Adeline, 95440 Ecouen, France  (FSC France Issuance Date  13-06-2018)  Fee Submitted Rs.50,000/- | Arterial Leadercath  Class D  Shelf Life: 5 Years  115  090/092/096/11/118/610/698/710/798 | Arterial Catheter for pressure Measurement | **Approved** subject to provision of complete stability studies. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. EUROSETS s.r.l,  Via Strada Statale 12, n.143  41036 Medolla (MO)  ITALY.  FSC Italy  Issued on March 23, 2018.  Fee Submitted Rs.50,000/- | SKIPPER STERILE  (OXYGENATORS)  EU5007 SKIPPER STERILE  Class B  Shelf Life : 03 years | Oxygenator. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. MDD Medical Device Development GmbH Steigacker 20, 78582 Balgheim / Germany.  FSC Germany  Issued on 20.02.2018.  Fee Submitted Rs.50,000/- | Everest Titanium Ligating Clip,  (Ligating Clips)  Everest titanium ligating clip small. 30 Cartridges of 6 clips (red)  EVC 010  Everest titanium ligating clip medium 30 Cartridges of 6 clips (blue)  EVC020  Everest titianium ligating clip medium/ large. 20 Cartridges of 6 clips (green)  EVC O30  Everest titanium ligating clip large. 20 Cartridges of 6 clips (orange)  EVC 040  Class : D  Shelf Life : 05 years | Hemostatic Ligating Clips | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. Technowood Corporation, 30-19 Kohoku, Adachi-ku, Tokyo, Japan.  FSC Japan  Issued on 30.10.2018.  Fee Submitted Rs.50,000/- | Technowood SoftNAV Catheter  (Angiography, Central Catheter)  Class : D  Shelf Life : 03 years  FL:4FR  H710-FL418, H710-FL420, H710-FL422, H710-FL419, H710-FL421, H710-FL423,  H710-FL418JSH , H710-FL420JSH, H710-FL422JSH , H710-FL419JSH,  H710-FL421JSH , H710-FL423JSH,  H710-FL4060, H710-FL4013, H710-FL4012,  H710-FL4011, H710-FL4361, H710-FL4363, H710-FL4362, H710-FL4122,  H710-FL4123, H710-FL445SH, H710-FL446SH, H710-FL401SH, H710-FL4601  H710-FL4711M,H710-FL4713M, H710-FL4731M, H710-FL4733M,  H710-FL4741M, H710-FL4743M, H710-FL4751M, H710-FL4753M  FL:5FR  H710-FL518, H710-FL520, H710-FL522, H710-FL519, H710-FL521,  H710-FL523, H710-FL518TJ, H710-FL520TJ, H710-FL522TJ, H710-FL519TJ,  H710-FL521TJ, H710-FL523TJ, H710-FL5060, H710-FL5013, H710-FL5012,  H710-FL5011, H710-FL5361, H710-FL5363, H710-FL5362, H710-FL5122,  H710-FL5123, H710-FL545, H710-FL546, H710-FL548, H710-FL5601,  H710-FL5661, H710-FL5662, H710-FL5671, H710-FL5672, H710-FL5307,  H710-FL5308, H710-FL5309, H710-FL5711M, H710-FL5713M, H710-FL5731M,  H710-FL5733M, H710-FL5741M, H710-FL5743M, H710-FL5751M,  H710-FL5753M  SL-:4FR  H710-SL418, H710-SL420, H710-SL422, H710-SL419, H710-SL421,  H710-SL423, H710-SL418JSH, H710-SL420JSH, H710-SL422JSH,  H710-SL419JSH, H710-SL421JSH, H710-SL423JSH, SVH3-SL418SH,  SVH3-SL420SH, SVH3-SL419SH, SVH3-SL421SH, H710-SL4060, H710-SL4013,  H710-SL4012, H710-SL4011, H710-SL4361, H710-SL4363, H710-SL4362,  H710-SL4122, H710-SL4123, H710-SL445SH, H710-SL446SH, H710-SL401SH,  H710-FL4601, H710-SL4711M, H710-FL4713M, H710-FL4731M,  H710-FL4733M, H710-FL4741M, H710-FL4743M, H710-FL4751M,  H710-FL4753M  SL:5FR  H710-SL518, H710-SL520, H710-SL522, H710-SL519, H710-SL521,  H710-SL523, H710-SL518TJ, H710-SL520TJ, H710-SL522TJ, H710-SL519TJ,  H710-SL521TJ, H710-SL523TJ, SVH3-SL518SH, SVH3-SL520SH, SVH3-SL519SH,  SVH3-SL521SH, H710-SL5060, H710-SL5013, H710-SL5012, H710-SL5011,  H710-SL5361, H710-SL5363, H710-SL5362, H710-SL5122, H710-SL5123,  H710-S545, H710-S54, H710-SL548, H710-SL5601, H710-SL5661,  H710-SL5662, H710-SL5671, H710-SL5672, H710-SL5307, H710-SL5308,  H710-SL5309, H710-SL5711M, H710-FL5713M, H710-FL5731M,  H710-FL5733M, H710-FL5741M, H710-FL5743M, H710-FL5751M,  H710-FL5753M  TIP SHAPE  JL 3.5, JL 4.0, JL 5.0, JR 3.5, JR 4.0, JR 5.0,  JL 3.5 MOD 2, JL 4.0 MOD 2, JL 5.0 MOD 2, JL 3.5 MOD 2, JL 4.0 MOD 2,  JL 5.0 MOD 2, JL 3.5 SAFETY, JL 4.0 SAFETY, JL 3.5 SAFETY, JL 4.0 SAFETY,  KIMTAC 2  SAITO 3.0, SAITO 3.5, SAITO 4.0, M-3 LR 3.0, M-3 LR 3.5, M-3 LR 4.0,  Toranomon 3.5  Toranomon 4.0  AL 1, AL2, AR MOD, AR MOD, IM, Mpa 1 small, Mpa 1 small, Mpa 1 small,  Mpa 1 small, Nishiya S, Nishiya S, Nishiya S, STRAIGHT, STRAIGHT, ANGLE 145,  ANGLE 145, ANGLE 145, ANGLE 155, MULTICURVE, MULTICURVE | angiographic Catheter | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. Technowood Corporation, 4-30-19 Kouhoku, adachi-ku Tokyo, Japan.  FSC Japan  Valid till March 7, 2020.  Fee Submitted Rs.50,000/- | Technowood SSS Guidewire  (Catheter Guidewire)  H502-3515S, H502-3518S,  H502-3520S, H502-3522S  H502-3526S, H502-3515A  H502-3518A, H502-3520A  H502-3522A, H502-3526A  H502-3515P3, H502-3518P3  H502-3520P3, H502-3522P3  H502-3526P3, H502-3515PK1.5  H502-3518PK1.5, H502-3520PK1.5  H502-3522PK1.5, H502-3526PK1.5  H502-3515BK2, H502-3518BK2  H502-3520BK2, H502-3522BK2  H502-3526BK2, H502-3515AM  H502-3518AM, H502-3520AM  H502-3522AM, H502-3515S  H502-3518S, H502-3520S  H502-3522S, H502-3526S  H502-3515A, H502-3518A  H502-3520A, H502-3522A  H502-3526A, H502-3515P3  H502-3518P3, H502-3520P3  H502-3522P3, H502-3526P3  H502-3515PK1.5, H502-3518PK1.5  H502-3520PK1.5, H502-3522PK1.5  H502-3526PK1.5, H502-3515BK2  H502-3518BK2, H502-3520BK2  H502-3522BK2, H502-3526BK2  H502-3515AM, H502-3518AM  H502-3520AM, H502-3522AM  H503-3515S, H503-3518S  H503-3520S, H503-3522S  H503-3526S, H503-3515A  H503-3518A, H503-3520A  H503-3522A, H503-3526A  H503-3515P3, H503-3518P3  H503-3520P3, H503-3522P3  H503-3526P3, H503-3151BK1.5  H503-3518BK1.5, H503-3520BK1.5  H503-3522BK1.5, H503-3526BK1.5  H503-3515BK2, H503-3518BK2  H503-3520BK2, H503-3522BK2  H503-3526BK2, H503-3515AM  H503-3518AM, H503-3520AM  H503-3522AM, H503-3526AM  H503-3151BK1.5M  H503-3518BK1.5M  H503-3520BK1.5M  H503-3522BK1.5M  H503-3526BK1.5M  H503L-3515BK1.5M  H503L-3518BK1.5M  H503L-3520BK1.5M  H503L-3522BK1.5M  H503L-3526BK1.5M  Class : D  Shelf Life : 03 years | Coronary Angiographic Guidewire. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. Eurosets srl  STRADA STATALE 12, n.143  41036 MEDOLLA (MO)  ITALY.  FSC Italy Issued on March 23, 2018.  Fee Submitted Rs.50,000/- | TRILLY STERILE  (OXYGENATORS)  (EU5032)  Class B  Shelf Life : 03 years. | Oxygenator. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s. On-X Life Technologies, Inc. 1300 East, Anderson, Lane Building B, Austin, Texas 78752, USA  FSC USFDA  Valid till March 7, 2020.  Fee Submitted Rs.50,000/- | **On-X Aortic Prosthetic Heart Valves**  **AORTIC HEART VALVE- Standard Sewing Ring**  1)      ONXA-19  2)      ONXA-21  3)      ONXA-23  4)      ONXA-25  5)      ONXA-27/29  Class : D  Shelf Life : 06 years | Aortic Heart Valve | **Approved**. |
|  | **M/s Allmed Solutions,** A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi  (ELI-00029)  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s Bactiguard AB, Alfred Nobels Alle 150, 146 48 Tullinge, Sweden  (FSC Sweden Valid Till  01-10-2023)  Fee Submitted Rs.50,000/- | BIP Foley Catheter (Latex)  Class C  Shelf Life: 5 Years  Pediatric 2-Way  Fr. 08, 10  Adult 2-Way  Fr. 12, 14, 16, 18, 20, 22, 24, 26, 28, 30  Adult 3-Way  Fr. 16, 18, 20, 22, 24, 26, | BIP Foley Catheter | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s Bactiguard AB, Alfred Nobels Alle 150, 146 48 Tullinge, Sweden  (FSC Sweden Valid Till  01-10-2023)  **Rs.50,000/- already submitted against Slip No. 0012677 dated 29-11-2013** | BIP Foley Catheter (Silicone)  Class C  Shelf Life: 5 Years  Pediatric 2-Way  Fr.6,8,10  Adult 2-Way  Fr. 12, 14, 16, 18, 20, 22, 24, 26,  Female 2-Way  Fr. 12, 14, 16, 18, 20, 22, 24, 26,  Tiemann Tip 2-Way  Fr. 10, 12, 14, 16, 18, 20, 22, 24  Adult 3-Way  Fr. 16, 18, 20, 22, 24, 26,  Female 3-Way  Fr. 16, 18, 20, 22, 24, 26, | BIP Foley Catheter | **Approved**. |
|  | **-do-**  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufactured By:** M/s Bactiguard AB, Alfred Nobels Alle 150, 146 48 Tullinge, Sweden  (FSC Sweden Valid Till  01-10-2023)  Fee Submitted Rs.50,000/- | BIP Endotracheal Tube  Class C  Shelf Life: 5 Years  311003010 BIP Endotracheal Tube ID 3.0  311003510 BIP Endotracheal Tube ID 3.5  311004010 BIP Endotracheal Tube ID 4,0  311004010 BIP Endotracheal Tube ID 4,5  311004510 BIP Endotracheal Tube ID 5,0  311005010 BIP Endotracheal Tube ID 5,5  311005510 BIP Endotracheal Tube ID 6,0  311006010 BIP Endotracheal Tube ID 6,5  311006510 BIP Endotracheal Tube ID 7,0  311007010 BIP Endotracheal Tube ID 7,5  311007510 BIP Endotracheal Tube ID 8,0  311008010 BIP Endotracheal Tube ID 8,5  311008510 BIP Endotracheal Tube ID 9,0  311009010 BIP Endotracheal Tube ID 9,5  311009510 BIP Endotracheal Tube ID 10,0  311010010 BIP Endotracheal Tube ID | BIP Endotracheal Tube | **Approved**. |
|  | **M/s Life Cares,**  M-20, Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahra-e-Faisal, Karachi  (ELI-00077)  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s Rontis Corporation S.A. Bahnhosfstrasse 7, CH-6301 Zug, Switzerland  (FSC Switzerland Valid Till 13-02-2021)  Fee Submitted Rs.50,000/- | Leader® Plus Cobalt Chromium Coronary Stent System  Class D  Shelf Life: 4 Years  Codes & Sizes as per FSC | Bare Metal Stent System | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s Rontis Corporation S.A. Bahnhosfstrasse 7, CH-6301 Zug, Switzerland  (FSC Switzerland Valid Till 13-02-2021)  Fee Submitted Rs.50,000/- | Europa Ultra TM Semi Compliant Coronary Balloon Catheter  Class D  Shelf Life: 4 Years | Catheter | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufactured By:** M/s Rontis Corporation S.A. Bahnhosfstrasse 7, CH-6301 Zug, Switzerland  (FSC Switzerland Valid Till 13-02-2021)  Fee Submitted Rs.50,000/- | Lotus II TM 0.017 Coronary Guidewire  Class D  Shelf Life: 4 Years  Codes and sizes as per FSC | guidewire | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufactured By:** M/s Rontis Corporation S.A. Bahnhosfstrasse 7, CH-6301 Zug, Switzerland  (FSC Switzerland Valid Till 13-02-2021)  Fee Submitted Rs.50,000/- | Abrax TM Sirolimus-Eluting Biodegradable Polymer Coronary Stent System  Class D  Shelf Life: 24 Months | Stent System | **Approved.** |
|  | **M/s Ham International** Mezzanine Floor, Plot No. LS 2, St 9, Block 15, KDA Scheme 36, Gulistan Johar, Karachi  (ELI-00008)  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s Shunmei Medical Co., Ltd., R401 of Building B, No.8 Jinlong 1st Road, Baolong Industrial Zone, Long Gang District, Shenzhen, China  (FSC UK Issuance Date  20-04-2017)  Fee Submitted Rs.50,000/- | Shunmei PTFE coated Guide wire  Class D  Shelf Life: 3 Years  Codes & Sizes codes as per FSC. | PTFE coated Guide wire | **Approved** subject to submission of Pakistan Embassy attested FSC from UK. |
|  | **M/s. Treu-Dynamic International.**  C-206, 2nd Floor city Towers, Main Boulevard, Gulberg, Lahore.  (ELI-00175)  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer**  M/s. SURGIVAL Co. S.A.U  C/Leonardo da Vinci 12-14 46980  Paterna (Valencia) Spain.  FSC Spain  Issued on March 14, 2018  Rs. 50,000 | **Genutech Total Knee Replacement system**  Class C  Shelf Life : 05 years  **Components of system:**  **Codes & Sizes as per FSC No. 16/2018 of Spain**   * PS Cemented Femoral Component * NPS Cemented Femoral Component * Revision Cemented Femoral Component * PS Cementless Femoral Component * NPS Cementless Femoral Component * PS Tibial insert * NPS Tibial insert * Revision Tibial insert * Tibial Tray * Revision Tibial Tray. * Patellar Component * Offset Revision Stem. * Straight Revision Stem. * Posterior Femoral supplement * Distal Femoral supplement * Tibial supplement | Total Knee Prosthesis. | The Board referred the matter to Dr. Khalid S. Aslam, Orthopaedic Surgeon, Quaid-e-Azam International Hospital for opinion whether in international practice the product under consideration is supplied sterile or are sterilized in the hospital before surgery. Secondly the components mentioned can be grouped together as one system to be used in surgery. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer**  **M/s. SURGIVAL Co. S.A.U**  Leonardo da Vinci 12-14 46980  Paterna (Valencia) Spain.  FSC Spain  Issued on March 14, 2018  Rs. 50,000 | **Total Hip Replacement System.**  Class C  Shelf Life: 05 years  **Consist on the following components :-**  **1. SELF-LOCKING STEM,**  Nitrogen S.S SELF-LOCKING STEM 12/14 6.25 mm (A1501009E)  Nitrogen S.S SELF-LOCKING STEM 12/14 7.5 mm (A1501010E)  Nitrogen S.S SELF-LOCKING STEM 12/14 10.0 mm (A1501020E)  Nitrogen S.S SELF-LOCKING STEM 12/14 11.25 mm (A1501021E)  Nitrogen S.S SELF-LOCKING STEM 12/14 12.50 mm (A1501030E)  Nitrogen S.S SELF-LOCKING STEM 12/14 13.75 mm (A1501031E)  Nitrogen S.S SELF-LOCKING STEM 12/14 15.00 mm (A1501040E)  17.50 mm (A1500014E)  Titanium SELF-LOCKING STEM 12/14 6.25 mm , TPS Cementless (A1502010E)  Titanium SELF-LOCKING STEM 12/14 7. 50 mm , TPS Cementless (A1502011E)  Titanium SELF-LOCKING STEM 12/14 10. 00 mm , TPS Cementless (A1502012E)  Titanium SELF-LOCKING STEM 12/14 11. 25 mm , TPS Cementless (A1502112E)  Titanium SELF-LOCKING STEM 12/14 12. 50 mm , TPS Cementless (A1502013E)  TitaniumSELF-LOCKING STEM 12/14 13.75 mm TPS Cementless (A1502113E)  TitaniumSELF-LOCKING STEM12/14 15.00 mm TPS Cementless (A1502014E)  Titanium SELF-LOCKING STEM 12/14 17.50 mm TPS Cementless (A1502015E)  Titanium SELF-LOCKING STEM 12/14 6.25 mm , HA Cementless (A1504010E)  Titanium SELF-LOCKING STEM 12/14 7. 50 mm , HA Cementless (A1504011E)  Titanium SELF-LOCKING STEM 12/14 10. 00 mm , HA Cementless (A1504012E)  Titanium SELF-LOCKING STEM 12/14 11. 25 mm , HA Cementless (A1504112E)  Titanium SELF-LOCKING STEM 12/14 12. 50 mm , HA Cementless (A1504013E)  TitaniumSELF-LOCKING STEM12/14 13.75 mm HA Cementless (A1504113E)  TitaniumSELF-LOCKING STEM 12/14 15.00 mm HA Cementless (A1504014E)  Titanium SELF-LOCKING STEM 12/14 17.50 mm HA Cementless (A1504015E)  Titanium Karey-C Femoral Stem Cemented 12/14No. 9 (F0005109E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 10 (F0005110E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 11 (F0005111E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 12 (F0005112E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 13 (F0005113E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 14 (F0005114E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 15 (F0005115E)  Titanium Karey-C Femoral Stem Cemented 12/14 No. 16 (F0005116E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 8 (F0005158E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 9 (F0005159E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 10 (F0005160E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 11 (F0005161E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 12 (F0005162E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 13 (F0005163E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 14 (F0005164E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 15 (F0005165E)  High Nitrogen S.S Karey-C Femoral Stem Cemented 12/14 No. 16 (F0005166E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 8 (F0005008E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 9 (F0005009E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 10 (F0005010E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 11 (F0005011E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 12 (F0005012E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 13 (F0005013E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 14 (F0005014E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 15 (F0005015E)  Titanium Karey-HA Femoral Stem Cementless 12/14 No. 16 (F0005016E)  Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.12 (F0005412E)  Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.14 (F0005414E)  Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.16 (F0005416E)  Titanium Karey-Revision HA Femoral Stem Cementless 12/14 No.18 (F0005418E)  Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 12 (F0005452E)  Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 14 (F0005454E)  Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 16 (F0005456E)  Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 18 (F0005458E)  Titanium Karey-Revision C Femoral Stem Cemented 12/14 No. 20 (F0005460E)  Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 0 (A2700000E)  Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 1 (A2700001E)  Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 2 (A2700002E)  Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 3 (A2700003E)  Nitrogen S.S Shine-C Femoral Stem Cemented 12/14 No. 4 (A2700004E)  2. **Femoral Head**  Stainless Steel Endocephalic Femoral Head, 12/14 38 mm  (A1513238E)  Stainless Steel Endocephalic Femoral Head, 12/14 39 mm  (A1513239E)  Stainless Steel Endocephalic Femoral Head, 12/14 40 mm  (A1513240E)  Stainless Steel Endocephalic Femoral Head, 12/14 41 mm  (A1513241E)  Stainless Steel Endocephalic Femoral Head, 12/14 42 mm  (A1513242E)  Stainless Steel Endocephalic Femoral Head, 12/14 43 mm  (A1513243E)  Stainless Steel Endocephalic Femoral Head, 12/14 44 mm  (A1513244E)  Stainless Steel Endocephalic Femoral Head, 12/14 45 mm  (A1513245E)  Stainless Steel Endocephalic Femoral Head, 12/14 46 mm  (A1513246E)  Stainless Steel Endocephalic Femoral Head, 12/14 47 mm  (A1513247E)  Stainless Steel Endocephalic Femoral Head, 12/14 48 mm  (A1513248E)  Stainless Steel Endocephalic Femoral Head, 12/14 49 mm  (A1513249E)  Stainless Steel Endocephalic Femoral Head, 12/14 50 mm  (A1513250E)  Stainless Steel Endocephalic Femoral Head, 12/14 51 mm  (A1513251E)  Stainless Steel Endocephalic Femoral Head, 12/14 52 mm  (A1513252E)  Stainless Steel Endocephalic Femoral Head, 12/14 53 mm  (A1513253E)  Stainless Steel Endocephalic Femoral Head, 12/14 54 mm  (A1513254E)  Stainless Steel Endocephalic Femoral Head, 12/14 55 mm  (A1513255E)  Stainless Steel Endocephalic Femoral Head, 12/14 56 mm  (A1513256E)  Stainless Steel Endocephalic Femoral Head, Neck-5 38 mm  (A1513338E)  Stainless Steel Endocephalic Femoral Head, Neck-5 39 mm  (A1513339E)  Stainless Steel Endocephalic Femoral Head, Neck-5 40 mm  (A1513340E)  Stainless Steel Endocephalic Femoral Head, Neck-5 41 mm  (A1513341E)  Stainless Steel Endocephalic Femoral Head, Neck-5 42 mm  (A1513342E)  Stainless Steel Endocephalic Femoral Head, Neck-5 43 mm  (A1513343E)  Stainless Steel Endocephalic Femoral Head, Neck-5 44 mm  (A1513344E)  Stainless Steel Endocephalic Femoral Head, Neck-5 45 mm  (A1513345E)  Stainless Steel Endocephalic Femoral Head, Neck-5 46 mm  (A1513346E)  Stainless Steel Endocephalic Femoral Head, Neck-5 47 mm  (A1513347E)  Stainless Steel Endocephalic Femoral Head, Neck-5 48 mm  (A1513348E)  Stainless Steel Endocephalic Femoral Head, Neck-5 49 mm  (A1513349E)  Stainless Steel Endocephalic Femoral Head, Neck-5 50 mm  (A1513350E)  Stainless Steel Endocephalic Femoral Head, Neck-5 51 mm  (A1513351E)  Stainless Steel Endocephalic Femoral Head, Neck-5 52 mm  (A1513352E)  Stainless Steel Endocephalic Femoral Head, Neck-5 53 mm  (A1513353E)  Stainless Steel Endocephalic Femoral Head, Neck-5 54 mm  (A1513354E)  Stainless Steel Endocephalic Femoral Head, Neck-5 55 mm  (A1513355E)  Stainless Steel Femoral Head 12/14, Short Neck 22 mm  (A1509060E)  Stainless Steel Femoral Head 12/14, Short Neck 26 mm  (A1509050E)  Stainless Steel Femoral Head 12/14, Short Neck 28 mm  (A1509040E)  Stainless Steel Femoral Head 12/14, Short Neck 32 mm  (A1509013E)  Stainless Steel Femoral Head 12/14, Medium Neck 22 mm  (A1509061E)  Stainless Steel Femoral Head 12/14, Medium Neck 26 mm  (A1509051E)  Stainless Steel Femoral Head 12/14, Medium Neck 28 mm  (A1509041E)  Stainless Steel Femoral Head 12/14, Medium Neck 32 mm  (A1509014E)  Stainless Steel Femoral Head 12/14, Long Neck 22 mm  (A1509062E)  Stainless Steel Femoral Head 12/14, Long Neck 26 mm  (A1509052E)  Stainless Steel Femoral Head 12/14, Long Neck 28 mm  (A1509042E)  Stainless Steel Femoral Head 12/14, Long Neck 32 mm  (A1509015E)  Stainless Steel Femoral Head 12/14, Extra Long Neck 26 mm  (A1509053E)  Stainless Steel Femoral Head 12/14, Extra Long Neck 28 mm  (A1509043E)  Alumina Ceramic Femoral Head 12/14, Short Neck 26 mm  (A1507050E)  Alumina Ceramic Femoral Head 12/14, Short Neck 28 mm  (A1507040E)  Alumina Ceramic Femoral Head 12/14, Medium Neck 26 mm  (A1507051E)  Alumina Ceramic Femoral Head 12/14, Medium Neck 28 mm  (A1507041E)  Alumina Ceramic Femoral Head 12/14, Long Neck 26 mm  (A1507052E)  Alumina Ceramic Femoral Head 12/14, Long Neck 28 mm  (A1507042E)  CrCoMo Femoral Head 12/14, Short Neck 22 mm  (A1506060E)  CrCoMo Femoral Head 12/14, Short Neck 26 mm  (A1506050E)  CrCoMo Femoral Head 12/14, Short Neck 28 mm  (A1506040E)  CrCoMo Femoral Head 12/14,Medium Neck 22 mm  (A1506061E)  CrCoMo Femoral Head 12/14, Medium Neck 26 mm  (A1506051E)  CrCoMo Femoral Head 12/14, Medium Neck 28 mm  (A1506041E)  CrCoMo Femoral Head 12/14,Long Neck 22 mm  (A1506062E)  CrCoMo Femoral Head 12/14, Long Neck 26 mm  (A1506052E)  CrCoMo Femoral Head 12/14, Long Neck 28 mm  (A1506042E)  CrCoMo Femoral Head 12/14, Extra Long Neck 26 mm  (A1506053E)  CrCoMo Femoral Head 12/14, Extra Long Neck 28 mm  (A1506043E)  Stainless Steel Biarticular Head 41 mm  (A1519041E)  Stainless Steel Biarticular Head 42 mm  (A1519042E)  Stainless Steel Biarticular Head 43 mm  (A1519043E)  Stainless Steel Biarticular Head 44 mm  (A1519044E)  Stainless Steel Biarticular Head 45 mm  (A1519045E)  Stainless Steel Biarticular Head 46 mm  (A1519046E)  Stainless Steel Biarticular Head 47 mm  (A1519047E)  Stainless Steel Biarticular Head 48 mm  (A1519048E)  Stainless Steel Biarticular Head 49 mm  (A1519049E)  Stainless Steel Biarticular Head 50 mm  (A1519050E)  Stainless Steel Biarticular Head 51 mm  (A1519051E)  Stainless Steel Biarticular Head 52 mm  (A1519052E)  Stainless Steel Biarticular Head 53 mm  (A1519053E)  Stainless Steel Biarticular Head 54 mm  (A1519054E)  Stainless Steel Biarticular Head 55 mm  (A1519055E)  Biarticular Head Polyethylene (UHMWPE) Insert 28 mm  A ( 41,42,43 mm ) (A1519141E)  Biarticular Head Polyethylene (UHMWPE) Insert 28 mm  B ( 44,45,46 mm ) (A1519144E)  Biarticular Head Polyethylene (UHMWPE) Insert 28 mm  C ( 47,48,49,50 mm ) (A1519147E)  Biarticular Head Polyethylene (UHMWPE) Insert 28 mm  D ( 51,52,53,54,55 mm ) (A1519151E)  Biarticular Head Polyethylene (UHMWPE) Insert 22 mm  A ( 41,42,43 mm ) (A1519241E)  Biarticular Head Polyethylene (UHMWPE) Insert 22 mm  B ( 44,45,46 mm ) (A1519244E)  Biarticular Head Polyethylene (UHMWPE) Insert 22 mm  C ( 47,48,49,50 mm ) (A1519247E)  Biarticular Head Polyethylene (UHMWPE) Insert 22 mm  D ( 51,52,53,54,55 mm ) (A1519251E)  3. **Acetabular Cup**  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 40 x 28 mm (A1512240E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 42 x 28 mm (A1512242E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 44 x 28 mm (A1512244E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 46 x 28 mm (A1512246E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 48 x 28 mm (A1512248E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 50 x 28 mm (A1512250E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 52 x 28 mm (A1512252E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 54 x 28 mm (A1512254E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 56 x 28 mm (A1512256E)  Polyethylene (UHMWPE) Antiluxation Acetabular Cup Type  Muller Cemented 58 x 28 mm (A1512258E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA)Cementless 46 mm (A2400646E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA)  Cementless 48 mm (A2400648E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 50 mm (A2400650E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 52 mm (A2400652E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +H hidroxiapatite (HA) Cementless 54 mm (A2400654E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 56 mm (A2400656E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 58 mm (A2400658E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 60 mm (A2400660E)  Titanium S.H.Y+ TI Plasma Spray (TPS) +Hidroxiapatite (HA) Cementless 62 mm (A2400662E)  S.H.Y Cup Polyethylene Insert (UHMWPE) 46 x 26 mm (A2400746E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 48 x 26 mm (A2400748E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 46 x 26 mm (A2400746E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 50 x 28 mm (A2400750E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 52 x 28 mm (A2400752E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 54 x 28 mm (A2400754E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 56 x 28 mm (A2400756E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 58 x 28 mm (A2400758E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 60 x 28 mm (A2400760E)  S.H.Y Cup Polyethylene Insert (UHMWPE ) 62 x 28 mm (A2400762E)  Cementless Quarter Cup Titanium 40 mm (A2401640E)  Cementless Quarter Cup Titanium 42 mm (A2401642E)  Cementless Quarter Cup Titanium 44 mm (A2401644E)  Cementless Quarter Cup Titanium 46 mm (A2401646E)  Cementless Quarter Cup Titanium 48 mm (A2401648E)  Cementless Quarter Cup Titanium 50 mm (A2401650E)  Cementless Quarter Cup Titanium 52 mm (A2401652E)  Cementless Quarter Cup Titanium 54 mm (A2401654E)  Cementless Quarter Cup Titanium 56 mm (A2401656E)  Cementless Quarter Cup Titanium 58 mm (A2401658E)  Cementless Quarter Cup Titanium 60 mm (A2401660E)  Cementless Quarter Cup Titanium 62 mm (A2401662E)  Cementless Quarter Cup Titanium 64 mm (A2401664E)  Cementless Quarter Cup Titanium 66 mm (A2401666E)  Cementless Quarter Cup Titanium 68 mm (A2401668E)  Quarter InsertAntiluxation 40 x22 mm (A2412240E)  Quarter Insert Antiluxation 42 x22 mm (A2412242E)  Quarter Insert Antiluxation 44x22 mm (A2412244E)  Quarter Insert Antiluxation 46x22 mm (A2412246E)  Quarter Insert Antiluxation 44x28 mm (A2412844E)  Quarter Insert Antiluxation 46x28 mm (A2412846E)  Quarter Insert Antiluxation 48x28 mm (A2412848E)  Quarter Insert Antiluxation 50x28 mm (A2412850E)  Quarter Insert Antiluxation 52x28 mm (A2412852E)  Quarter Insert Antiluxation 54x28 mm (A2412854E)  Quarter Insert Antiluxation 56x28 mm (A2412856E)  Quarter Insert Antiluxation 58x28 mm (A2412858E)  Quarter Insert Antiluxation 60x28 mm (A2412860E)  Quarter Insert Antiluxation 62x28 mm (A2412862E)  Quarter Insert Antiluxation 64x28 mm (A2412864E)  Quarter Insert Antiluxation 66x28 mm (A2412866E)  Quarter Insert Antiluxation 68x28 mm (A2412868E)  Quarter Insert Antiluxation 48x32 mm (A2413248E)  Quarter Insert Antiluxation 50x32 mm (A2413250E)  Quarter Insert Antiluxation 52x32 mm (A2413252E)  Quarter Insert Antiluxation 54x32 mm (A2413254E)  Quarter Insert Antiluxation 56x32 mm (A2413256E)  Quarter Insert Antiluxation 58x32 mm (A2413258E)  Quarter Insert Antiluxation 60x32 mm (A2413260E)  Quarter Insert Antiluxation 62x32 mm (A2413262E)  Quarter Insert Antiluxation 64x32 mm (A2413264E)  Quarter Insert Antiluxation 66x32 mm (A2413266E)  Quarter Insert Antiluxation 68x32 mm (A2413268E)  Quarter Insert Antiluxation 52x36 mm (A2413652E)  Quarter Insert Antiluxation 54x36 mm (A2413654E)  Quarter Insert Antiluxation 56x36 mm (A2413656E)  Quarter Insert Antiluxation 58x36 mm (A2413658E)  Quarter Insert Antiluxation 60x36 mm (A2413660E)  Quarter Insert Antiluxation 62x36 mm (A2413662E)  Quarter Insert Antiluxation 64x36 mm (A2413664E)  Quarter Insert Antiluxation 66x36 mm (A2413666E)  Quarter Insert Antiluxation 68x36 mm (A2413668E)  Quarter Insert Neutral 44x28 mm (A2402844E)  Quarter Insert Neutral 46x28 mm (A2402846E)  Quarter Insert Neutral 48x28 mm (A2402848E)  Quarter Insert Neutral 50x28 mm (A2402850E)  Quarter Insert Neutral 52x28 mm (A2402852E)  Quarter Insert Neutral 54x28 mm (A2402854E)  Quarter Insert Neutral 56x28 mm (A2402856E)  Quarter Insert Neutral 58x28 mm (A2402858E)  Quarter Insert Neutral 60x28 mm (A2402860E)  Quarter Insert Neutral 62x28 mm (A2402862E)  Quarter Insert Neutral 64x28 mm (A2402864E)  Quarter Insert Neutral 66x28 mm (A2402866E)  Quarter Insert Neutral 68x28 mm (A2402868E)  Quarter Insert Neutral 48x32 mm (A2403248E)  Quarter Insert Neutral 50x32 mm (A2403250E)  Quarter Insert Neutral 52x32 mm (A2403252E)  Quarter Insert Neutral 54x32 mm (A2403254E)  Quarter Insert Neutral 56x32 mm (A2403256E)  Quarter Insert Neutral 58x32 mm (A2403258E)  Quarter Insert Neutral 60x32 mm (A2403260E)  Quarter Insert Neutral 62x32 mm (A2403262E)  Quarter Insert Neutral 64x32 mm (A2403264E)  Quarter Insert Neutral 66x32 mm (A2403266E)  Quarter Insert Neutral68x32 mm (A2403268E)  Quarter Insert Neutral 52x36 mm (A2403652E)  Quarter Insert Neutral 54x36 mm (A2403654E)  Quarter Insert Neutral 56x36 mm (A2403656E)  Quarter Insert Neutral 58x36 mm (A2403658E)  Quarter Insert Neutral 60x36 mm (A2403660E)  Quarter Insert Neutral 62x36 mm (A2403662E)  Quarter Insert Neutral 64x36 mm (A2403664E)  Quarter Insert Neutral 66x36 mm (A2403666E)  Quarter Insert Neutral 68x36 mm (A2403668E)  Quarter Insert Neutral 56x40 mm (A2404056E)  Quarter Insert Neutral 58x40 mm (A2404058E)  Quarter Insert Neutral 60x40 mm (A2404060E)  Quarter Insert Neutral 62x40 mm (A2404062E)  Quarter Insert Neutral 64x40 mm (A2404064E)  Quarter Insert Neutral 66x40 mm (A2404066E)  Quarter Insert Neutral 68x40 mm (A2404068E)  4. **Screw for Cup**  SHY Screw for Cup L= 20 mm (A2400520)  SHY Screw for Cup L= 25 mm (A2400525)  SHY Screw for Cup L= 30 mm (A2400530)  SHY Screw for Cup L= 35 mm (A2400535)  SHY Screw for Cup L= 40 mm (A2400540)  SHY Screw for Cup L= 45 mm (A2400545) | The total hip replacement System is Group of Medical Devices used as System under the name of the total Hip replacement system. | The Board referred the matter to Dr. Khalid S. Aslam, Orthopaedic Surgeon, Quaid-e-Azam International Hospital for opinion whether in international practice the product under consideration is supplied sterile or are sterilized in the hospital before surgery. Secondly the components mentioned can be grouped together as one system to be used in surgery. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Wuxi BoTEC Medical Innovation Co., Ltd. No. 8-9 Jingrui Rd, Zhangjing, Xibei Town, Xishan Area, Wuxi, Jiangsu Province, 214194 P.R. China  FSC Germany  Issued on 01.10.2018  Fee Submitted Rs.50,000/- | **Anterior Spinal fixation System**  OSTEOSYNTHESİS SYSTEM.having following parts  PINE ROD  PINE FIXED AXIAL SCREW  PINE MULTI AXIAL SCREW  PINE MULTI AXIAL Reduction SCREW  PINE SET SCREWw  PINE CROSS LINK  Hopper Plates, Screw set  Eagle Plates, screw set  Octopus plates, screw set  Leopard Plates, Screw set  Rhino Plates, Screw set  Double thread Screws  Hummer Screws  DORADO Wire.  Class D  Shelf Life : 05 years | Botec Osteosynthesis System  Description of Device, Presentation form and List of Instruments used to implant the  Device.  The Botec Osteosynthesis Implants Group of Medical Devices used as System.  The Botec Spinal System consists mainly of three key elements: the Spinal Screw (Fixed Head, Multiaxial, and  Reduction), Titanium Rod, and Cross Link. | The Board referred the matter to Dr. Khalid S. Aslam, Orthopaedic Surgeon, Quaid-e-Azam International Hospital for opinion whether in international practice the product under consideration is supplied sterile or are sterilized in the hospital before surgery. Secondly the components mentioned can be grouped together as one system to be used in surgery. |
|  | M/s. Pak Punjab Cardex Medical System, R-202, eden Height Jail Road, Lahore.  ELI-00174  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Elixir Medical Corporation, 920N.McC Arthy Blvd., Suite 100 Milpitas CA 95035 USA.  **Authorized Representative**  M/s. Acorn Regulatory Consultancy Services Ltd., Knockmorris, Cahir Co. tipperary, Ireland.  FSC Ireland  Valid till 03.10.2022.  Fee Submitted Rs.50,000/- | **DESyne X2 NECSS**  Novolimus Drug Eluting Stent System  SZR2514, SZR2518  SZR2523, SZR2528  SZR2532, SZR2538  SZR2714, SZR2718  SZR2723, SZR2728  SZR2732, SZR2738  SZR3014, SZR3018  SZR3023, SZR3028  SZR3032, SZR3038  SZR3514, SZR3518  SZR3523, SZR3528  SZR3532, SZR3538  SZR4014, SZR4018  SZR4023, SZR4028  SZR4032, SZR4038  Class D  Shelf Life : 03 years | Novolimus Drug Eluting Stent System | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Elixir Medical Corporation, 920N.McC Arthy Blvd., Suite 100 Milpitas CA 95035 USA.  **Authorized Representative**  M/s. Acorn Regulatory Consultancy Services Ltd., Knockmorris, Cahir Co. tipperary, Ireland.  FSC Ireland  Valid till 26.07.2022  Fee Submitted Rs.50,000/- | **DESyne NECSS**  Novolimus Drug Eluting Stent System  SER2514, SER2518  SER2523, SER2528  SER2532, SER2538  SER2714, SER2718  SER2723, SER2728  SER2732, SER2738  SER3014, SER3018  SER3023, SER3028  SER3032, SER3038  SER3514, SER3518  SER3523, SER3528  SER3532, SER3538  SER4014, SER4018  SER4023, SER4028  SER4032, SER4038  Class D  Shelf Life : 03 years | Novolimus Drug Eluting Stent System | **Approved**. |
|  | M/s. Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore.  ELI-00147 | **Legal Manufacturer:**  M/s. Biosensors International Pte. Ltd. (BSI)  36 Jalan Tukang, Singapore 619266.  **Authorized Representative:**  M/s. Shanghai International Holding Corp. GmbH, eiffestrabe 80, 20537 Hamburg, Germany.  FSC Germany  Issued on 14th August, 2018  Fee Submitted Rs.50,000/- | **Biosenser Thermodilution Catheter and kit**  SIZES AS PER FSC  TD1504, TD1604, TD1704, TD1755, TD2504, TD2604, TD2704, TD2755  BIOTRAY TD1504, BIOTRAY TD1604, BIOTRAY TD1704, BIOTRAY TD1755, BIOTRAY TD2504, BIOTRAY TD2604, BIOTRAY TD2704, BIOTRAY TD2755, BIOTRAY TD1502, BIOTRAY TD1602, BIOTRAY TD1702, BIOTRAY TD1603, BIOTRAY TD1703, BIOTRAY TD2502, BIOTRAY TD2602, BIOTRAY TD2702, BIOTRAY TD2603, BIOTRAY TD2703.  Class D  Shelf Life : 03 years | Thermodilution Catheter | **Approved**. |
| 1. . | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. Biosensors International Pte. Ltd. (BSI)  36 Jalan Tukang, Singapore 619266.  **Authorized Representative:**  M/s. Shanghai International Holding Corp. GmbH, eiffestrabe 80, 20537 Hamburg, Germany.  FSC Germany  Issued on 22nd July, 2018 | **Biosenser Bipolar Pacing Catheter**  Sizes:  BP2502-10, BPX2502-10, BP2502CS-10, BPX2502CS-10.  Class D  Shelf Life : 03 years  Fee Submitted Rs.50,000/- | Bipolar pacing catheter is made of radiopaque polyurethane tubing material that allows the use of fluoroscopy for guiding the catheter during catheter insertion or to verify its position when necessary. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. OSYPKA AG, Earl-H, Wood-Strasse 1, 79618 Rheinfelden, Germany.  FSC Germany  Issued on February 4, 2019  Fee Submitted Rs.50,000/- | **OSYPKA TME (Heart Wire)**  (Temporary Myocardial Electrode)  SIZES / CODES AS PER FSC:  45001, 45002, 45016-01, 45017-01, 45023-02, 45053, 45112, 45200, 45200-G, 45200WS, 45201, 45201WS, 45202, 45202WS, 45001N, 45002N, 45016-01N, 45017-01N, 45023-02N, 45053N, 45112N, 45200N, 45200-GN, 45200WSN, 45201N, 45201WSN, 45202N, 45202WSN, 45009-02, 45009C02, 45011, 45011WS, 45028, 45028BLWS-C, 45028-C, 45041-02, 45041WS02, 45042-02, 45042C02, 45042WS02, 45042WSC02, 45043, 45044-01, 45044C01-PE, 45044WS01, 45044WSC01-PE, 45045, 45045-V, 45045WS, 45055, 45056, 45056-PE, 45057, 45066-PE, 45072-SL, 45111, 45113, 45205, 45205WS, 45206, 45206WS, 45207, 45207WS, 45209, 46013-02, 46013C02, 46013WSC02, 46014-02, 46016-01, 46017-02, 46031, 46033-01, 46033C01, 46033WS01, S5676-01, S5676C01, 45009-02N, 45009C02N, 45011N, 45011WSN, 45028N, 45028BLWS-CN, 45028-CN, 45041-02N, 45041WS02N, 45042-02N, 45042C02N, 45042WS02N, 45042WSC02N, 45043N, 45044-01N, 45044C01-PEN, 45044WS01N, 45044WSC01-PEN, 45045N, 45045-VN, 45045WSN, 45055N, 45056N, 45056-PEN, 45057N, 45066-PEN, 45072-SLN, 45111N, 45113N, 45205N, 45205WSN, 45206N, 45206WSN, 45207N, 45207WSN, 45209N, 46013-02N, 46013C02N, 46013WSC02N, 46014-02N, 46016-01N, 46017-02N, 46031N, 46033-01N, 46033C01N, 46033WS01N, S5676-01N, S5676C01N.  Class D  Shelf Life : 03 years | OSYPKA Temporary Myocardial Electrodes (TMEs) | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. OSYPKA AG, Earl-H, Wood-Strasse 1, 79618 Rheinfelden, Germany.  FSC Germany  Issued on February 4, 2019  Fee Submitted Rs.50,000/- | **CERABLATE Cool Cardiac Ablation Catheter**  SIZES / CODES AS PER FSC:  283120, 283121, 283122, 283123, 283124, 283125, 283126, 283127, 283128, 283129, 283130, 283131, 283132, 283133, 283134, 283135, 283136, 283137.  Class D  Shelf Life : 03 years | Cardiac Ablation Catheter. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. OSYPKA AG, Earl-H, Wood-Strasse 1, 79618 Rheinfelden, Germany.  FSC Germany  Issued on February 4, 2019  Fee Submitted Rs.50,000/- | **FINDER/Pure Intracardiac Diagnostic Catheter**.  SIZES / CODES AS PER FSC:  24481, 24485, 24489, 24415, 24420, 24424, 24482, 24486, 24490, 24416, 24421, 24425, 24483, 24487, 24491, 24484, 24488, 24492, 24418, 24423, 24427, 24470, 24446, 24477, 24401, 24406, 24410, 24471, 24474, 24478, 24472, 24475, 24479, 24473, 24476, 24480, 24404, 24409, 24403, 24493, 24499, 24429, 24434, 24438, 24444, 24494, 24500, 24430, 24435, 24439, 24495, 24498, 24501, 24496, 24502, 24432, 24437, 24441, 24443, 24510, 24511, 24512, 24513, 24514, 24515, 24516, 24517, 24520, 24521, 24522, 24523, 24524, 24525, 24526, 24527.  Class D  Shelf Life : 03 years | diagnostic catheters are intended for temporary intracardiac ECG  recording and stimulation of the heart in connection with an external stimulator within the scope of electrophysiological examinations. | **Approved.** |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. OSYPKA AG, Earl-H, Wood-Strasse 1, 79618 Rheinfelden, Germany.  FSC Germany  Issued on February 4, 2019  Fee Submitted Rs.50,000/- | VACS Percutaneous Transluminal Valvuloplasty Balloon Catheter.  SIZES / CODES AS PER FSC:  YA0010, YA0011, YA0012 YA0013, YA0014, YA0015 YA0016, YA0018, YA0019 YA0020, YA0021, YA0022 YA0023, YA0024, YA0025 YA0026, YA0027, YA0028 YA0029, YA0030, YA0035 YA0036, YA0037, YA0038 YA0043, YA0044, YA0045 YA0046, YA0047, YA0048 YA0049, YA0050, YA0051 YA0052, YA0053, YA0054 YA0055, YA0056, YA0059 YA0060, YA0061, YA0062 YA0063, YA0064, YA0065 YA0066, YA0067, YA0068 YA0069, YA30520, YA30620 YA30720, YA30820, YA30830 YA31020, YA31030, YA31040 YA31220, YA31230, YA31240 YA31260, YA31430, YA31440 YA31630, YA31640, YA31660 YA31830, YA31840, YA31860 YA32040, YA32060, YA32240 YA32260, YA32340, YA32440 YA32460, YA32540, YA32640 YA32660, YA32840, YA32860 YA33040, YA33060  Class D  Shelf Life : 03 years | Percutaneous Transluminal Valvuloplasty Balloon Catheter. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. OSYPKA AG, Earl-H, Wood-Strasse 1, 79618 Rheinfelden, Germany.  FSC Germany  Issued on February 4, 2019  Fee Submitted Rs.50,000/- | CERABLATE Easy/TC Cardiac Ablation Catheter.  SIZES / CODES AS PER FSC:  283080, 283081, 283082, 283083, 283084, 283085, 283086, 283087, 283088, 283089, 283090, 283091, 283092, 283093, 283094, 283095, 283096, 283097.  Class D  Shelf Life : 03 years | Cardiac Ablation Catheter. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. Prodimed SAS,  6 Rue Louis Armand - 95130 Le, Plessis Bouchard, France.  FSC France  Issued on 9th October, 2018  Fee Submitted Rs.50,000/- | SELDICATH  (Arterial Catheter)  SIZES / CODES AS PER FSC:  3842.09, 3843.09, 3843.12,  3844.09, 3844.12, 3846.09,  3846.12, 3848.12, 3849.12,  3871.07, 3871.10, 3872.07,  3872.10, 3872.13, 3873.10,  3873.13, 3874.10, 3874.13,  3874.17, 3874С10, 3876.10  3876.13, 3876.17, 3876.20,  3881.10, 3881.13, 3881.13L,  3882.10, 3822.13, 3882.17,  3882.20, 3883.10, 3883.13,  3883.17, 3883.20.  Class D  Shelf Life : 05 years | Arterial  catheter | **Approved**. |
|  | **M/s Briogene** Private Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi  (ELI-00015)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date 21-02-2018)  Fee Submitted Rs.50,000/- | Artus® CT/NG QS-RGQ Kit (96)  Class C  Shelf Life: 17 Months  Model: 4569365 | In vitro nucleic acid amplification test for the quantitation of CMV DNA in human plasma | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date 21-02-2018)  Fee Submitted Rs.50,000/- | Artus HSV-1/2 RG PCR Kit (24), V1  Artus HSV-1/2 RG PCR Kit (96), V1  Class C  Shelf Life: 24 Months  4500263, 4500265 | The artus HSV-1/2 RG PCR Kit is a real-time based polymerase chain reaction (PCR) assay for the detection and discrimination of human herpes simplex virus 1 and 2 DNA | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date 21-02-2018)  Fee Submitted Rs.50,000/- | Artus BK Virus RG PCR Kit (24), V1  Artus BK Virus RG PCR Kit (96), V1  Class C  Shelf Life: 24 Months  4514263, 4514265 | The Artus BK Virus PCR Kit is an in vitro nucleic acid amplification test for the quantitation of BK virus DNA in human Plasma or urine | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date 21-02-2018)  Fee Submitted Rs.25000/- | QFT-Plus tubes (50xTB1/TB2/Nil/Mitogen)  Class B  Shelf Life: 15 Months  622526 | Evacuated blood collection tube IVD, lithium heparin/gel separator  QuantiFERON® -TB Gold Plus (QFT-Plus) Blood Collection Tubes | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date 21-02-2018)  Fee Submitted Rs.50,000/- | Artus HCV QS RGQ Kit, V1  24 Test / Kit  72 Test / Kit  Class D  Shelf Life: 10 Months  4518363, 4518366, | IVD for Molecular Detection kit for viral load monitoring of Hepatitis C | **Approved subject to verification of Fee Challan**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qiagen GmbH Qiagen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date 21-02-2018).  Fee Submitted Rs.50,000/- | QuantilFERON® TB Glod Plus  Code 622120  Class C  Shelf Life: 36 Months | IVD Kit for stimulation of effector T cells in whole blood with a specific antigen(s) or mitogen, and the subsequent simple quantification of the resulting interferon-gamma in the plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Qiagen GmbH, Qiagen Str. 1, 40724 Hilden, Germany  (FSC Germany Issue Date 21-02-2018)  Fee Submitted Rs.50,000/- | Artus® HI Virus-1 RG RT-PCR Kit  1. Artus® HI Virus-1 RG RT-PCR Kit (24), V1  Code: 4513263  2. Artus® HI Virus-1 RG RT-PCR Kit (96), V1  Code: 4513265  Class C  Shelf Life: 20 Months | An in vitro nucleic acid amplification test for the quantitation of HIV type 1 RNA in human plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Qiagen GmbH, Qiagen Str. 1, 40724 Hilden, Germany  (FSC Germany Issue Date 14-12-2018)  Fee submitted Rs 50,000/- | Artus® HCV QS-RGQ Kit (V2)  1. Artus HCV QS-RGQ Kit (72), V2  Code: 4538366  Class C  Shelf Life: 12 Months | An in vitro nucleic acid amplification test for the quantitation of hepatitis C virus (HCV) RNA in human EDTA plasma. | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Qiagen GmbH, Qiagen Str. 1, 40724 Hilden, Germany  (FSC Germany Issue Date 21-02-2018) | Artus® M.tuberculosis RG PCR Kit  1. Artus® M.tuberculosis RG PCR Kit (24), V1  Code: 4555263  2. Artus M.tuberculosis RG PCR Kit (96), V1  Code: 4555265  Class C  Shelf Life: 12 Months  Fee submitted Rs 50,000/- | An in Vitro nucleic acid amplification test for the detection of all members of the M.tubercluosis complex (M.tubercluosis, M.africanum, M. hovis, M. bovis BCG, M. microti, M. pinnipedii) in human sputum, BAL, bronchial secretion, CSF, stomach fluid or peritoneal punction samples. | **Approved**. |
|  | **M/s Intra Health,** 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi  (ELI-00049)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Qingdao DMD Medical Technology Co. Ltd., No. 873, Hetao Subdistrict Office, Hongdao Economic Zone, Qingdao, Shandong, China  (FSC China Valid Till  01-10-2020)  FSC Germany Issue Date 19-10-2018)  Fee Submitted Rs.50,000/- | Ligating Clip (Maxi Clip)  Class C  Shelf Life: 3 Years  PLTX220, PLTX230, PLTX240, PLTX250. | Titanium Ligation Clip | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Qingdao DMD Medical Technology Co. Ltd., No. 873, Hetao Subdistrict Office, Hongdao Economic Zone, Qingdao, Shandong, China  (FSC China Valid Till  01-10-2020)  (FSC Germany Issue Date 19-10-2018)  Fee Submitted Rs. 50,000/- | MAXi-CLiP®  Class C  Shelf Life: 3 Years  Models:  TCLT100, TCLT200,  TCLT300, TCLT400; TCTL5200, TCTL1200, TCTL1201, TCTL1202, TCTL2200, TCTL3200, TCTL4200, TCTL100-24, TCTL200-24, TCTL1201-24, TCTL2200-24 | Titanium Ligating Clip | **Approved.** |
|  | **M/s. Healthline Pharmaceutical Pvt Ltd.**Office No.402, Al-Hafeez Heights, Gulberg-3, Lahore.  (ELI-00  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer**  M/s. Preservation Solutions,  1099 Proctor Drive, Elkhorn Wisconsin WI 53121 USA.  **Name of Disributor:**  M/s Bridge To Life Ltd., 128 Suber Rd, Suite A, Colimbia, SC USA 29210.  FSC USFDA  Valid till February 28, 2021  Fee Submitted Rs. 50,000/- | Belzer UW Cold Storage Solution 1000 ml.  Codes not mentioned  Class D  Shelf Life: 24 months. | Belzer UW Cold Storage Solution in intended for the flushing of kidney, liver and pancreas organs at the time of removal from the donar in prepartion for sotrge, transportation and eventual transplantation into a recipient. | **Approved** subject to provision of ISO 13485 and Embassy attested FSC. |
|  | **M/s Pharma Consultant Pakistan (Pvt) Ltd.,** Suit No.207, 207 A Khan Tower, DHA Square Walton Road, Lahore  (ELI-00176)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date 02-03-2018)  Fee Submitted Rs. 50,000/- | Sorin Annuloplasty Devices Sovering Mitral Ring,  Class D  Shelf Life: 5 Years  ICV0839/SA26M, ICV0840/SA28M, ICV0841/SA30M | Annuloplasty Ring | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date (02-03-2018)  Fee Submitted Rs. 50,000/- | Perceval S Biological Heart Valve (Bovine)  Class D  Shelf Life: 4 Years  ICV1208/PVS21, ICV1209/PVS23, ICV1210/PVS25, ICV1211/PVS27 | Biological Heart Valve  (Bovine) | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  **Manufacturer:**  M/s LivaNova Canada Corp., 5005 North Fraser Way, Burnaby, British Colombia, V5J 5M1 Canada  (FSC Italy Issuance Date (02-03-2018)  Fee Submitted Rs. 50,000/- | Carbomedics Carbo-Seal (Aortovalvular Prostheses)  Class D  Shelf Life: 4 Years  AP-021, AP-023,AP-025, AP-027, AP-029,  AP-031, AP-033 | Aortovalvular Prostheses | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date 02-03-2018)  Fee Submitted Rs. 50,000/- | Carbomedics Annuloflo Devices for Annuloplasty  Class D  Shelf Life: 5 Years  AR-726, AR-728, AR-730,  AR-732, AR-734, AR-736, | Annuloplasty Ring | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date 02-03-2018)  Fee Submitted Rs. 50,000/- | Solo Smart Biological Heart Valve  Class D  Shelf Life: 4 Years  ICV1246/ART19SMT, ICV1247/ART21SMT, ICV1248/ART23SMT, ICV1264/ART25SMT, ICV1265/ART27SMT | Stent-less Biological Heart Valve | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date 02-03-2018)  Fee Submitted Rs. 50,000/- | Pericarbon More-mod Mitral  Class D  Shelf Life: 4 Years  ICV0766/PS19, ICV0767/PS21,  ICV0768/PS23, ICV0769/PS25,  ICV0770/PS27, ICV0771/PS29,  ICV0772/PS31, ICV0773/PS33 | Biological Heart Valve | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Legal Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date (02-03-2018)  Fee Submitted Rs. 50,000/- | Devices for Annuloplasty Memo 3D,  Class D  Shelf Life: 5 Years  ICV0966/SMD24, ICV0967/SMD26,  ICV0968/SMD28,  ICV0969/SMD30,  ICV0970/SMD32,  ICV0971/SMD32,  ICV0972/SMD36,  ICV0973/SMD38 | Annuloplasty Ring | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date 02-03-2018)  Fee Submitted Rs. 50,000/- | Carbomedics Heart Valve (Mitral)  Class D  Shelf Life: 5 Years  Carbomedics Standard Mitral  M7-016, M7-018, M7-021,  M7-023, M7-025, M7-027,  M7-029, M7-031, M7-033  Carbomedics Orbis Mitral  M2-021, M2-023, M2-025,  M2-027, M2-029, M2-031,  M2-033  Carbomedics Optiform Mitral  F7-021, F7-023, F7-025,  F7-027, F7-029, F7-031,  F7-033 | Mechanical Heart Valve | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issuance Date 02-03-2018)  **Fee submitted Rs. 50,000/-** | Carbomedics Heart Valve (Aortic)  Class D  Shelf Life: 5 Years  Carbomedics Standard Aortic  A5-016, A5-018, A5-019, A5-021, A5-023, A5-025, A5-027, A5-029, A5-031  Carbomedics Reduced Aortic  R5-019, R5-021, R5-023,  R5-025, R5-027, R5-029  Carbomedics Supra-Annular Aortic (Top Hat)  S5-019, S5-021, S5-023,  S5-025, S5-027  Carbomedics Orbis Aortic  A1-019, A1-021, A1-023, A1-025 A1-027, A1-029,  A1-031 | Mechanical Heart Valve | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do- | **Manufacturer:**  M/s LivaNova Canada Corp., 5005 North Fraser Way Burnaby, British Columbia V5J 5M1, Canada  (FSC Canada Issuance Date 05-07-2018)  **Fee submitted Rs. 50,000/-** | Crown PRT  Class D  Shelf Life: 5 Years  CNA19, CNA21, CNA23, CNA25, CNA27, CNA29 | Aortic Pericardial Heart Valve | **Approved** subject to provision of credential of manufacturer, GMP inspection report and stability studies. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issue Date  02-03-2018)  Fee submitted: Rs 50,000/- | Carbomedics Standard Mitral  Class D  Shelf Life: 5 Years  M7-016, M7-018, M7-021,  M7-023, M7-025, M7-027,  M7-029, M7-031, M7-033 | Prosthetic Heart Valve | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Sorin Group Italia S.r.l., Via Crescentino sn, 13040 Saluggia (VC) Italy  (FSC Italy Issue Date  02-03-2018)  Fee submitted: Rs 50,000/- | Carbomedics Standard Aortic  Class D  Shelf Life: 5 Years  Codes: A5-016, A5-018, A5-019, A5-021, A5-023, A5-025, A5-027, A5-029, A5-031 | Prosthetic Heart Valve | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s LivaNova Canada Corp., 5005 North Fraser Way Burnaby, British Columbia V5J 5M1, Canada  (FSC Canada Issue Date  05-07-2018)  Fee submitted: Rs.50,000/- | Crown PRT  Class D  Shelf Life: 5 Years  CNA19, CNA21, CNA23, CNA25, CNA27, CNA29 | Aortic Pericardial Heart Valve | **Approved**. |
|  | **M/s The Searle Company Limited,** 1st Floor, NICL Building, Abbasi Shaheed Road, Karachi  (ELI-00057)  Evaluator:  Muhammad Ayub Naveed | **Manufactured By:** M/s Abu Dhabi Medical Devices Co, L.L.C Mussafah City M43 –Block 124, P O Box 30485, Abu Dhabi, UAE  (FSC UAE Valid Till  23-01-2019)  **Fee. submitted Rs. 25000/-** | Medco® Inject Single Use Syringe 10ml  Class B  Shelf Life: 3 Years | Sterile Hypodermic Syringes | **Approved** subject to foreign inspection of the manufacturer abroad. The Board also authorized the Secretary, MDB to issue registration letter if the manufacturing plant is aqpproved by the expert panel. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/Manufacturing site:** M/s Abu Dhabi Medical Devices Co, L.L.C  Mussafah City M43 –Plot 124, P O Box 30485, Abu Dhabi, UAE  (FSC UAE Valid Till  27-12-2020)  Fee submitted Rs.25000/- | Medeco® Inject Re-use Prevention Syringe  Class B  Shelf Life: 3 Years  2/3 ml and 5 ml | Re-Use Prevention Syringes | **Approved** subject to foreign inspection of the manufacturer abroad. The Board also authorized the Secretary, MDB to issue registration letter if the manufacturing plant is aqpproved by the expert panel. |
|  | M/s. 4A InternationalPlot 7, street No 11,lawyers Society, Chaklala, Rawalpindi.  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer**  M/s. Detro Healthcare Kimya Sanayi A.S. Ataturk mh. Adnan Menderes cd. No: 7 Esemyurt / Istanbul, Turkey.  FSC Spain  Issued on 14th Nov, 2018  Fee submitted Rs.50,000/- | Detro FORTE  (Gluteraldeyude 2%)  Detro Forte 5 L  Class C  Shelflife : 02 years | Instrument and Endoscope Disinfectant | **Approved**. |
|  | M/s. A.K Pharma (Pvt) Ltd., Zone 2557, 2nd Floor, Adjucent Total Parco, Firdos Market, Lahore.  ELI-00360  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. Silhouette Lift Inc., I Technology Drive Suite F211 Irvine, California 92618 USA.  **Manufacturing Site:**  M/s. Vaupell Corporate Office, 1144-N, W 53rd Seattle, WA 98107 USA.  FSC U.K  Issued on 11.04.2018 | Silhouette Soft  SMS22  SMS23  SMS25  SMS100  SMS102  Class D  Shelf Life : 18 months | Silhouette Soft is intended to be used for facial reconstruction in the treatemnt, for instance, of facial lipoatrophy or morphological asymmetry. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. AQTIS Medical BV Yalelaan 44,3584 CM Utrecht, the Netherlands.  FSC Netherlands  Valid till 0108.2022 | Aqtis Medical Dermal Filler  EllanseTM S  EllanseTM M  EllanseTM L  EllanseTM E  Class D  Shelf Life : 02 years | ELLANSE TM is a sterile, latex-free, non-pyrogenci, totally bio resorable, non-permanent implant, whose principle component is synthetic Poly-e-Caprolacton (PCL) microsphers suspended ina gel carrier of phosphate buffered saline (Ph.Eur), glycerin (Ph.Eur) and carboxymethylcelluose (USP). | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. Obvieline SAS,  8 Chemin du Jubin, F-69570, France  FSC France  Issued on 17.01.2018 | **Perfectha**  (Cross linked injectable Hyaluronic acid)  **Perfectha(R) Finelines (FDFL)**  **Perfectha(R) Complement(PDC)**  **Perfectha(R) Derm (PD)**  **Perfectha(R) Deep (PDD)**  **Perfectha(R) Subskin (PDSS3)**  **Perfectha(R) Subskin (PDSS1)** | Perfectha is a line of re asorbable hyaluronic cid (HA) gel implants intended for reconstructive purposes in the treatment, for  instance, of facial lipoatrophy, or  morphological asymmetry associated with the aging process or other underlying conditions.  Perfectha is for intradermal and subcutaneous application and is implanted in the areas of the face and hands to fill skin depressions and Iso for the augmentation of tissue volume. | **Approved**. |
|  | M/s. TEK Enterprises, Office No. MZ-9, al-Hafeez Heights Sir Syed Road, Gulberg, Lahore.  ELI-00189 | **Legal Manufacturer :**  M/s. ASAHI Intecc co., ltd.,3-100 Akatsuki-cho,  Seto, Aichi 489-0071 Japan.  **Manufacturing Sites:**  1) ASAHI INTECC CO., LTD.  3-100 Akatsuki-cho,  489-0071 Seto, Aichi, Japan.  2) ASAHI INTECC (Thailand) CO., LTD.  158/1 Moo 5 Bangkadi Industrial Park,  Tiwanon Road, Tambol Bangkadi,  Amphur Muang,  Pathumthani 12000, Thailand.  3) ASAHI INTECC HANOI CO., LTD.  THANG LONG Industrial Park,Dong Anh District, Hanoi, Vietnam  FSC Japan  Issued on 25th July, 2018 | **ASAHI Peripheral Guide Wire**  (Peripheral Guide Wire)   * ASAHI Peripheral Guide Wire ASAHI Gladius * ASAHI Peripheral Guide Wire ASAHI Halberd * ASAHI Peripheral Guide Wire ASAHI Gaia PV * ASAHI Peripheral Guide Wire ASAHI Astato XS 40 * ASAHI Peripheral Guide Wire Astato XS 20 * ASAHI Peripheral Guide Wire Astato 30 * ASAHI Peripheral Guide Wire Regalia XS 1.0 * ASAHI Peripheral Guide Wire Treasure 12 * ASAHI Peripheral Guide Wire Treasure Floppy   Class C  Shelf Life : 03 years | This Peripheral guide wire has a coil-type distal end or a plastic covered-type distal end. The coil is partly or entirely radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire’s distal end by fluoroscopy. The core shaft surface is coated with Polytetrafluoroethylene (PTFE). About 2cm of the distal end can be shaped.  **Intended Use:**  This Product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer :**  M/s. ASAHI Intecc co., ltd.,3-100 Akatsuki-cho,  Seto, Aichi 489-0071 Japan.  **Manufacturing Sites:**  1) ASAHI INTECC (Thailand) CO., LTD.  158/1 Moo 5 Bangkadi Industrial Park,  Tiwanon Road, Tambol Bangkadi,  Amphur Muang,  Pathumthani 12000, Thailand.  FSC Japan  Issued on 18th October, 2018 | **Asahi Sasuke Double Lumen Catheter (RX/OTW)**  (Double Lumen Catheter)  Flush needle is included in the package of ASAHI SASUKE with thedevice.  Class D  Shelf Life : 03 years | **Intended use:**  This product is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary arterial vasculature. | **Approved**. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer :**  M/s. ASAHI Intecc co., ltd.,3-100 Akatsuki-cho,  Seto, Aichi 489-0071 Japan.  **Manufacturing Sites:**  ASAHI INTECC (Thailand) CO., LTD., 158/1 Moo 5 Bangkadi Industrial Park,  Tiwanon Road, Tambol Bangkadi, Amphur Muang,  Pathumthani 12000, Thailand.  FSC Japan  Issued on 25th July , 2018 | **ASAHI Corsair Pro**  (Microcatheter)  Class D  Shelf Life : 03 years | **Intended use:**  The ASAHI Corsair Pro is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculature, and can be used to exchange one guide wire for another. The ASAHI Corsair Pro is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculature. this device is not intended for use in neurovasculature. | **Approved**. |
|  | **M/s Global Marketing Services,** 111, Hali Road Westridge 1, Rawalpindi  (ELI-000109)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Cordis Cashel Cahir Road Cashel Co. Tipperary , Ireland  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  (FSC Ireland Valid Till  11-04-2023)  **Fee Rs. 50000/-** | SMART® ControlTM Nitinol Stent System  Class C  Shelf Life: 2 Years  Codes & sizes as per FSC OF Ireland | Nitinol Stent System is Designed to deliver a self expanding stent to the peripheral vasculature via a sheathed delivery system | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  (FSC USFDA Valid Till  13-08-2019)  **Fee Rs. 50000/-** | High Flow Diagnostic Catheter  Class D  Shelf Life: 3 Years  527710 Cath. Judkins L4.5 7HF 100cm | Coronary Angiographic Diagnostic Catheters | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Cordis Cashel Cahir Road Cashel Co. Tipperary , Ireland  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  (FSC Ireland Valid Till  09-01-2023)  Fee submitted Rs.50,000/- | MAXI LD PTA Balloon Dialtation Catheter  Class D  Shelf Life: 1.5 Years  Codes & sizes as per FSC | PTA Balloon Dialtation Catheter | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Cordis Corporation 14201 N.W. 60th Ave. Miami Lakes, FL 33014 USA  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  (FSC USFDA Valid Till  15-06-2019)  **Rs.50,000/-** | ADROIT Guiding Catheters  Class D  Shelf Life: 3 Years  Codes & Sizes as per USDFA FSC | Guiding Catheters | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Cordis Corporation 14201 N.W. 60th Ave. Miami Lakes, FL 33014 USA  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  **Contract Manufacturer:**  M/s Nitinol Devices & Components Costa Rica S.R.L. Coyol Free Zone, Building B14, B15, B25 El Coyol, Alajuela 2 01 02 Costa Rica  (FSC USFDA Valid Till  29-08-2019)  **Rs.50,000/-** | POWERFLEX® PRO PTA Balloon Dilatation Catheter  Class D  Shelf Life: 3 Years  Codes & Sizes as per FSC | PTA Balloon Dialtation Catheter | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/**  **Manufacturering Site:**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11thDecember, 2017  Rs. 50,000 | **VIDAS CMV IGM**  (Cytomegalovirus (CMV) immunoglobulin M (IgM) antibody IVD)  VIDAS CMV IGM  Class C  Shelf Life : 11 months approx.. | IVD for automated qualitative enzyme immunoassay for use on the VIDAS family instruments, for the detection of anti-cytomegalovirus IgM (CMVM) in human serum, using the ELFA technique (Enzyme Linked Fluorescent Assay) | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed. | **Legal Manufacturer**  **and Manufacturing site:**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee submitted Rs. 50,000 | **VIDAS RUB IGM**  (Rubella virus immunoglobulin M (IgM) antibody IVD)  VIDAS CMV IGG  Class C  Shelf Life : 11 months approx.. | VIDAS CMV IgG is an automated quantitative enzyme immunoassay for use on the VIDAS family instruments for the quantitative measurement, of anti-cytomegalovirus IgG (CMVG) in human serum, using the technique ELFA (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer**  **and Manufacturing site:**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee submitted Rs. 50,000 | **VIDAS RUB IGM**  (Rubella virus immunoglobulin M (IgM) antibody IVD)  VIDAS RBM IGM  Class C  Shelf Life : 11 months approx.. | IVD for qualitative automated enzyme immunoassay for use on the VIDAS family instruments, for the detection of anti-rubella IgM (RBM) in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer**  **and Manufacturing site:**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee submitted Rs. 50,000 | **VIDAS TPSA**  (Total prostate specific antigen (PSA) IVD)  VIDAS TPSA  Class C  Shelf Life : 12 months approx.. | IVD for automated quantitative test for use on the VIDAS family instruments, for the quantitative  measurement of prostate specific antigen (PSA) levels in human serum or plasma (lithium heparin or EDTA), using the  ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer**  **and Manufacturing site:**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee submitted Rs. 50,000 | **VIDAS TOXO IGM**  (Toxoplasma gondii immunoglobulin M (IgM) antibody IVD)  VIDAS TOXO IGM  Class C  Shelf Life : 10 months | IVD for automated qualitative test for use on the VIDAS family instruments, for the detection of anti-toxoplasma IgM in serum using the ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer**  **and Manufacturing site:**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee submitted Rs. 50,000 | **VIDAS RUB IGG II**  (Rubella virus immunoglobulin G (IgG) antibody IVD)  VIDAS RUB IGG II  Class C  Shelf Life : 13 months | VIDAS RUB IgG II (RBG) is an automated quantitative test for use on the VIDAS family instruments, for the quantitative measurement of immunoglobulins G (IgG) directed against the Rubella virus in human serum or plasma (heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  Vizumax Diagnostics LLC  609 Broadway Avenue,  Orlando, Florida 32803,  USA  **Manufacturing Site:**  Vizumax Diagnostics LLC  2225E Belt Line Rd # 105,  Carrolton, Texas 75006,  USA.  FSC USFDA  Valid until May 3, 2020  Fee submitted Rs.25,000/- | **VIZUMAX HD**  (Barium Sulfate)  VIZUMAX HD 98% - 340 g (Product #2030-16)  VIZUMAX HD 98% - 5 kg (Product #2030-50)  Class B  Shelf Life : 02 years | Vizumax HD 98% is a high-density barium sulfate that is used to help doctors examine the esophagus, stomach and intestines, using x-rays. The chemical formula of barium sulfate is BaSO4. This product is indicated for use as a contrast agent in radiographic studies. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP 32574, Mexico  (FSC USFDA Valid Till  13-08-2019).  Fee submitted: Rs 50,000/- | SUPER Torque® Angiographic Catheter  Class D  Shelf Life: 3 Years  6F Super Torque Angiographic Catheter   * 532618 * 532619 * 532620 * 532621 * 532622 * 532623 * 532624 * 532625 * 532627 * 532628 * 532640 * 532642 * 532644 * 532645 * 532646 * 532647 * 532648 * 532649 * 532650S * 532652S * 532654S * 532660 * 532661 * 532662 * 532663 * 532664 * 532668 * 532669 * 532670 * 532672 * 532680N * 532681 * 532682 * 532683 * 532684 * 532685 * 532685N * 532686 * 532695 * 532696 * 532697 * 532698 * 532699 * 455660 * 455660D * 455661 * 455662 * 455663 * 455665 * 455666 * 455671 * 455672 * 455686 * 455689 * 455698   Super Torque Angiographic Catheter   * 455610T * 455611T * 455613E * 455623 * 455636 * 455637 * 532410T * 532411T * 532412T * 532413T * 532420T * 532421T * 532422T * 532424 * 532425 * 532426 * 532427 * 532430 * 532431 * 532432 * 532457 * 532482 * 532506 * 532507 * 532508 * 532539F8 * 532555H8 * 532564V8 * 532569H8   4F Super Torque Angiographic Catheter   * 532405 * 532414 * 532415 * 532416 * 532417 * 532436 * 532437 * 532438 * 532461 * 532463 * 532470 * 532433 * 532434 * 532439 * 532440 * 532441 * 532442 * 532443 * 532444 * 532445 * 532447 * 532448 * 532449 * 532462 * 532473 * 532474 * 532478 * 532489 * 532490 * 532491 * 532492 * 532493 * 532494 * 532497   5F Super Torque Angiographic Catheters   * 532501 * 532502 * 532503 * 532504 * 532505 * 532509 * 532510 * 532511 * 532512 * 532513 * 532514 * 532515 * 532516 * 532517 * 532518 * 532519 * 532520 * 532521 * 532522 * 532523 * 532524V8 * 532533 * 532541H0 * 532543H0 * 532546 * 532547 * 532548 * 532549H0 * 532565 * 532566 * 532567 * 532568 * 532571 * 532576 * 532578 * 532579 * 532586 * 532589 * 532591 * 532592 * 532593 | Indicated for the angiographic visualization and linear measurement of the arterial and venous vasculature for a wide range of disease processes such as coronary artery disease, peripheral vascular disease, embolization of anomalous vessels and endovascular aortic repair (AAA, TEVAR). | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Cordis Cashel Cahir Road Cashel Co. Tipperary , Ireland  **Manufacturing Site:**  Nitinol Devices, S.R.L.  Coyol Free Zone, Buildings B14, B15 and B25 El Coyol, Alajuela  20102, Costa Rica  (FSC Ireland Valid Till  06-09-2023)  Fee submitted: Rs 50,000/- | SABERTM PTA Balloon Dilatation Catheter  Class D  Shelf Life: 3 Years  Codes   * 48002002S * 48002003S * 48002004S * 48002006S * 48002008S * 48002010S * 48002015S * 48002020S * 48002025S * 48002030S * 48006002S * 48006003S * 48006004S * 48006006S * 48006008S * 48006010S * 48006015S * 48006020S * 48006025S * 48006030S * 48002502S * 48002503S * 48002504S * 48002506S * 48002508S * 48002510S * 48002515S * 48002520S * 48002525S * 48002530S * 48007002S * 48007003S * 48007004S * 48007006S * 48007008S * 48007010S * 48003002S * 48003003S * 48003004S * 48003006S * 48003008S * 48003010S * 48003015S * 48003020S * 48003025S * 48003030S * 48008002S * 48008003S * 48008004S * 48008006S * 48008008S * 48008010S * 48003502S * 48003503S * 48003504S * 48003506S * 48003508S * 48003510S * 48003515S * 48003520S * 48003525S * 48003530S * 48009002S * 48009003S * 48009004S * 48009006S * 48009008S * 48009010S * 48004002S * 48004003S * 48004004S * 48004006S * 48004008S * 48004010S * 48004015S * 48004020S * 48004025S * 48004030S * 48010002S * 48010003S * 48010004S * 48010006S * 48010008S * 48010010S * 48005002S * 48005003S * 48005004S * 48005006S * 48005008S * 48005010S * 48005015S * 48005020S * 48005025S * 48005030S * 48002002X * 48002003X * 48002004X * 48002006X * 48002008X * 48002010X * 48002015X * 48002020X * 48002025X * 48002030X * 48006002X * 48006003X * 48006004X * 48006006X * 48006008X * 48006010X * 48006015X * 48006020X * 48006025X * 48006030X * 48002502X * 48002503X * 48002504X * 48002506X * 48002508X * 48002510X * 48002515X * 48002520X * 48002525X * 48002530X * 48007002X * 48007003X * 48007004X * 48007006X * 48007008X * 48007010X * 48003002X * 48003003X * 48003004X * 48003006X * 48003008X * 48003010X * 48003015X * 48003020X * 48003025X * 48003030X * 48008002X * 48008003X * 48008004X * 48008006X * 48008008X * 48008010X * 48003502X * 48003503X * 48003504X * 48003506X * 48003508X * 48003510X * 48003515X * 48003520X * 48003525X * 48003530X * 48004002X * 48004003X * 48004004X * 48004006X * 48004008X * 48004010X * 48004015X * 48004020X * 48004025X * 48004030X * 48005002X * 48005003X * 48005004X * 48005006X * 48005008X * 48005010X * 48005015X * 48005020X * 48005025X * 48005030X | Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter with a distal inflatable | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Cordis Corporation 14201 N.W. 60th Ave. Miami Lakes, FL 33014 USA  **Manufacturing Sites:**  (i) M/s Lake Region Medical, 340 Lake Hazeltine Dr, Chaska, MN 55318 USA  (ii) M/s Lake Region Medical Limited, Butlersland,New Ross, Wexford, Ireland  (FSC USFDA Valid Till  14-06-2019) | SHINOBI® Plus Steerable Guidewire  1. 547214 SGW SHINOBI PLUS 180cm  2. 547214X SGW SHINOBI PLUS 300cm  Class D  Shelf Life : 2 Years  Fee submitted: 50,000/- | Used to aid in the introduction and positioning of catheters and interventional devices within the coronary and peripheral vasculature | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  (FSC USFDA Valid Till  13-08-2019).  Fee submitted: Rs 50,000/- | TEMPO® Angiographic Catheter  Class D  Shelf Life: 3 Years  TEMPO 4F   * 451401F5 * 451401H5 * 451401L5 * 451401V5 * 451401V5J * 451402F5 * 451402H5 * 451402L5 * 451402V5 * 451403F5 * 451403H5 * 451403L5 * 451403V5 * 451404F5 * 451404V5 * 451406H0 * 451406H2 * 451406P0 * 451406P2 * 451406S0 * 451406S2 * 451406V0 * 451407H2 * 451407S2 * 451407V0 * 451408V2 * 451412H0 * 451413H0 * 451413T0 * 451413V0 * 451414H0 * 451415H0 * 451415T0 * 451415V0 * 451418S0 * 451420H0 * 451421H0 * 451423H0 * 451424H0 * 451425H0 * 451430H0 * 451430H0J * 451430H2 * 451431H0 * 451431H2 * 451432H0 * 451432H2 * 451435H0 * 451435H0J * 451439H0 * 451439H0J * 451442V0 * 451442V2 * 451443H0 * 451443V0 * 451443V0J * 451443V2 * 451444V0 * 451444V2 * 451446S0 * 451446S2 * 451447S0 * 451447S2 * 451449V0 * 451450V0 * 451450V0J * 451455V0 * 451456V0 * 451456V0J * 451457V0   TEMPO 5F   * 451501F5 * 451501H5 * 451501L5 * 451501V5 * 451502F5 * 451502L5 * 451502V5 * 451503F5 * 451503H5 * 451503L5 * 451503V5 * 451504F5 * 451504L5 * 451504V5 * 451506H0 * 451506H2 * 451506P0 * 451506P2 * 451506S0 * 451506S2 * 451506V0 * 451507H0 * 451507H2 * 451507S0 * 451507S2 * 451507V0 * 451508V2 * 451512H0 * 451513H0 * 451513V0 * 451514H0 * 451515H0 * 451515T0 * 451515V0 * 451518S0 * 451520H0 * 451521H0 * 451523H0 * 451524H0 * 451525H0 * 451530H0 * 451530H2 * 451531F2 * 451531H0 * 451531H2 * 451532H0 * 451532H2 * 451535H0 * 451539H0 * 451542V0 * 451542V2 * 451543H0 * 451543V0 * 451544V0 * 451544V2 * 451546S0 * 451546S2 * 451546V2 * 451547S0 * 451547S2 * 451549V0 * 451550V0 * 451550VJ * 451555V0 * 451556V0 * 451557V0 * 451591V5 * 451593V5 | Angiographic Catheter | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA  **Manufacturing Site:**  M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico  (FSC USFDA Valid Till  13-08-2019)  Fee submitted: Rs 50,000/- | TEMPO® AQUA® Angiographic Catheter  Class D  Shelf Life: 3 Years  **TEMPO AQUA — 4F**   * 452407H0 * 452412H0 * 452413H0 * 452414H0 * 452418S0 * 452421H0 * 452423H0 * 452430H0 * 452431H0 * 452435H0 * 452442V0 * 452443S0 * 452443V0 * 452447S0 * 452450V0   **TEMPO AQUA — 5F**   * 452507H0 * 452514H0 * 452518S0 * 452521H0 * 452523H0 * 452530H0 * 452531H0 * 452535H0 * 452542V0 * 452543S0 * 452543V0 * 452547S0 * 452550V0 | Angiographic Catheter | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Cordis Cashel Cahir Road Cashel Co. Tipperary , Ireland  **Manufacturing Site:**  M/s Burpee Material Technology LLC, 15 Christopher Way, Eatontown, New Jersey, 07724 USA  (FSC Ireland Valid Till  14-06-2022)  Fee submitted: Rs 50,000/- | SMART® Flex Vascular Stent System  Class D  Shelf Life: 2 Years   * SF08030MV * SF05040MV * SF06040MV * SF07040MV * SF05060MV * SF06060MV * SF07060MV * SF08060MV * SF05080MV * SF06080MV * SF07080MV * SF05100MV * SF06100MV * SF07100MV * SF08100MV * SF05120MV * SF06120MV * SF07120MV * SF05150MV * SF06150MV * SF07150MV * SF08150MV * SF05200MV * SF06200MV * SF07200MV * SF08040SV * SF08080SV * SF08120SV * SF08200SV * SF08040MV * SF08080MV * SF08120MV * SF08200MV * SF09020SV * SF10020SV * SF09030SV * SF10030SV * SF09040SV * SF10040SV * SF09060SV * SF10060SV * SF09080SV * SF10080SV * SF09100SV * SF10100SV * SF09020MV * SF10020MV * SF09030MV * SF10030MV * SF09040MV * SF10040MV * SF09060MV * SF10060MV * SF09080MV * SF10080MV * SF09100MV * SF10100MV * SF05030SV * SF06030SV * SF07030SV * SF08030SV * SF05040SV * SF06040SV * SF07040SV * SF05060SV * SF06060SV * SF07060SV * SF08060SV * SF05080SV * SF06080SV * SF07080SV * SF05100SV * SF06100SV * SF07100SV * SF08100SV * SF05120SV * SF06120SV * SF07120SV * SF05150SV * SF06150SV * SF07150SV * SF08150SV * SF05200SV * SF06200SV * SF07200SV * SF05030MV * SF06030MV * SF07030MV | Self expanded Nitinol Vascular Stent System | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  Same as above  FSC France Issued on 11th December, 2017  Fee Submitted Rs. 50,000/- | VIKIA HIV ½  HIV(Human Immunodefi-ciency Virus)  VIKIA HIV 1/2  Class D  Shelflife : 24 months | VIKIA HIV 1/2 is a rapid diagnostic test for the detection of serum antibodies to HIV in human serum, plasma or whole blood.  The test is intended for use only by healthcare professionals in laboratories or for decentralized near-patient diagnostic  testing. | **Rejected.**  The request of the firm has been acceded for withdrawal of application |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee Submitted Rs. 50,000/- | VIDAS HBs Ag Ultra  HBsAg (Hepatitis B virus surface antigen) kit  Class D  Shelflife : 13 months | Is is an automated qualitative test kit for use on the VIDAS family instruments for the detection of hepatitis B surface antigen (HBs Ag) in human serum or plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  Same as above  FSC France  Issued on 11th December, 2017  Fee Submitted Rs. 50,000/- | VIKIA HBs Ag  HBs Ag (Hepatitis B virus surface antigen)  VIKIA HBs Ag  Class D  Shelflife : 02 years approx.. | VIKIA® HBsAg is a qualitative test based on the association of monoclonal and polyclonal antibodies specific to HBsAg.  This test uses the principle of lateral immunochromatography for the detection of circulating HBs antigen. It is used for the detection of the main sub-types ad and ay in serum, plasma, and whole blood | **Rejected**.  The request of the firm has been acceded for withdrawal of application |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France  Issued on 11th December, 2017  Fee Submitted Rs. 50,000/- | VIDAS anti-HCV  HCV (Hepatitis C Virus) kit  Class D  Shelflife : 15 months | It is an automated qualitative test kit for use on the instruments of the VIDAS family, for the detection of IgG antibodies to hepatitis C virus (anti-HCV) in human serum or plasma (heparin) using the ELFA technique. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMerieux SA  376 Chemin de I’Orme  69280 Marcy I’Etoile – France  **Manufacturing Site:**  M/s. BioMerieux Shangai Biotech Co Ltd, N 4633 Pusan Road, Kangqiao Industrial Park, Pudong Specifial Economic Zone, Shanghai 201315 – PR China  FSC France  Issued on 18th June, 2018  Fee Submitted Rs. 50,000/- | VIKIA ANTI-HCV  (Anti HCV Hepatitis C Virus) kit  Class D  Shelflife : 30 months | It is a rapid test kit for the qualitative detection of lgG antibodies to Hepatitis C Virus (anti – HCV) in human serum, plasma, or whole blood. | **Rejected.**  The request of the firm has been acceded for withdrawal of application. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. Sacace Biotechnologies s.r.l. via Santasi snc-8004-santa Agata,De’ Goti(BN), Italy 44 22100 Como, Italy.  **Manufacturing site**;  Via scalbirini, 44 22100 Como, Italy.  FSC Italy  Issued on 14th May, 2018  Fee Submitted Rs. 50,000/- | HCV Real-TM Quant DX  (HCV Hepatitis C Virus Quantitative)  V1-96/3FRT  Class D  Shelflife : 01 year | It is a Real-Time Amplification test for the Quantitative detection of Hepatitis C Virus in human plasma and the simultaneous detection of a HCV-specific Internal Control (IC), by dual  color detection. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. Sacace Biotechnologies s.r.l. via Santasi snc-8004-santa Agata,De’ Goti(BN), Italy 44 22100 Como, Italy.  **Manufacturing site**;  Via scalbirini, 44 22100 Como, Italy.  FSC Italy  Issued on 14th May, 2018  Fee Submitted Rs. 50,000/- | HBV Real-TM Quant DX  (HBV Hepatitis B Virus Quantitative)  V5-96/3FRT  Class D  Shelflife : 01 year | It is a Real-Time Amplification test for the Quantitative detection of Hepatitis B Virus in human plasma and the simultaneous detection of a HBV-specific Internal Control (IC), by dual color detection. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. Cepheid 904  Caribbean Drive Sunnyvale,  CA 94089 USA  FSC USDFA  Valid till December 12, 2020  Fee Submitted Rs. 50,000/- | Xpert® HIV-1 Viral Load  (HIV-1 VL (Human immunodeficiency virus 1 Viral Load) test kit  V5-96/3FRT  Class D  Shelflife : 01 year | It is usedin conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. Cepheid 904  Caribbean Drive Sunnyvale,  CA 94089 USA  FSC USDFA Valid till December 12, 2020  Fee Submitted Rs. 50,000/- | Xpert® HCV Viral Load  (HCV VL Hepatitis C Virus Viral Load) test kit  GXHCV-VL-CE-10  Class D  Shelflife : 01 year | Thbe Assay, performed on GeneXpert® Instrument Systems, is designed for the rapid quantitation of Hepatitis C Virus (HCV) RNA in human | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France Issued on 11th December, 2017  Fee Submitted Rs. 50,000/- | VIDAS HIV Duo Quick  HIV (Human immunodeficiency virus) test kit  Class D  Shelflife : 01 year | it is an automated HIV infection screening test for use on the VIDAS family instruments, for the combined detection of anti-HIV-1 (groups M and O) and anti-HIV-2 total immunoglobu-lins and HIV-1 p24 antigen in human serum or plasma (lithium heparin or EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France Issued on 11th December, 2017  Fee Submitted Rs. 50,000/- | VIDAS HBs Ag Ultra  HBsAg (Hepatitis B virus surface antigen)  Class D  Shelflife : 13 months | it is an automated qualitative test for use on the VIDAS family instruments for the detection of hepatitis B surface antigen (HBs Ag) in human serum or plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  **Manufacturering Site**  M/s. BioMérieux SA  376 chemin de l’Orme  69280 Marcy l’Etoile – France  FSC France Issued on 11th December, 2017 | VIDAS anti-HCV  HCV (Hepatitis C Virus) test kit  Class D  Shelflife : 15 months | it is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of IgG antibodies to hepatitis C virus (anti-HCV) in human serum or plasma (heparin) using the ELFA technique (Enzyme Linked Fluorescent Assay). The detection of these specific antibodies, in conjunction with other clinical information, aids in the diagnosis of infection in persons with symptoms of hepatitis and in persons at risk for hepatitis C infection. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. BioFire Diagnostics, LLC, 515 Colorow Drive,  Salt Lake City, UT 84108  USA.  FSC USFDA Valid till December 04, 2019  Fee Submitted Rs. 50,000/- | FilmArray® Respiratory Panel 2 plus (RP2plus)  RFIT-ASY-0136  RFIT-ASY-0137  Class C  Shelflife : 12 months | The FilmArray RP2plus pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from 22 different respiratory pathogens from a single NPS specimen in approximately 45 minutes. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. Adaltis S.r.l.  Via Durini, 27 – 20122 Milano – Italy  **Manufacturing Site:**  **M/s. Adaltis S.r.l.**  Via Luigi Einaudi, 7 – 00012 Guidonia Montecelio (Roma) – Italy (Production, Warehouse, & shipment)  Via Andrea Costa, 2 – 40134 Bologna – Italy  FSC Italy Issued on 13th March, 2018  Fee Submitted Rs. 50,000/- | **EIAgen HCV Ab (v.4)**  (HCV Ab – Hepatitis C Virus Antibody) test kit  \Codes:  071067  071064  071068  Class D  Shelflife : 15 months | Fourth generation enzyme linked immunosorbent assay (ELISA) for the determination of antibodies to Hepatitis C Virus in human plasma (EDTA, Heparin, & Citrate) and sera. The kit may be used for the screening of blood units of HCV-infected patients.  For invitro diagnostic use only. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  Cepheid AB  Röntgenvägen 5, SE-171 54  Solna, Sweden  FSC Sweden Valid until December 12, 2018 | Xpert® CT/NG  (chlamydial trachomatis / Neisseria gonorrheal) test kit  Codes:  GXCT/NG-CE-10  GXCT/NG-CE-120  Class C  Shelflife : 24 months | The Assay, performed on the GeneXpert® Instrument System, are qualitative in vitro real-time PCR tests for the automated and rapid detection and differentiation of genomic DNA from Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) to aid in the diagnosis of chlamydial and/or gonorrheal urogenital disease. | **Approved.** The FSC is valid till 2020. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. BioFire Diagnostics, LLC, 515 Colorow Drive,  Salt Lake City, Utah 84108  USA.  FSC USFDA  Valid till December 04, 2019 | FilmArray® Gastrointestinal (GI) Panel  Codes:  RFIT-ASY-0104  RFIT-ASY-0116  Class B  Shelflife : 12 months | The FilmArray GI pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid using a combination of genus level assays that detect a broad range of organisms, species-specific assays, and assays for specific virulence markers (e.g. toxin genes). | **Approved** subject provision of to differential fee of Rs. 25000/- and the Class is classified as C instead of B. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. BioFire Diagnostics, LLC, 515 Colorow Drive,  Salt Lake City, Utah 84108  USA.  FSC USFDA  Valid till December 04, 2019 | FilmArray® Pneumonia Panel plus  (Test kit)  Codes: RFIT-ASY-0142  RFIT-ASY-0143  Class C  Shelflife : 12 months | The FilmArray Pneumonia Panel plus pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from lower respiratory pathogens within a single sputum-like or BAL-like specimen. The rigid plastic component (fitment) of the FilmArray Pneumonia Panel plus pouch contains reagents in freeze-dried form. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. Laboratory Grifols, S.A,: Poligono Levante. C/Can Guasch, 2. Industrial 08150 Parets del Valles (Barcelona) Spain.  **Manufacturing Site:**   1. **PASSEIG Fluvial, 24 Polingono Industrial Autopista-08150- Parets dEl valles (Barcelona) Spain.** 2. **Avenida Juan Carlos I, 97 -30565- Las Torres De Cotillas (Murcia) Spain.** 3. **Poligono Industrial Los Llanos C/Martte, 4-30565-Las Torres De Cotillas (Murcia) Spain.**   FSC Spain  Valid till 08-01-2020 | **Transfer Grifols**  (Transfer Blood Bags)  - Transfer Grifols 150  - Transfer Grifols 300  - Transfer Grifols 400  - Transfer Grifols 600  -  Class C  Shelflife : 05 years | Blood bag without anticoaggulant | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. Laboratory Grifols, S.A,: Poligono Levante. C/Can Guasch, 2. Industrial 08150 Parets del Valles (Barcelona) Spain.  **Manufacturing Site:**   1. **PASSEIG Fluvial, 24 Polingono Industrial Autopista-08150- Parets dEl valles (Barcelona) Spain.** 2. **Avenida Juan Carlos I, 97 -30565- Las Torres De Cotillas (Murcia) Spain.** 3. **Poligono Industrial Los Llanos C/Martte, 4-30565-Las Torres De Cotillas (Murcia) Spain.**   FSC Spain  Valid till 08-01-2020 | **CPD Adenine Grifols**  (Blood Bags containing anti-coagulant Citrate Phosphat Dextrose Adenine)  CPD Adenine Grifols Single S.K.  CPD Adenine Grifols Double S.K.  CPD Adenine Grifols Triple S.K.  CPD Adenine Grifols Quadruple S.K.  Class D  Shelflife : 04 years | CPD Adenine Grifols are blood bags containing CPD-A as an anti-coagulannt. CPD intended to be used for the extraction, fractionatioon, preservation, and transfusion of blood. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. BioFire Diagnostics, LLC, 515 Colorow Drive,  Salt Lake City, Utah 84108  USA.  FSC USFDA  Valid till December 04, 2019 | FilmArray® Meningitis/Encephalitis (ME) Panel  Codes:  RFIT-ASY-0119  RFIT-ASY-0118  Class C  Shelflife : 01 year | The FilmArray ME pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid using a combination of assays that detect a broad range of organisms. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer :**  M/s. BioFire Diagnostics, LLC, 515 Colorow Drive,  Salt Lake City, Utah 84108  USA.  FSC USFDA  Valid till December 04, 2019 | FilmArray® Blood Culture Identification (BCID) Panel  Codes:  RFIT-ASY-0127  RFIT-ASY-0126  Class B  Shelflife : 04 months | The FilmArray BCID pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid using a combination of assays to identify individual species as well as groups of organisms at the family, genus, complex, and/or species level. | **Approved** subject to provision of differential fee of Rs. 25000/- and the Class is classified as C instead of B. |
|  | **M/s. Intek Corporation,** Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi.  (ELI-00034)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer**  M/s. HAGMED sp. z o.o. sp.k. UI. Tomaszowska 32,  96-200 Rawa Mazowiecka, Poland.  FSC Poland  Issued on 28th November, 2018  Rs. 50,000 | **Temporary transvenous pacing electrode:**  **Size Varainats:**  ES1Z ESM3Z ES2Z ESM4Z ES3Z ESM1J ES4Z ESM2J ES1J ESM3J ES2J ESM4J ES3J ESM1P ES4J ESM2P ES1P ESM3P ES2P ESM4P ES3P ESB1 ES4P ESB2 ESM1Z ESB3 ESM2Z ESB4  Class D  Shelf Life : 04 years | The temporary transvenous pacing electrode is used for temporary transvenous pacing (up to 2 weeks) mainly for reanimation of patients with sudden ventricular arrest. It can be used in present or threatening bradycardia caused by conduction system disease or acute myocardial infarction. Indication for use may be treatments, during which may occur a clinically significant decrease of heart rate, as well as need to manage recurrent, dangerous ventricular arrhythmias. The electrode is disposable, sterile, non-toxic, pyrogen free, and it is detectable under fluoroscopy. | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** OrbusNeich Medical B.V.,  Address: Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, the Netherlands.  FSC Netherland  Valid until March 5, 2023  Fee Submitted Rs. 50,000/- | **Teleport MicroCatheter** (Micro Catheter)  Size Variants: 220 -13-2000 220 -15-2000 221 -13-2000 221 -15-2000  Class D  Shelf Life : 02 years | Micro Catheter | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** OrbusNeich Medical B.V.,  Address: Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, the Netherlands.  FSC Netherland  Valid until March 5, 2023  Fee Submitted Rs. 50,000/- | **Combo Plus Dual Therapy Stent Delivery System**  (Stent Delivery System)  **Size Variants:** 225-092-11 225-232-11 227-092-11 227-232-11 230-092-11 230-232-11 235-092-11 235-232-11 240-092-11 240-232-11 225-132-11 225-282-11 227-132-11 227-282-11 230-132-11 230-282-11 235-132-11 235-282-11 240-132-11 240-282-11 225-152-11 225-332-11 227-152-11 227-332-11 230-152-11 230-332-11 235-152-11 235-332-11 240-152-11 240-332-11 225-182-11 230-382-11 227-182-11 235-382-11 230-182-11 240-382-11 235-182-11  240-182-11  Class D  Shelf Life : 538 days | The COMBO Plus stent system is a coronary balloon expandable stent which consist of a 316L stainless steel alloy coated with a biocompatible, biodegradable polymer containing sirolimus (also known as rapamycin). Covalently attached to this matrix is a layer of murine, monoclonal, anti-human CD34 antibody. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer/ Manufacturing Site:** i) M/s Microvention, Inc., 1311 Valencia Avenue Tustin, CA 92780, USA  ii) M/s Ashitaka Factory of Terumo Corp., 150 Maimaigi-Cho Fujinomiya, Sizuoka 418-0015, Japan  (FSC USFDA Valid Till  31-08-2019)  Fee Submitted Rs. 50,000/- | Traxcess 14 Guidewire  Class D  Shelf Life: 3 Years  Codes & Sizes as per FSC. | Guidewire | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer**  Microvention Europe:  30 bis rue du Vieli Abreuvior, 78100 Saint Germain e Laye, France  **Production Sites**  MicroVension,Inc.  1311 Valencia Avenue Tustin, California, 92780 USA  MicroVension Inc.  35 Enterprise, Aliso Viejo,  CA 92656, USA  MicroVension Costa Rica S.R.L Edificio B33  Zona Franca Coyol  Alajuela, Costa Rica  FSC France  Issued on 18th January, 2018  Fee Submitted Rs. 50,000/- | SOFIA PLUS  Percutaneous Catheter (Distal Access + Aspiration)  Size Variants:  DA6125ST  DA6131ST  DA6135ST  Class D  Shelflife : 03 years | Sophia Plus is intravascular distal access/guiding catheter and can be used for clot aspiration and delivery of stent, balloon, flow diverters, retrieval devices etc. | **Approved**. |
|  | **M/s. Nisa Impex (Private) Ltd.,** Maxim Arcade, Plot No. 13-14, Usman Block, Jeddah Town, Phse I, Opp: DHA-II, G.T. Road, Islamabad.  (ELI-00064)  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China.  FSC China  Valid until March 27, 2020  Rs. 100,000  (Already submitted on 15-3-2016) | Nisa IV Cannula  Sizes:  0.7 x19, 0.9x19,0.9x258, 1.1 x 32, 1.1 x 38, 1.3 x 45, 1.6x 38, 1.6x45, 2.1x38, 2.1x45  Class B  Shelf Life : 05 years | Intra venous Disposable Cannula | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | **-do-**  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China.  FSC China  Valid until June 6, 2019  Rs. 100,000 (Already submitted) | Nisa Blood Transfusion Set  Sizes:  0.7, 0.8, 0.9 & 1.2  Class B  Shelf Life : 05 years | Blood Transfusion Set | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China.  FSC China  Valid until March 27, 2020  Rs. 100,000 (Already submitted) | Nisa Wound Plast  (Wound Plast)  Sizes:  60x30, 70x18, 70x35, 70x45, 70x60, 70x90, 70x110, 80x50, 80x120  Class B  Shelf Life : 05 years | Wound Plast | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China.  FSC China  Valid until March 27, 2020  Rs. 100,000 (Already submitted) | Nisa Stomach Tube  Sizes:  5F,6F, 8F, 12F, 14F, 16F, 18F, 20F, 22F, 24 F  Class B  Shelf Life : 05 years | Stomach Tube | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal manufacturer** M/s. Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co. Ltd., No. 46, 7th Group, Wanjie Village, Xinping Town, Xinjin County, Chengdu City, P.R. China.  FSC China  Valid until March 27, 2020  Rs. 100,000 (Already submitted) | Nisa Scalp Vain Set  Sizes:  14G - 27 G  Class B  Shelf Life : 05 years | Scalp Vain Set | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | **M/s. Digital Imaging Systems,** 121- Habitat Apartments, Shadman II, Ghaus -ul-Azam Road, Lahore, Lahore  (ELI-00094)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 06-12-2018  Fee Submitted Rs. 50,000/- | **AMPLATZER Sizing Balloon**  (Cardiac Catheter, Balloon, Sizing)  9-SB-018, 9-SB-024,  9-SB-034,  Class D  Shelf Life: 3 years | Cardiac Balloon Catheter | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 06-12-2018  Fee Submitted Rs. 50,000/- | **AMPLATZER Septal Occluder**  9-ASD-004, 9-ASD-005, 9-ASD-006,  9-ASD-007, 9-ASD-008,9-ASD-009,  9-ASD-010, 9-ASD-011, 9-ASD-012,  9-ASD-013,9-ASD-014, 9-ASD-015,  9-ASD-016, 9-ASD-017, 9-ASD-018,  9-ASD-019, 9-ASD-020, 9-ASD-022,  9-ASD-024, 9-ASD-026,9-ASD-028,  9-ASD-030, 9-ASD-032, 9-ASD-034,  9-ASD-036,9-ASD-038, 9-ASD-040,  Class D  Shelf Life: 5 years | Atrial Septal Defects (ASD) Occluder  . | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 06-12-2018  Fee Submitted Rs. 50,000/- | **AMPLATZER Guidewires**  (Catheter Guidewire)  9-GW-001, 9-GW-002,  9-GW-003, 9-GW-004  Class D  Shelf Life: 5 years | Coronary Guidewire | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 06-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer Multi Fenestrated Septal Occluder ‘Cribriform’**  (Cardiac Occluder)  9-ASD-MF-018, 9-ASD-MF-025,  9-ASD-MF-030, 9-ASD-MF-035,  9-ASD-MF-040  Class D  Shelf Life: 5 years | Atrial Septal Defects (ASD) Occluder | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 06-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer PFO Occluder**  9-PFO-018, 9-PFO-025,  9-PFO-030, 9-PFO-035  Class D  Shelf Life: 5 years | PFO Occluder | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | Amplatzer TorqVue Exchange System  (Cardiac Occulder delivery kit)  9-EITV09F45/80,  9-EITV12F45/80,  9-EITV06F180/80,  9-EITV08F180/80,  9-EITV10F180/80  Class D  Shelf Life: 3 years | Cardiac Occulder delivery kit | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | Amplatzer Duct Occluder II (Cardiac Occulder)  9-PDA2-03-04,  9-PDA2-04-04,  9-PDA2-05-04,  9-PDA2-06-04,  9-PDA2-03-06,  9-PDA2-04-06  9-PDA2-05-06,  9-PDA2-06-06,  9-PDA2AS-03-02-L,  9-PDA2AS-03-04-L,  9-PDA2AS-03-06-L,  9-PDA2AS-04-02-L,  9-PDA2AS-04-04-L,  9-PDA2AS-04-06-L,  9-PDA2AS-05-02-L,  9-PDA2AS-05-04-L,  9-PDA2AS-05-06-L  Class D  Shelf Life: 5 years | PDA Occluder | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  274-R&I 12.03.2019  Rs. 50,000  89-P-DD(MD) 28-03-2019  Fee Submitted Rs. 50,000/- | **Amplatzer TorqVue Delivery System**  (Cardiac Occulder delivery kit)  9-ITV06F45/60,  9-ITV07F45/60,  9-ITV08F45/60,  9-ITV07F45/80,  9-ITV08F45/80,  9-ITV09F45/80  9-ITV10F45/80,  9-ITV12F45/80,  9-ITV13F45/80,  9-ITV05F180/60,  9-ITV06F180/60,  9-ITV06F180/80  9-ITV07F180/80,  9-ITV08F180/80,  9-ITV09F180/80  Class D  Shelf Life: 3 years | Cardiac Occulder delivery kit. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer TorqVue LP Delivery System**  (Cardiac Occulder delivery kit)  9-TVLP4F90/060,  9-TVLP4F90/080,  9-TVLP5F90/060,  9-TVLP4F90/080  Class D  Shelf Life: 3 years | Cardiac Occulder delivery kit | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer Muscular VSD Occluder**  (Cardiac Occulder)  9-VSD-MUSC-004,  9-VSD-MUSC-006,  9-VSD-MUSC-008,  9-VSD-MUSC-010,  9-VSD-MUSC-012,  9-VSD-MUSC-014,  9-VSD-MUSC-016,  9-VSD-MUSC-018,  Class D  Shelf Life: 5 years | VSD Occulder | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer Duct Occluder**  (Cardiac Occulder)  9-PDA-003, 9-PDA-004,  9-PDA-005, 9-PDA-006,  9-PDA-007, 9-PDA-008,  9-PDA-009  Class D  Shelf Life: 5 years | Duct Occluder | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer Memberanous VSD Occluder**  (Cardiac Occulder)  9-VSD-MEMB-004,  9-VSD-MEMB-005,  9-VSD-MEMB-006,  9-VSD-MEMB-007,  9-VSD-MEMB-008,  9-VSD-MEMB-009,  9-VSD-MEMB-010,  9-VSD-MEMB-011,  9-VSD-MEMB-012,  9-VSD-MEMB-013,  9-VSD-MEMB-014,  9-VSD-MEMB-015,  9-VSD-MEMB-016,  9-VSD-MEMB-017,  9-VSD-MEMB-018  Class D  Shelf Life: 5 years | VSD Occluder | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer Vascular Plug**  (Embolization Implant, Vascular)  9-PLUG-004, 9-PLUG-006,  9-PLUG-008, 9-PLUG-0010,  9-PLUG-012, 9-PLUG-014,  9-PLUG-016,  9-AVP2-003, 9-AVP2-004,  9-AVP2-006, 9-AVP2-008,  9-AVP2-010, 9-AVP2-012,  9-AVP2-014, 9-AVP2-016,  9-AVP2-018, 9-AVP2-020,  9-AVP2-022,  9-AVP3-042, 9-AVP3-063,  9-AVP3-084, 9-AVP3-103,  9-AVP3-105, 9-AVP3-123,  9-AVP3-125, 9-AVP3-143,  9-AVP3-145,  9-AVP038-004, 9-AVP038-005, 9-AVP038-006, 9-AVP038-007, 9-AVP038-008  Class C  Shelf Life: 5 years | Embolization Implant, Vascular | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer / Manufacturing Site:**  M/s. AGA Medical Corporation,  5050 Nathan Lane North,  Plymouth, Minnesota, 55442, USA  FSC Belgium  Issued on 07-12-2018  Fee Submitted Rs. 50,000/- | **Amplatzer PI Muscular VSD** Occluder  (Cardiac Occulder)  9-VSDMUSCPI-016,  9-VSDMUSCPI-018,  9-VSDMUSCPI-020,  9-VSDMUSCPI-022,  9-VSDMUSCPI-024  Class D  Shelf Life: 5 years | VSD Occluder | **Approved**. |
|  | **M/s. K.M. Enterprises,**  605-D-Block, M.A. Johar Town, Lahore.  (ELI-00054)  Evaluator:  Muhammad Ayub Naveed | M/s. Karex Industries Sdn. Bhd., PTD., Malaysia  FSC Malaysia valid till 11th May, 2019  Rs. 50,000 Fee already submitted with documents dated 10th March, 2017 | Carex Male Latex Condom  P53S – Natural  Length: Min 180 mm without teat  Width :53 ±2 mm  Thickness : 0.065 mm (+0.015mm, - 0.020 mm)  Lubricant details : 0.55g ±0.15g  Class D  Shelflife : 03 years | Latex Male Condom | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:**  M/s. Euromed for Medical Industries,  Area No. 10, Block (i) Free Zone, Nasr City, Cairo Egypt.  FSC Egypt Issue date  06-03-2018  Fee submitted: Rs. 25,000 | Euro-Ject (Disposable Syringe)  1ml, 3ml, 5ml, 10ml  Class B  05 years | Sterile, single-use syringe | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. Sizes demanded on Form-7A shall be granted.  Sizes not on free sale certificate |
|  | **M/s. Unique Pharma,**  House No. 1775/21, Street No. 1, Tariqabad, MDA Road, Multan.  (ELI-00068)  Evaluator:  Muhammad Ayub Naveed | M/s. Shanghai Kindly Enterprise Development Group Co., Ltd., 658, Gaochao Road, Shanghai, 201803, China  FSC China  Valid till 18.01.2020  Also provided  FSC Germany  Issued on 06.11.2018  Fee submitted Rs. 25,000 | Easy Pro Disposable Syringe  1ml,2ml,2.5ml,3ml,5ml,10ml,20ml,25ml,30ml,35ml,50ml,60ml  Class B  Shelf Life : 05 years | Disposable Syringe | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed. | M/s. Shanghai Kindly Enterprise Development Group Co., Ltd., 658, Gaochao Road, Shanghai, 201803, China  FSC China  Valid till 18.01.2020  Also provided  FSC Germany  Issued on 06.11.2018  Fee submitted Rs. 25,000 | Hypodermic Needles  0.3,0.33,0.36,0.4,0.45,0.5,0.55,0.6,0.7,0.8,0.9,1.1,1.2  Class B  Shelf Life : 05 years | Hypodermic Needle | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed. | M/s. Shanghai Kindly Enterprise Development Group Co., Ltd., 658, Gaochao Road, Shanghai, 201803, China  FSC China Valid till 18.01.2020  Also provided FSC Germany Issued on 06.11.2018  Fee submitted Rs. 25,000 | “Uni-Set” Infusion Set  IVA002,IVA004,IVA008  Class B  Shelf Life : 05 years | IV Infusion Sets | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed. | M/s. Shanghai Kindly Enterprise Development Group Co., Ltd., 658, Gaochao Road, Shanghai, 201803, China  FSC China Valid till 18.01.2020  Also provided FSC Germany Issued on 06.11.2018  Fee submitted Rs. 25,000 | “Uni-Set”  IVA002,IVA004,IVA008  Class B  Shelf Life : 05 years | Infusion Set with Burette | **Approved**. |
|  | **M/s BSN Medical (Pvt) Ltd.,** A/69, SITE Manghopir Road, Karachi  (ELI-00011)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  (FSC Germany Issuance Date 23-10-2018)  **Fee Rs.50,000/-** | Cutimed® Sorbact® Hydroactive  Class C  Shelf Life: 3 Years  Codes & Sizes as per FSC of Germany | Non – adhesive gel dressing with Bacteria-binding action. | **Approved**. |
|  | M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi  (ELI-00090) | **Manufacturer:**  M/s Shenzhen Homed Medical Device Co. Ltd., 3rd Floor, Block1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, PR China  (FSC China Valid Till  19-10-2019)  Fee submitted Rs. 25,000/- | Perfect Piston Compressor Nebulizer  Class B  Shelf Life: Not Applicable | Nebulizer is intend for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Tianchang Hengsheng Medical Devices Co. Ltd., Qinlan Industrial Park Tianchang City, Anhui Province, China  (FSC China Valid Till  18-03-2020)  Fee submitted Rs. 25,000/- | Perfect Disposable Sterile Latex Surgical Gloves  Class B  Shelf Life: 5 Years  6, 6.5, 7, 7.5, 8, 8.5, 9 | Disposable Latex Surgical Gloves, Sterile is used during Surgical Operations to Protect patient and user, may prevent cross infection | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | **M/s Hospicare Systems**, Mezzanine Floor, Rabbiya Garden, Block 3, MCHS, Shaheed-e-Millat Road, Karachi  (ELI-00274)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Cincinnati Sub-Zero Products, LLC 12011 Mosteller Road Cincinnati, OH 45241, USA  (FSC USFDA Valid Till  19-07-2019)  Fee Submitted Rs.50,000/- | Hemotherm 400CE® Dual Reservoir Cooler / Heater System  Class C  Shelf Life: 12 Years  Model: 400CE® | Hemotherm 400 CE Heater/ Cooler System | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Cincinnati Sub-Zero Products, LLC 12011 Mosteller Road Cincinnati, OH 45241, USA  (FSC USFDA Valid Till  19-07-2019)  Fee Submitted Rs.50,000/- | Warm Air® Model 135 Convective Warming System  Class C  Shelf Life: 7 Years | Warm Air System | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Cincinnati Sub-Zero Products, LLC 12011 Mosteller Road Cincinnati, OH 45241, USA  (FSC USFDA Valid Till  19-07-2019)  Fee Submitted Rs.50,000/- | Norm-O-Temp Model 111W Hyperthermia System and Accessories Including Blankets and Pads.  Class C  Shelf Life: 10 Years | Norm-O-Temp Hyperthermia System | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Cincinnati Sub-Zero Products, LLC 12011 Mosteller Road Cincinnati, OH 45241, USA  (FSC USFDA Valid Till  19-07-2019)  Fee Submitted Rs.50,000/- | Blanketrol III Model 233 Hyper/Hypothermia System and Accessories  Class C  Shelf Life: 12 Years | Blanketrol III Hyper/Hyperthermia System | **Approved**. |
|  | **M/s Premier Agencies**, 60, Muslimabad, Jamshed Quarters, M.A. Jinnah Road Extension, Karachi  (ELI-00050)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s Becton Dickson and Company 1 Becton Drive, Franklin Lakes NJ 07417, USA  **Manufacturing Site:**  M/s Becton Dickinson Medical (S) PTE Ltd., 30 TUAS Avenue 2, Singapore  (FSC Singapore Valid Till  23-01-2019)  Fee Submitted  **Rs.25,000/-** | BD Micro-Fine TM + Pen Needle  Class B  Shelf Life: 5 Years  BD Micro-Fine TM + Pen Needle 0.25MM (31G) \* 8MM | BD Micro-Fine TM + Pen Needle is a sterile single use device designed for the parenteral administration of a drug. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s Becton Dickson and Company 1 Becton Drive, Franklin Lakes NJ 07417, USA  **Manufacturing Site:**  M/s Becton Dickinson Medical (S) PTE Ltd., 30 TUAS Avenue 2, Singapore  (FSC Singapore Valid Till  23-01-2019)  (FSC Ireland Valid Till  23-11-2022)  Fee Submitted **Rs.25,000/-** | BD Micro-Fine TM + Pen Needle  Class B  Shelf Life: 5 Years  BD Micro-Fine TM + Pen Needle 0.23MM (32G) \* 4MM | BD Micro-Fine TM + Pen Needle is a sterile single use device designed for the parenteral administration of a drug. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:**  M/s Becton Dickson and Company 1 Becton Drive, Franklin Lakes NJ 07417, USA  **Manufacturing Site:**  M/s Becton Dickinson Medical (S) PTE Ltd., 30 TUAS Avenue 2, Singapore  (FSC Singapore Valid Till  23-01-2019)  (FSC Ireland Valid Till  23-11-2022)  Fee Submitted **Rs.25,000/-** | BD Micro-Fine TM + Pen Needle  Class B  Shelf Life: 5 Years  BD Micro-Fine TM + Pen Needle 0.25MM (31G) \* 5MM | BD Micro-Fine TM + Pen Needle is a sterile single use device designed for the parenteral administration of a drug. | **Approved**. |
|  | **M/s Ghazali Brothers,** 1st Floor, Azzainab Court Compbell Street, Karachi  (ELI-00240)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:**  M/s Zhejiang Kindly Medical Devices Co., Ltd., No.758, 5th Binhai Road Binhai Industrial Park, Longwan District 325025 Wenzhou, Zhejiang Province, P.R China  (FSC China Valid Till  25-05-2019)  Fee Submitted Rs.50,000/- | SpineLP Disposable Anaesthesia Needles  Class D  Shelf Life: 5 Years  27G (0.4), 26G (0.45), 25G (0.5), 24G (0.55), 23G (0.6), 22G (0.7), 21G (0.8), 20G (0.9), 19G (1.1), 18G (1.2), 17G (1.4), 16G (1.6), 15G (1.8), 14G (2.1) | Anaesthesia (Spinal Needle) | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Market By:**  M/s Togo Medikit Co., Ltd., 13-2, Yushima, 1 Chome, Bunkyo-ku, Tokyo, 113-0034, Japan  **Manufacturing Site:**  M/s Togo Medikit Co., Ltd., Hyuga Factory 17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City, Miyazaki Prefecture 883-0062, Japan  (FSC Japan Issuance Date 30-11-2018)  **Rs.100,000/-**  **Fee Already Submitted against Slip No. 0069284 dated 16-12-15** | Supercath 5  Class B  Shelf Life: 5 Years  SP125-14-31T, SP125-16-31T, SP125-24-19T, SP125-18-31T, SP125-20-31T, SP125-22-31T, SP125-22-25T, SP125-24-19T, SP125-14-31WT,  SP125-16-31WT,  SP125-24-19WT,  SP125-18-31WT,  SP125-20-31WT,  SP125-22-31WT,  SP125-22-25WT,  SP125-24-19WT | I.V Catheter (Safety) | **Approved**. |
|  | **M/s Sure Bio-Diagnostics**& Pharmaceuticals, EE-10, Defense View Phase-II, Near Iqra University Shaheed-e-Millat Express Way, Karachi  (ELI-00084)  Evaluator:  Muhammad Ayub Naveed | **Owner Operator/**  **Manufacturer:**  M/s Diagnostic Automation / Cortez Diagnostics Inc., 21250 Califa St, Suite 102 and 116 Woodland Hills, CA 91367, USA  (FSC USFDA Valid Till  29-07-2020)  Fee Submitted  **Rs.25,000/-** | AccuDiag TM Total Human IgE ELISA Kit  Class B  Shelf Life: 12 Months | In- vitro diagnostic test kit for qualitative analysis of anti IgE antibodies based on solid phase enzyme linked immunosorbent assay. | **Approved**. |
|  | **M/s Shirazi Trading** Company (Pvt) Ltd., 114-C, Al-Murtaza Commercial Lane 3, Off Khayaban-e-Iqbal, Khayaban-e-Shaheen, DHA Phase 8, Karachi  (ELI-00263)  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Ge Hualun Medical Systems Co., Ltd., No 1, Yong Chang North Road, Beijing Economic Technological Development Zone 100176 Beijing, China  (FSC China Valid Till  30-05-2020)  Fee Submitted Rs.50,000/- | X-Ray System, Diagnostic, General Purpose, Fixed, Digital Brivo XR 575  Class C  Shelf Life: N/A | Stationary Basic Diagnostic X-Ray System Digital | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Healthcare Japan Corportion 7-127, Asahigaoka 4-Chome, Hino-Shi, Tokyo 191-8503, Japan  (FSC Japan Issuance Date 07-04-2016)  Fee Submitted Rs.50,000/- | Revlolution EVO  Class C  Shelf Life: N/A  226ACBZX00037000 | X-Ray System, Diagnostic, Computed Tomography, Full Body | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road, No.22 GaoLang Esat Road, Wuxi National Hi-Tech Dev. Zone, 214028 Jiangsu, China  (FSC China Valid Till  09-01-2020)  Fee Submitted Rs.50,000/- | Anesthesia Machine 9100c NXT  Class C  Shelf Life: N/A | Anesthesia System | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Medical Systems, LLC 3000 N Grandview Blvd. Waukesha, WI 53188, USA  (FSC USFDA Valid Till  09-04-2020)  Fee Submitted Rs.50,000/- | System, Tomography, Computed, Emission Discovery IQ  Class C  Shelf Life: N/A | Emission Computed Tomography System | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Hangwei Medical Systems Co., Ltd., West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, Beijing 100176, China  (FSC China Valid Till  03-07-2019)  Fee Submitted Rs.50,000/- | Computed Tomography System Optima CT520  Class C  Shelf Life: N/A | X Ray System, Diagnostic, Computed Tomography, Full Body | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road Wuxi National Hi-Tech Dev. Zone, 214028 Jiangsu, China  (FSC China Valid Till  26-09-2020)  Fee Submitted Rs.50,000/- | Anesthesia Machine (Carestation 30)  Class C  Shelf Life: 10 Years | Anesthesia Workstation, General Purpose | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Hangwei Medical Systems Co., Ltd., West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, Beijing 100176, China  (FSC China Valid Till  14-05-2019)  Fee Submitted Rs.50,000/- | Computed Tomography System (Revolution ACT)  Class C  Shelf Life: N/A | X Ray System, Diagnostic, Computed Tomography, Full Body | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Hangwei Medical Systems Co., Ltd., West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, Beijing 100176, China  (FSC China Valid Till  11-01-2020)  Fee Submitted Rs.50,000/- | Computed Tomography System (Optima CT540)  Class C  Shelf Life: N/A | X Ray System, Diagnostic, Computed Tomography, Full Body | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Datex-Ohmeda, Inc., 3030 Ohmeda Drive Madison, WI 53718, USA  (FSC USFDA Valid Till  08-10-2020)  Fee Submitted Rs.50,000/- | Gas-Machine, Anesthesia (Aisys CS2)  Class C  Shelf Life: N/A | Anesthesia Workstation, General-Purpose | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road, No.22 GaoLang Esat Road, Wuxi National Hi-Tech Dev. Zone, 214028 Jiangsu, China  (FSC China Valid Till  29-01-2020)  Fee Submitted Rs.50,000/- | Patient Monitor ( B 40)  Class C  Shelf Life: N/A | Single-Patient Physiologic Monitoring System | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s GE Medical Systems (China) Co., Ltd., No. 19, Changjiang Road, No.22 GaoLang Esat Road, Wuxi National Hi-Tech Dev. Zone, 214028 Jiangsu, China  (FSC China Valid Till  29-01-2020)  Fee Submitted Rs.50,000/- | Patient Monitor (B 20)  Class C  Shelf Life: N/A | Single-Patient Physiologic Monitoring System | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufactuer:**  M/s GE Medical Systems, LLC 3000N Grandview BLVD. Waukesha, WI 53188, USA  **Manufacturer:** M/s GE Hangwei Medical Systems Co., Ltd., West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, Beijing 100176, China  (FSC USFDA Valid Till  07-11-2020)  Fee Submitted Rs.50,000/- | System, X-Ray, Tomography, Computed (Revolution Frontier)  Class C  Shelf Life: N/A | X-Ray System, Diagnostic, Computed Tomography, Full-Body | **Approved**. |
|  | **M/s Sorabjee Patel**& Co., 45 Badri Building I.I Chundrigar Road, Karachi  (ELI-00067) | **Manufacture:**  M/s Arcadophta Sarl 11, Rue Antoine Ricord 31100 Toulouse, France  (FSC France Issuance Date  13-01-2016) | Fractionated Silicon oil for Ophthalmic use ARCIOLANE 1300 and ARCIOLANE 5500  Class C  Shelf Life: 3 Years | Fractionated Silicone Oil | **Approved.** |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-06-2018)  Fee Submitted Rs.50,000/- | RayOne Toric (RAO610T)  Class C  Shelf Life: 5 Years | Hydrophilic Flodable IOL | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-06-2018)  Fee Submitted Rs.50,000/- | RayOne Trifocal (RAO603F)  Class C  Shelf Life: 5 Years | Hydrophilic Flodable IOL | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Arcadophta Sarl 11, Rue Antoine Ricord 31100 Toulouse, France  (FSC France Issuance Date  13-01-2016)  Fee Submitted Rs.50,000/- | Gas for Ophthalmic Surgery Arceole Single Dose SF6, Arceole Single Dose C2f6, Arceole Single Dose C3F8  Class C  Shelf Life: 3 Years | SF6: Sulfur Hexafluoride  C2F6: Hexafluoroethane  C3F8: Octafluoropropane | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-01-2018)  Fee Submitted Rs.50,000/- | Methylvisc 2.0% (R-MLV20)  Class C  Shelf Life: 3 Years | Hydroxy Propylmethyl Cellulose | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-06-2018)  Fee Submitted Rs.50,000/- | RayOne Spheric (RAO100C)  Class C  Shelf Life: 5 Years | Hydrophilic Flodable IOL | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Arcadophta Sarl 11, Rue Antoine Ricord 31100 Toulouse, France  (FSC France Issuance Date  13-01-2016)  Fee Submitted Rs.50,000/- | Liquid Porfluorocatbone for Ophthalmic use ARCALINE/ARCOTANE  Class C  Shelf Life: 3 Years | These gases are used in the retinal detachment of the eye | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-06-2018)  Fee Submitted Rs.50,000/- | RayOne Hydrophobic Aspheric (RAO800C)  Class C  Shelf Life: 5 Years | Hydrophilic Flodable IOL | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-01-2018)  Fee Submitted Rs.50,000/- | OphteisBio 1.8% (R-OPB18)  Class C  Shelf Life: 5 Years | Viscoelastic Solution for intraocular use | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacture:**  M/s Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, UK  (FSC UK Issuance Date  04-06-2018)  Fee Submitted Rs.50,000/- | RayOne Aspheric (RAO600C)  Class C  Shelf Life: 5 Years | Hydrophilic Foldable IOL | **Approved.** |
|  | **M/s. Progressive Corporation,** 147-D, Commercial Broadway, Phase-8 DHA, Lahore.  (ELI-00114)  Evaluator:  Muhammad Ayub Naveed | M/s. Suzhou Junkang Medical Technology Co., Ltd,  No.28 Wutaishan Road, SND, Suzhou, Jiangsu, China.  FSC China Valid till 11-07-2020  FSC Germany  Issued on 17-01-2018  Fee Submitted  Rs. 25,000 | High Flux Hemodialyzer, Hollow Fiber Hemodialyzer  LoF10, L0F12, LoF14, LoF16, LoF18, LoF20  Class B  Shelf Life : 03 years | The Hemodialyzer adaptively be used for hemodialysis in chronic or acute renal failure patients. | **Approved** subject to Embassy attested FSC. |
|  | **M/s Bio Medics Medical System,** F-597, F-Block, Satellite Town, Rawalpindi  (ELI-00022)  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Serumwerk Bernburg Vertriebs GmbH Hallesche Landstrabe 105 b 06406 Bernburg, Germany  (FSC Germany Issuance Date  19-10-2018)  Fee: Rs.50,000/- | Diacart (Bicarbonate Cartidge for Haemodialysis)  Class C  Shelf Life: 36 Months  650g, 720g, 750g, 760g, 1100g | Sodium Bicarbonate Cartidge for Haemodialysis | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer**   1. M/s. Nanjing ECO Microwave System Co., Ltd., 3rd& 4th Floors, J5 Building NJUT Science Industrial Park No. 15, Wanshou Road, Pukou District, 211800 Nanjing, China. 2. M/s. Easter Vargas Pizarro, Traductora e Interprete Jurada Ingles, Poligono Industrial Las Salinas   C/o. Manantial, 13 – Oficina 103, Edificio CEEI, 11500 EI Puerto de Santa Maria, Spain  **FSC Spain**  Issued on 9th June, 2017  Fee Rs. 50,000 | ECO Microwave Therapeutic System  (Microwave Therapeutic System)  ECO-100A2  ECO-100E2  ECO-100E  ECO-100D1  ECO-100D  ECO-100D2  Class C  Shelf Life : N.A | The system consists of microwave source, microwave radiator, control system, display system and temperature measurement system. A mamimum of 2 microwave sources can be configured for each product. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer**  M/s. Nanjing ECO Microwave System Co., Ltd., 3rd& 4th Floors, J5 Building NJUT Science Industrial Park No. 15, Wanshou Road, Pukou District, 211800 Nanjing, China.   1. M/s. Easter Vargas Pizarro, Traductora e Interprete Jurada Ingles, Poligono Industrial Las Salinas   C/o. Manantial, 13 – Oficina 103, Edificio CEEI, 11500 EI Puerto de Santa Maria, Spain  FSC Spain  Issued on 9th June, 2017  Fee Rs. 50,000 | ECO Disposable Microwave  (Microwave Therapeutic System)  ECO-100AI1,  ECO-100AI20C,  ECO-100AI21C,  ECO-100Al22,  ECO-100AI5C,  ECO-100AL5C,  ECO-100AL22C,  ECO-100CL5C,  ECO- 100CL22C,  ECO-100A113C,  ECO-100AL13C,  ECO-100A1123C  ECO-100AL23C,  ECO- 100AI8C,  ECO- 100AL81C,  ECO- 100A1110C,  ECO-100AL10C,  ECO-MAU 1C,  ECO- 100AL81C,  ECO-100CL8,  ECO-100CL10,  ECO- 100CL11,  ECO- 100CL8C,  ECO-100CL10C,  ECO-100CL11C,  ECO-100AI25,  ECO-100F-2522,  ECO-100F-1210,  Class C  Shelf Life : N.A | This product consists of disposable microwave antenna and cooling circulation system. Dispoable microwave antenna consists of radiator, handle, microwave cable and cooling medium pipe. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer:** M/s Serumwerk Bernburg Vertriebs GmbH Hallesche Landstrabe 105 b 06406 Bernburg, Germany  (FSC Germany Issuance Date  19-10-2018) | DiaCart  Bicarbonate Cartridge for Haemodialysis  Class C  Shelf Life: 36 Months  650g, 720g, 750g, 760g, 1100g  Fee submitted: Rs.50,000/- | Sodium Bicarbonate Cartridge for Haemodialysis | **Rejected.** The product has already been registered at serial no. 219.  *(Duplication)* |
|  | **M/s B.Braun Pakistan (**Pvt) Ltd.,  The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi  (ELI-00006)  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s B. Braun Melsungen AG Carl-Braun-Strabe 1 34212 Melsungen, Germany  **Manufacturing Site:**  M/s Natec Medical Ltd., Maeva Centre Building, Silicon Avenue, Ebene Business Park, Reduit 72201, Mauritius  (FSC Germany Issuance Date  29-11-2018)  Fee submitted: Rs.50,000/- | SeQuent NEO NC  Class D  Shelf Life: 3 Years  5023900 SEQUENT NEO NC 2.0 X 8 MM  5023901 SEQUENT NEO NC 2.25 X 8 MM  5023902 SEQUENT NEO NC 2.5 X 8 MM  5023903SEQUENT NEO NC 2.75 X 8 MM  5023904 SEQUENT NEO NC 3.0 X 8 MM  5023905 SEQUENT NEO NC 3.25 X 8 MM  5023906 SEQUENT NEO NC 3.5 X 8 MM  5023907 SEQUENT NEO NC 4.0 X 8 MM  5023908 SEQUENT NEO NC 4.5 X 8 MM  5023910 SEQUENT NEO NC 2.0 X 10 MM  5023911 SEQUENT NEO NC 2.25 X 10 MM  5023912 SEQUENT NEO NC 2.5 X 10 MM  5023913 SEQUENT NEO NC 2.75 X 10 MM  5023914 SEQUENT NEO NC 3.0 X 10 MM  5023915 SEQUENT NEO NC 3.25 X 10 MM  5023916 SEQUENT NEO NC 3.5 X 10 MM  5023917 SEQUENT NEO NC 4.0 X 10 MM  5023918 SEQUENT NEO NC 4.5 X 10 MM  5023920 SEQUENT NEO NC 2.0 X 12 MM  5023921 SEQUENT NEO NC 2.25 X 12 MM  5023922 SEQUENT NEO NC 2.5 X 12 MM  5023923 SEQUENT NEO NC 2.75 X 12 MM  5023924 SEQUENT NEO NC 3.0 X 12 MM  5023925 SEQUENT NEO NC 3.25 X 12 MM  5023926 SEQUENT NEO NC 3.5 X 12 MM  5023927 SEQUENT NEO NC 4.0 X 12 MM  5023928 SEQUENT NEO NC 4.5 X 12 MM  5023930 SEQUENT NEO NC 2.0 X 15 MM  5023931 SEQUENT NEO NC 2.25 X 15 MM  5023932 SEQUENT NEO NC 2.5 X 15 MM  5023933 SEQUENT NEO NC 2.75 X 15 MM  5023934 SEQUENT NEO NC 3.0 X 15 MM  5023935 SEQUENT NEO NC 3.25 X 15 MM  5023936 SEQUENT NEO NC 3.5 X 15 MM  5023937 SEQUENT NEO NC 4.0 X 15 MM  5023938 SEQUENT NEO NC 4.5 X 15 MM  5023940 SEQUENT NEO NC 2.0 X 20 MM  5023941 SEQUENT NEO NC 2.25 X 20 MM  5023942 SEQUENT NEO NC 2.5 X 20 MM  5023943 SEQUENT NEO NC 2.75 X 20 MM  5023944 SEQUENT NEO NC 3.0 X 20 MM  5023945 SEQUENT NEO NC 3.25 X 20 MM  5023946 SEQUENT NEO NC 3.5 X 20 MM  5023947 SEQUENT NEO NC 4.0 X 20 MM  5023948 SEQUENT NEO NC 4.5 X 20 MM  5023960 SEQUENT NEO NC 2.0 X 30 MM  5023961 SEQUENT NEO NC 2.25 X 30 MM  5023962 SEQUENT NEO NC 2.5 X 30 MM  5023963 SEQUENT NEO NC 2.75 X 30 MM  5023964 SEQUENT NEO NC 3.0 X 30 MM  5023965 SEQUENT NEO NC 3.25 X 30 MM  5023966 SEQUENT NEO NC 3.5 X 30 MM  5023967 SEQUENT NEO NC 4.0 X 30 MM  5023968 SEQUENT NEO NC 4.5 X 30 MM | Non-Compliant PTCA Balloon Catheter | **Approved.** |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:**  M/s B. Braun Melsungen AG Carl-Braun-Strabe 1 34212 Melsungen, Germany  **Manufacturing Site:**  M/s Braun Medical Industries Sdn. Bhd., Bayan Lepas Free Industrial Zone 11900 Penang, Malaysia  (FSC Germany Issuance Date  10-01-2019)  Fee Submitted Rs.50,000/- | Spinocan® (Needle for Spinal Anaesthesia)  Class D  Shelf Life: 5 Years  4501144, 4501195, 4501373, 4501900, 4501918, 4502140, 4502906, 4503902, 4505751, 4505905, 4506014, 4507401, 4507754, 4507908, 4509757, 4509900, 4504917, 4505913, 4506090 | Spinal Needle for Spinal and Diagnostic Puncture | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:**  M/s B. Braun Melsungen AG Carl-Braun-Strabe 1 34212 Melsungen, Germany  **Manufacturing Site:**  M/s Braun Medical Industries Sdn. Bhd., Bayan Lepas Free Industrial Zone 11900 Penang, Malaysia  (FSC Germany Issuance Date 10-01-2019)  Fee Submitted Rs.50,000/- | Pencan® (Needles for Spinal Anaesthesia)  Class D  Shelf Life: 5 Years  4502043, 4502051, 4502116, 4502124 | Spinal Needle for spinal and Diagnostic Puncture | **Approved**. |
|  | **M/s Otsuka Pakistan Limited**, 30-B, SMCHS, Karachi  (ELI-00243)  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:**  M/s Otsuka Electronics Co., Ltd., 3-26-3, Shodai-Tajika, Hirakata, Osaka, 573-1132, Japan  **Manufacturing Site:**  M/s Otsuka Electronics Co., Ltd., Shiga Plant 1-10, Sasagaoka, Minakuchi, Koka, Shiga, 528-0061, Japan  (FSC Japan Issue Date  07-12-2018) | Otsuka Infrared Spectrophotometer POCone  Option: POC-AS10  Class B  Shelf Life: not applicable  Fee submitted: Rs. 50,000/- | Analyzer designed for on-site performance of the 13C-urea breath test for detection of H.Pylori infection | **Approved.** Shelf life is not applicable. |
|  | **M/s Anwar & Sons**, Apartment No.10, Safari Villas-2, Commercial Complex, Phase-7, Bahria Town Rawalpindi  (ELI-00017)  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Mascia Brunelli S.p.A., Viale Monza 272 – 20128 Milano, Italy  (FSC Italy Issuance Date  03-03-2017)  Fee submitted: Rs.50,000/- | Cutanplast®  Class D  Shelf Life: 05 Years  Cutanplast Standard  Ref : 05170502 70x50x10mm (20 Pcs)  Cutanplast Special  Ref : 05380502 70x50x1mm  (20 Pcs)  Cutanplast Anal  Ref :05480302 80x30 Ǿmm  (20 Pcs)  Cutanplast Dental  Ref: 05610101 10x10x10 mm  (24 Pcs)  Cutanplast Film  Ref: 05770202 200x70x0.5mm (20 Pcs)  Cutanplast Dial  Ref: 05230302 30x30x10mm  (20 Pcs)  Cutanplast  Ref: 05520602 20x60x7 mm  (20 Pcs)  Cutanplast Large  Ref: 058801251 80x125x10mm (10 Pcs)  Cutanplast Small  Ref: 05850302 50x30x10mm  (20 Pcs) | Sterile, Haemostat Gelatin Sponge | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Mascia Brunelli S.p.A., Viale Monza 272 – 20128 Milano, Italy  (FSC Italy Issuance Date  03-03-2017) | Emosist ®   1. **Ref :06125513 Size 1.25x5 cm (10pcs)** 2. **Ref :06755013 Size 7.5 x5 cm (10pcs)** 3. **Ref :06201013 Size 10x20 cm (10pcs)**   **4. Ref :06355013 Size 35 x 5 c(10 pcs)**  Class D  Shelf Life : 03 years  Fee submitted: Rs.50,000/- | Oxidized Regenerated Cellulose | **Approved**. |
|  | M/s Krestacorp, 76-C, 3rd Floor, Suit No.2, Khayaban-e-Jami, Street No.9, DHA Phase 7, Karachi  (ELI-00258)  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:** M/s Jei Daniel Biotech Corp., Jinan Facility, A201, 1st Building No69, Hua Yang Road Jinan, ShangDong, China.  (FSC China Valid Till  10-05-2020) | Klear  Human Chorionic Gonadotropin (HCG) Rapid Test Kit (Colloidal Gold)  Class B  Shelf Life: 3 Years  Fee submitted: Rs.50,000/- | Rapid Self Pregnancy Test Strip | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  **Only one brand shall be given.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:** M/s Jei Daniel Biotech Corp., Jinan Facility, A201, 1st Building No69, Hua Yang Road Jinan, ShangDong, China.  (FSC China Valid Till  10-05-2020)  Fee submitted: Rs.50,000/- | OneTest  Human Chorionic Gonadotropin (HCG) Rapid Test Kit (Colloidal Gold)  Class B  Shelf Life: 3 Years | Rapid Self Pregnancy Test Strip | Product is similiar at serial no. 229. only brand is change. therefore, Already considered at serial no. 229. |
|  | **M/s Trans Angio System**, 507, Progressive Square, Block-6, PECHS, Shahrah-e-Faisal, Karachi  (ELI-00172)  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Translumina GmbH Neue Rottenburger Strabe 50, 72379 Hechingen, Germany  (FSC Germany Issuance Date 24-10-2017)  Fee submitted Rs 50,000/- | Yukon Chrome PC  Class D  Shelf Life: 18 Months  T-CMG2008PC, T-CMG2012PC, T-CMG2016PC, T-CMG2018PC, T-CMG2021PC, T-CMG2024PC, T-CMG2028PC, T-CMG2032PC, T-CMG2508PC, T-CMG2512PC, T-CMG2516PC, T-CMG2518PC, T-CMG2521PC, T-CMG2524PC, T-CMG2528PC T-CMG2532PC, T-CMG27508PC, T-CMG27512PC, T-CMG27516PC, T-CMG27518PC, T-CMG27521PC, T-CMG27524PC, T-CMG27528PC, T-CMG27532PC, T-CMG27540PC, T-CMG3008PC, T-CMG3012PC, T-CMG3016PC, T-CMG3018PC, T-CMG3021PC, T-CMG3024PC, T-CMG3028PC, T-CMG3032PC, T-CMG3040PC, T-CMG3508PC, T-CMG3512PC, T-CMG3516PC, T-CMG3518PC, T-CMG3521PC, T-CMG3524PC, T-CMG3528PC, T-CMG3532PC, T-CMG3540PC,  T-CMG4008PC, T-CMG4012PC, T-CMG4016PC, T-CMG4018PC, T-CMG4021PC, T-CMG4024PC, T-CMG4028PC, T-CMG4032PC, T-CMG4040PC | Sirolimus Eluting CoCr Coronary Stent System | **Approved**. |
|  | **M/s Royal Enterprises**, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062)  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Jiangsu Folee Medical Equipment Co., Ltd.  No. 16, Xingmao Road, Zhenjiang City, China  (FSC China Valid Till  31-08-2019)  Fee submitted: Rs.25,000/- | Folee Portable Phlegm Suction Unit  Class B  Shelf Life: Not applicable  H003-A, H003-B, H003-C | For sucking thick liquid such as pus-blood and phelgm under negative pressure | **Approved.** Shelf life not applicable. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Jiangsu Folee Medical Equipment Co., Ltd.  No. 16, Xingmao Road, Zhenjiang City, China  (FSC China Valid Till  31-08-2019) | Folee Bedsore Prevention Mattress  Class B  Shelf Life: Not applicable  J001, J001-A, J002, J003, J003-A J006, J009-A  Fee submitted: Rs.25,000/- | Bedsore Prevention Mattress | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  Shelf life not applicable. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacture:**  M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China  (FSC China Valid Till  31-08-2019) | Folee Oxygen Concentrator ( Model: Y007-1)  Class B  Shelf Life: Not applicable  Fee Submitted: Rs. 25,000/- | Used to generate oxygen for the oxygen- deficient patients | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  Shelf life not applicable. |
|  | **M/s Matrix Pharma** (Pvt) Ltd., Plot No. 12, Sector 15, Korangi Industrial Area, Karachi  (ELI-00039)  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8th Street, Hangzhou Econ. & Tech. Development Zone, China  **Manufacturing site:**  No. 866, Moganshan Road (No. 700, Shixiang Road), Hangzhou, China  (FSC China Valid Till  17-09-2020) | Bonisa® Bone Repairing Material (0.5 mg rhBMP-2/vial)  Class D  Shelf Life: 02 Years  Fee Submitted: Rs 50,000/- | Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) with osteoinductive bioactivity, indicated for use in bone defect, bone nonunion, bone delayed union or nonunion resulted from various causes, spinal fusion joint fusion and orthopaedic implantation | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  The Board referred the product for expert opinion from Dr. Khalid S. Aslam, whether the product is required in orthopaedic surgery and how effective it is? |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8th Street, Hangzhou Econ. & Tech. Development Zone, China  **Manufacturing site:**  No. 866, Moganshan Road (No. 700, Shixiang Road), Hangzhou, China  (FSC China Valid Till  17-09-2020) | Bonisa® Bone Repairing Material (2.0 mg rhBMP-2/vial)  Class D  Shelf Life: 02 Years  Fee Submitted: Rs 50,000/- | Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) with osteoinductive bioactivity, indicated for use in bone defect, bone nonunion, bone delayed union or non-union resulted from various causes, spinal fusion joint fusion and orthopaedic implantation | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  The Board referred the product for expert opinion from Dr. Khalid S. Aslam, whether the product is required in orthopaedic surgery and how effective it is? |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8th Street, Hangzhou Econ. & Tech. Development Zone, China  **Manufacturing site:**  No. 866, Moganshan Road (No. 700, Shixiang Road), Hangzhou, China  (FSC China Valid Till  17-09-2020) | Bonisa® Bone Repairing Material (1.0 mg rhBMP-2/vial)  Class D  Shelf Life: 02 Years  Fee Submitted: Rs 50,000/- | Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) with osteoinductive bioactivity, indicated for use in bone defect, bone nonunion, bone delayed union or non-union resulted from various causes, spinal fusion joint fusion and orthopaedic implantation | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  The Board referred the product for expert opinion from Dr. Khalid S. Aslam, whether the product is required in orthopaedic surgery and how effective it is? |
|  | **M/s Ali Gohar & Company** (Pvt) Ltd., State Life Building 1-B, I.I Chundrigar Road, Karachi  (ELI-00004)  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  M/s Alcon Research, Ltd.,  6065 Kyle Lane Huntington, WV 25702, USA  (FSC Belgium Issue Date  15-10-2018)  FSC Australia Issue Date  23-08-2018) | ACRYSOF® IQ PanOptixTM Toric Presbyopia-Correcting IOL  Class C  Shelf Life: 5 years  Model: TFNT20, TFNT30, TFNT40, TFNT50, TFNT60  Fee Submitted: Rs 50,000/- | Sterile, ultraviolet and blue-light filtering, Acrylic Foldable Single-Piece Intraocular Lens | **Approved** subject to provision of stability studies data supporting 5 years shelf. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  1) M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  2) M/s Alcon Laboratories Ireland Cork Business & Technology Park, Model Farm Road, Cork, Ireland  (FSC US FDA Valid Till  13-02-2020)  (FSC Ireland Valid Till  17-01-2023)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® Single Piece IOL  Class C  Shelf Life: 5 years.  Model: SA60AT  Fee Submitted: Rs 50,000/- | Sterile, UV absorbing, acrylic, foldable, single-piece posterior chamber Intraocular Lens | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  1) M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  2) M/s Alcon Laboratories Ireland Cork Business & Technology Park Model Farm Road, Cork Ireland  (FSC US FDA Valid Till  13-02-2020)  (FSC Ireland Valid Till  17-01-2023)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® IQ Aspheric Natural Single-Piece Intraocular Lens  Class C  Shelf Life: 5 years  SN60WF  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering, acrylic, foldable, single-piece, posterior chamber Intraocular Lens | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  1) M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  2) M/s Alcon Laboratories Ireland Cork Business & Technology Park Model Farm Road, Cork Ireland  (FSC US FDA Valid Till  13-02-2020)  (FSC Ireland Valid Till  17-01-2023)  (FSC Australia Issue Date 23-08-2018) | ACRYSOF® IQ ReSTOR® Multifocal Intraocular Lens  Class C  Shelf Life: 5 years  SN6AD1  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering, foldable, single-piece, apodized, diffractive, aspheric, posterior chamber Intraocular Lens | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099**Manufacturing Site:**  1) M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  2) M/s Alcon Laboratories Ireland Cork Business & Technology Park Model Farm Road, Cork Ireland  (FSC US FDA Valid Till  13-02-2020)  (FSC Ireland Valid Till  17-01-2023)  (FSC Belgium Issue Date  09-06-2017) | ACRYSOF® IQ Toric Astigmatism Intraocular Lens  Class C  Shelf Life: 5 years  SN6AT2, SN6AT3, SN6AT4, SN6AT5, SN6AT6, SN6AT7, SN6AT8, SN6AT9  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering acrylic, foldable, toric, aspheric, optic, single-piece posterior chamber lens | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  1) M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  2) M/s Alcon Laboratories Ireland, Cork Business & Technology Park Model Farm Road, Cork Ireland  (FSC US FDA Valid Till  13-02-2020)  (FSC Ireland Valid Till  17-01-2023)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® IQ Aspheric IOL with the UltraSert® Pre-Loaded Delivery System  Class C  Shelf Life: 5 years  AU00T0  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering acrylic, foldable, single-piece posterior chamber intraocular lens with the UltraSert® Pre-Loaded Delivery System | **Approved** subject to provision of stability studies data supporting 5 years shelf. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  (FSC US FDA Valid Till  13-02-2020)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® IQ Aspheric  Natural IOL with Acrysert C Delivery System  Class C  Shelf Life: 5 years  SN6CWS  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering acrylic, foldable, single-piece posterior chamber intraocular lens with Acrysert C Delivery System | **Approved** subject to provision of stability studies data supporting 5 years shelf. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  (FSC USFDA Valid Till  13-02-2020)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® Multi Piece IOL  Class C  Shelf Life: 5 years  MA60AC, MA60MA  Fee Submitted: Rs 50,000/- | Sterile, UV absorbing, acrylic, foldable, multi-piece posterior chamber intraocular lens | **Approved** subject to provision of stability studies data supporting 5 years shelf. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  (FSC Belgium Issue Date  09-06-2017)  (FSC US FDA Valid Till  13-02-2020)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® IQ RESTOR® Multifocal Toric IOL  Class C  Shelf Life: 5 years  SND1T2, SND1T3, SND1T4, SND1T5, SND1T6  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering, acrylic, foldable, apodized, diffractive, aspheric, posterior chamber intraocular lens | **Approved** subject to provision of stability studies data supporting 5 years shelf. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Maufacturer:** M/s Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas, USA 76134-2099  **Manufacturing Site:**  M/s Alcon Research, Ltd., 6065 Kyle Lane Huntington, WV 25702, USA  (FSC Belgium Issue Date  17-11-2017)  (FSC Australia Issue Date  23-08-2018) | ACRYSOF® IQ PanOptixTM Presbyopia-Correcting IOL  Class C  Shelf Life: 5 years  TFNT00  Fee Submitted: Rs 50,000/- | Sterile, UV and blue light filtering, foldable, multi-focal intraocular lens | **Approved** subject to provision of stability studies data supporting 5 years shelf. |
|  | M/s IBL Healthcare, 1st Floor, N.I.C.L Building Abbasi-Shaheed Road, Karachi  (ELI-00119)  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Bausch & Lomb Incorporated, 1400 North Goodman Street, Rochester, NY 14609, USA  **Manufacturing Site:**  M/s Bausch & Lomb - IOM S.p.A., Via Pasubio 34, 20846 Macherio (MB), Italy  (FSC Italy Issue Date  17-09-2018) | Bausch + Lomb ReNu Multiplus Multipurpose Solution  Class C  Shelf Life: 24 Months  Fee Rs 50,000/- | Multipurpose Contact Lens Care Solution | **Approved** subject to provision of Essential principles of safety and performance. |
|  | **M/s Mars Enterprises**, Office No.4, Jason Centre, 2nd Floor, BC-8, Block No.9, Clifton, Karachi  (ELI-00097)  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Yiles Medical Co., Ltd., Chuangye Road 1199, Jinxian, Nanchang City, 331700 Jiangxi, China  (FSC China Valid Till  07-02-2020) | Icare™  Nebulizer Mask for Single Use  Class B  Shelf Life: 05 Years  Adult, Child (Pediatric) | Nebulizer mask for single use, sterile | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts.  Also subject to provision of Essential principles of safety and performance and Declaration of conformity. |
|  | **M/s. Physiomed** (Pvt) Ltd, 268/3, Kamal Road Saddar Rawalpindi.  (ELI-00199)  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site**  M/s. Irvine Biomedical Inc., a St. Jude Medical Company, 2375, Morse Avenue, Irvine CA, 92614, USA  FSC Belgium  Issue Date: 12-01-2018 | Therapy ® Ablation Catheters  Models  83302 83306  83309 83351  83403 83404  83405 83408  83411 83417  83432 83453  83456 83459  83513 83516  83701 83702  83703 83704  83708  Class D  Shelf Life : 03 years  Fee- Rs. 50,000/- | Indicated for use in the treatment of AV nodal reentrant tachycardia, for ablation of accessory pathways, and for the creation of complete AV block in atrial arrhythmias. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Name of Manufacturer/**  i) St. Jude Medical 5050 Nathan Lane North Plymouth, MN USA 55442  ii) St. Jude Medical Costa Rica Ltda. Edificio No. 44 Calle 0, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela COSTA RICA 1897-4050  FSC USFDA  Valid upto 27-3-2020 | FlexAbility ® Sensor Enabled Catheter  Models  A-FASE-DD, A-FASE-DF, A-FASE-FF, A-FASE-FJ, A-FASE-JJ, A-FASE-D, A-FASE-F, A-FASE-J  Class D  Shelf Life : 36 Months  Fee- Rs. 50,000 | Intended for creating lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of arrhythmias. Used with compatible magnetic tracking systems to enable catheter positioning and navigation. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Name of Manufacturer/**  i) St. Jude Medical 5050 Nathan Lane North Plymouth, MN USA 55442  ii) St. Jude Medical Costa Rica Ltda. Edificio No. 44 Calle 0, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela COSTA RICA 1897-4050  FSC USFDA  Valid upto 27-3-2020 | FlexAbility® Ablation Catheter  Models  A701124, A701125, A701127, A701128, A701129, A701157, A701158, A701159  Class D  Shelf Life : 36 Months  Fee- Rs. 50,000 | Intended for creating focal endocardial lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of arrhythmias. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | i) St. Jude Medical Costa Rica Ltda. Edificio No. 44 Calle 0, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela COSTA RICA 187-4050  ii) St. Jude Medical  14901 DEVEAU PL. MINNETONKA, MN USA 55345  iii) St. Jude Medical 5050 Nathan Lane North Plymouth, MN USA 55442  FSC USFDA valid till 29-01-2020  Rs. 50,000 | Livewire ® Streerable  Electrophysiology Catheter.  401572, 401578, 401580, 401581, 401582, 401586, 401600, 401603, 401606, 401648, 401652, 401653,  401654, 401655, 401780, 401781, 401782, 401786,  401904, 401905, 401908, 401914, 401915, 401917,  401918, 401923, 401926, 401932, 401933, 401934, 401935, 401938, 401939, 401940, 401941, 401942, 401949, 401990, 402019, 402022, 402023, 402024,  402032  Class D  Shelflife : 03 years | Electrophysiology Catheter. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed. | **Legal and Original Manufacturer**  i) St. Jude Medical 5050, Nathan Lane North Plymouth, MN USA 55442  **Manufacturing Sites:**  M/s. St. Jude Medical Costa Rica Ltda, Edificio # 44 Calle O, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela Costa Rica 187-4050  b) M/s. St. Jude Medical 5050, Nathan Lane North Plymouth, MN USA 55442  FSC USFDA  Valid till November 07, 2019 | AdvisorTM FL Circular Mapping Catheter, Sensor Enabled  (Circular Mapping Catheter)  D-AVSE-010-F15, D-AVSE-010-F20, D-AVSEDF10-F15, D-AVSE-DF10-F20  Class D  Shelf Life 18 months | The advisor FL, SE catheter is a sensor-enabled steerable electrophysiology catheter used for recording intracardia signals and cardiac stimulation during diagnostic electrophysiology studies. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer**  M/s. St. Jude Medical 14901 DEVEAU PL Minnetonka, MN USA 55345  **Legal Manufacturing Site**  M/s. St. Jude Medical 5050 Nathan Lane North Plymouth, MN USA 55442  FSC USFDA  Valid till October 08, 2020 | Peel Away Introducers  (Peel away introducers)  405100, 405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405132, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405256, 405258, 405259, 405269, 405270, 405400, 405404, 405408, 405412, 405418, 405420, 405422, 405424, 405428, 405444  Class D  Shelf Life : 03 Years | Peel-away Hemostasis Introducers are intended for the introduction of angiographic catheters, closed end catheters, balloon catheters, and electrodes into a vessel where minimizing blood loss is essential. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal and Original Manufacturer**  i) M/s. St. Jude Medical Puerto LLc, Lot A Interior #2 Rd km.67.5, Santana Industrial Park, Arecibo PR 00612, USA  ii) M/s. St. Jude Medical Operations(M) sdn. Bhd Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, Malaysia.  FSC USFDA  Valid till March 06, 2019  Rs. 50,000 | Assurity MRI  (Pacemaker)  PM 1272, PM 2272  Class D  Not mentioned | Implantation of a single-chamber pulse generator or dual-chamber pulse generator, or CRT-P is indicated in one or more of the following permanent condition:  i) Syncope  ii) Presyncope  iii) Fatigue  iv) Disorientation  v) or any combination of above symptoms. | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer / Manufacturing Site**  M/s. St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342 USA  **Applicant for certificate**:  M/s. St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 box F1, 1935 Zaventem, Belgium.  FSC Belgium  Issue date : November 07, 2017  Rs. 50,000 | CPS AimTM SL  (Sittable Inner Catheter) with integrated valve  DS2N021-59, DS2N022-59,  DS2N023-59, DS2N021-65, DS2N022-65, DS2N023-65,  DS2N024-65, DS2N025-65,  Class D  Shelf Life : 03 Years | The CPS delivery tools help provide access to the venous system and aid in the delivery of the left ventricular lead during cardiac Resynchronization Therapy (CRT) procedure. | **Approved**. |
|  | **M/s. Iqbal & Company**  Alfalah Manzil Opp. National Police Foundation, Street No.26, Sector E-11/4, Islamabad.  (ELI-00117)  Evaluator:  Unum Zia Shamsi | **Manufacturer**  M/s. Intra special catheters GmbH, OststraBe 2,  66780 Rehlingen Siersburg/ Germany.  FSC Germany  Issued on 10.01.2019 | Microseld PEBAX  (Arterial Catheter Kit)   |  |  | | --- | --- | | 305 043 | 3F- 4cm | | 305 053 | 3F- 5cm | | 305 063 | 3F - 6cm | | 305 064 | 4F - 6cm | | 305 083 | 3F - 8cm | | 305 084 | 4F- 8cm | | 305 113 | 3F - 11cm | | 305 114 | 4F - 11cm | | 305 153 | 3F- 15cm | | 305 154 | 4F- 15cm | | 305 203 | 3F- 20cm | | 305 204 | 4F- 20cm |   Class D  Shelf Life : 05 years  Fee submitted: Rs. 25,000 | Arterial catheter for arterial blood pressure measurement and blood gas analysis, using the seldinger technique. | **Approved** subject to provision of differential fee Rs. 25000/- |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer**  M/s. Intra special catheters GmbH, OststraBe 2,  66780 Rehlingen Siersburg/ Germany.  FSC Germany  Issued on 10.01.2019 | Microseld PTFE  (Arterial Catheter Kit)  302 022 — 2F-2cm  302 032 — 2F-3cm  302 042 — 2F-4cm  302 043 — 3F-4cm  302 062 — 2F-6cm  302 063 — 3F-6cm  302 064 — 4F-6cm  302 065— 5F-6cm  302 082— 2F-8cm  302 083— 3F-8cm  302 084— 4F-8cm  302 085— 5F-8cm  302 113— 3F-11cm  302 114— 4F-11cm  302 115— 5F-11cm  302 153— 3F-15cm  302 154— 4F-15cm  302 155— 5F-15cm  302 203— 3F-20cm  302 204— 4F-20cm  302 205— 5F-20cm  Class D  Shelf Life: 05 years  Fee submitted Rs. 50,000 | Arterial catheter for arterial blood pressure measurement and blood gas analysis, using the seldinger technique. | **Approved.** |
|  | M/s. Medicamp International. Office No. 1, First Floor, Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi.  (ELI-00200)  Evaluator:  Unum Zia Shamsi | **M/s. Genicon**  6869 Stapoint Ct., Suite 114, Winter Park, Florida 32792 USA  (FSC US FDA valid 27-11-2019) | GeniClip™  (Titanium Hemostatic Clip)  350-000-103 GeniClip Medium/ Large  350-000-104 GeniClip Large  Class C  Shelf life: 03 years  Fee submitted: Rs. 50,000/- | Intended for use during procedures for the purpose of approximating soft tissues, closing of vessels and other structures in order to stop bleeding or to connect internal tissues to aid in healing | **Approved** subject to provision of Stability studies supporting shelf life. |
|  | **M/s. Medicamp International**, Office No. 1, First Floor, Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah, Rawalpindi.  (ELI-00200)  Evaluator:  Unum Zia Shamsi | **M/s. Genicon**  6869 Stapoint Ct., Suite 114, Winter Park, Florida 32792 USA  (FSC US FDA valid 27-11-2019) | GeniClip Applier™ (Reusable)  350-010-001 GeniClip Applier  350-010-002 GeniClip Applier  350-010-003 GeniClip Applier  Class B  Shelf life: 200 sterilization cycles  Fee submitted: Rs. 25,000/- | Applied in endoscopic procedures for occlusion of vessels and other small tissue structures as well as for  radiographic markings | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **M/s. Genicon**  6869 Stapoint Ct., Suite 114, Winter Park, Florida 32792 USA  (FSC US FDA valid 27-11-2019) | **GeniFlow™**  (Single Use Suction /Irrigation System-Gravity)  1. 700-000-005 GeniFlow  Gravity single spike suction  irrigation no probe  2. 700-005-010 GeniFlow  Gravity Single Spike Suction  Irrigation With 5x33 Probe  3. 700-005-005 GeniFlow  Gravity Single Spike Suction  Irrigation With 5x28 Probe  4. 700-005-010 GeniFlow  Gravity Dual Spike Suction  Irrigation With 5x33 Probe  5. 700-005-033 Single Use  Suction Irrigation Probe 5x33  6. 700-005-045 Single Use  Suction Irrigation Probe 5x45  7. 700-010-005 GeniFlow  Gravity Dual Spike Suction  Irrigation with 10x33 Probe  8. 700-010-033 Single Use  Suction Irrigation Probe 10x33  9. 700-105-010 GeniFlow  Gravity Dual Spike Suction  Irrigation with 5x33 and  10x33 Probe  10. 700-000-010 GeniFlow  Gravity single spike suction  irrigation with 5x33  Class B  Shelf life: 3.5 years  Fee submitted: Rs. 25,000/- | To provide suction and irrigation function to help flush blood and tissue debris from the operative site during laproscopy to aid visualization | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **M/s. Genicon**  6869 Stapoint Ct., Suite 114, Winter Park, Florida 32792 USA  (FSC US FDA valid 27-11-2019) | **GeniSurge®**  (Monopolar 5mm Disposable Laparoscopic Instrument)  **Curved Maryland Dissector**  Non Ratcheting 533-005-905  **Atraumatic Fenestrated Grasper**  Ratcheting 533-005-920  **Babcock grasper**  Ratcheting 533-005-925  **Maxi grip fenestrated grasper**  Ratcheting 533-005-945  **Straight scissors**  533-005-935  **Curved Metzenbaum scissors**  533-005-910  Class C  Shelf Life: 03 years  Fee submitted: Rs. 50,000/- | Sterile, packaged single-use monopolar instruments including graspers, dissectors and scissors intended to grasp, manipulate, cut and caurterize soft tissue | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **M/s. Genicon**  6869 Stapoint Ct., Suite 114, Winter Park, Florida 32792 USA  (FSC US FDA valid 27-11-2019) | **Natura™**  (Natura Optical Bladeless Trocar)   * 210-005-050 Natura 5x70 Trocar * 210-005-051 Natura 5x70 Trocar with 1 cannula threaded * 210-005-052 Natura 5x70 Trocar with 2 cannula threaded * 210-005-150 Natura 5x100 Trocar * 210-005-151 Natura 5x100 Trocar with 1 cannula threaded * 210-005-152 Natura 5x100 Trocar with 2 cannula threaded * 210-005-250 Natura 5x150 Trocar * 210-005-251 Natura 5x150 Trocar with 1 cannula threaded * 210-005-252 Natura 5x150 Trocar with 2 cannula threaded * 210-010-150 Natura 10x100 Trocar * 210-010-151 natura 10x100 Trocar with 1 cannula threaded * 210-010-152 natura 10x100 Trocar with 2 cannula threaded * 210-010-250 natura 10x150 Trocar * 210-010-251 natura 10x150 Trocar with 1 cannula threaded * 210-010-252 natura 10x150 Trocar with 2 cannula threaded * 210-012-150 natura 12x100 Trocar * 210-012-151 natura 12x100 Trocar with 1 cannula threaded * 210-012-250 natura 12x150 Trocar * 210-012-251 natura 12x150 Trocar with 1 cannula threaded * 210-015-150 natura 15x100 Trocar * 210-015-151 natura 15x100 Trocar with 1 cannula threaded * 210-015-250 natura 15x150 Trocar * 210-015-251 natura 15x50 Trocar with 1 cannula threaded * 210-103-051 Natura 3x60 trocar with 1 cannula smooth. * 210-105-052 natura 5x70 Trocar with 2 cannula smooth * 210-105-051natura 5x70 Trocar with 1 cannula smooth. * 210-105-151 natura 5x100 Trocar with 1 cannula smooth * 210-105-152 natura 5x100 Trocar with 2 cannula smooth * 210-105-251 natura 5x150 Trocar with 1 cannula smooth * 210-105-252 natura 5x150 Trocar with 2 cannula smooth * 210-110-151 natura 10x100 Trocar with 1 cannula smooth * 210-110-152 natura 10x100 Trocar with 2 cannula smooth * 210-110-251 natura 10x150 Trocar with 1 cannula smooth * 210-110-252 natura 10x150 Trocar with 2 cannula smooth * 210-112-151 natura 12x100 Trocar with 1 cannula smooth * 210-115-251 natura 15xp/'150 Trocar with 1 cannula smooth   Class B  Shelf Life: 05 years  Fee submitted: Rs. 25,000/- | Intended for surgical insertion into the peritoneal cavity for the purpose of establishing a port of entry for instrumentation and for visualization during laparoscopic for primary and secondary insertion. | **Approved**. |
|  | M/s. Easha Enterprises. Office No 376, Pak Khaleej Center Saidpur Road, Rawalpindi.  (ELI-00203)  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing site:**  M/s. Vascular Innovations Co. Ltd.,  88/38 Moo 1, 345 Road, Bangtanai Pakkret, Nonthaburi-11120  Thailand  FSC U.K  Issued on 26-11-2018  FSC Thailand  Valid till 07-06-2020 | Cocoon Septal Occluder  **Codes:-**   1. COA08 2. COA10 3. COA12 4. COA14 5. COA16 6. COA18 7. COA20 8. COA22 9. COA24 10. COA26 11. COA28 12. COA30 13. COA32 14. COA34 15. COA36 16. COA38 17. COA 40   Class D  Shelf Life : 03 years  Fee --Rs. 50,000 | It is percutaneous, transcatheter, atrial septal defect (ASD) closure device intended for the occlusion of secundum type ASD. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing site:**  M/s. Vascular Innovations Co. Ltd.,  88/38 Moo 1, 345 Road, Bangtanai Pakkret, Nonthaburi-11120  Thailand  FSC U.K  Issued on 26-11-2018  FSC Thailand  Valid till 07-06-2020 | COCOON PFO Occulder  **Codes:**   1. CPF18 2. CPF25 3. CPF30 4. CPF35   Class D  Shelf Life : 03 years  Fee --Rs. 50,000 | It is a percutaneous, transcatheter closure device intended for the occlusion  of normal and aneurysm type PFOs. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing site:**  M/s. Vascular Innovations Co. Ltd.,  88/38 Moo 1, 345 Road, Bangtanai Pakkret, Nonthaburi-11120  Thailand  FSC U.K  Issued on 26-11-2018  FSC Thailand  Valid till 07-06-2020 | Cocoon VSD Occluder   1. COV0404 2. COV0604 3. COV0804 4. COV1004 5. COV1204 6. COV0407 7. COV0607 8. COV0807 9. COV1007 10. COV1207 11. COV0410 12. COV0610 13. COV0810 14. COV1010 15. COV1210   Class D  Shelf Life : 03 years  Fee --Rs. 50,000 | It is a percutaneous, transcatheter ventricular septal defect (VSD) closure device intended for the occlusion of hemodynamically significant ventricular septal defects. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing site:**  M/s. Vascular Innovations Co. Ltd.,  88/38 Moo 1, 345 Road, Bangtanai Pakkret, Nonthaburi-11120  Thailand  FSC U.K  Issued on 26-11-2018  FSC Thailand  Valid till 07-06-2020 | Cocoon Duct Occluder   1. COP0406 2. COP0608 3. COP0810 4. COP1012 5. COP1214 6. COP1416 7. COP1618 8. COP1820   Class D  Shelf Life : 03 years  Fee --Rs. 50,000 | It is a percutaneous transcatheter device specially designed for closure of normally located patent ductus arteriosus with the narrowest diameter ranging from 2mm to 16mm. Treatment is also feasible in pediatric population. | **Approved**. |
|  | **M/s. Optisurg**  17- C1, Valencia Town, Lahore.  (ELI-00305)  Evaluator:  Unum Zia Shamsi | **Manufacturer**  M/s. Medicontur Medical Engineering Ltd., Herceghalmi Road I, 2072 Zsambek, Hungary.  FSC Hungary  Issued on 31-01- 2018 | Medicontur  Bi-Flex M: 677MY  Class C  Shelf Life : 05 years  Fee--Rs. 50,000 | Aspheric hydrophylic acrylic multifocal intraocular lens with blue light filter for implantation into capsular bag. | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer**  M/s. Medicontur Medical Engineering Ltd., Herceghalmi Road I, 2072 Zsambek, Hungary.  FSC Hungary  Issued on 31-01- 2018 | Medicontur  Bi Flex Pre loaded: 677P  Class C  Shelf Life : 03 years  Fee-- Rs. 50,000 | Aspheric hydrophylic acrylic intraocular lens for MedJet Preloaded injection system (Capsular fixation) | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer**  M/s. Medicontur Medical Engineering Ltd., Herceghalmi Road I, 2072 Zsambek, Hungary.  FSC Hungary  Issued on 31-01- 2018 | Medicontur  Bi Flex: 677AB  Class C  Shelf Life : 05 years  Fee--Rs. 50,000 | Aspheric hydrophylic acrylic foldable intraocular lens for implantation into capsular bag. | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | **M/s. MED Lab Services**, Office No. 1, First Floor, ABC Plaza, Commecial Center, Satellite Town, Rawalpindi.  (ELI-00056)  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  M/s. Immunotech s.r.o. Radiova 1122/1, 102 00 Praha, Czech Republic  FSC Czech Republic  Valid until 31-03-2021 | Cluster: Diabetes assay   1. Insulin(e) IRMA kit   Size: 100 tests  Code: IM3210   1. C-PEPTIDE IRMA kit   Size: 100 tests  Code: IM3639  Class B  Shelf Life: 13 weeks  Fee submitted: Rs. 25,000/- | **Insulin(e) IRMA kit:** Immunoradiometric assay for the in vitro determination of insulin in human serum and plasma. For in vitro diagnostic use.  **C-Peptide IRMA kit:** Immunoradiometric assay for the in vitro determination of c-peptide in human serum, plasma and urine. For in vitro diagnostic use. | **Decision: Deferred.** The board discussed the matter at length and decided that since products are already grouped as Kits, therefore, as per para 2 of Schedule B of Medical Devices Rules, 2017 can only grouped in one of the catagories, namely, single, set, system, family, in-vitro test kit or in-vitro cluster. Reagents and articles can be grouped as clusters. Firm has applied multiple kits as CLUSTERS. Board directed the firm to apply these kits separately. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:**  M/s. Immunotech s.r.o. Radiova 1122/1, 10227 Praha, Czech Republic  FSC Czech Republic  Valid until 14-02-2023  Fee submitted: Rs. 25,000/- | Cluster: Cancer Marker Cluster   1. CEA IRMA KIT   Size: 100 tests  Code: IM2204  Shelf life: 13 weeks   1. CEA IRMA KIT   Size: 400 tests  Code: IM2274  Shelf life: 13 weeks  3. IRMA CA125 antigen  Size: 100 tests  Code: IM2233  Shelf life: 09 weeks  4. IRMA CA125 antigen  Size: 50 tests  Code: B64312  Shelf life: 09 weeks  5. IRMA MUC-1 gene associated antigen (CA 15-3) Size: 100 tests  Code: IM2397  Shelf life: 09 weeks  6. IRMA MUC-1 gene associated antigen (CA 15-3) Size: 50 tests  Code: B64314  Shelf life: 09 weeks  7. IRMA CA 19-9 antigen  Size: 100 tests  Code: IM3151  Shelf life: 09 weeks  8. IRMA CA 19-9 antigen  Size: 50 tests  Code: B64313  Shelf life: 09 weeks  Class B | **CEA IRMA KIT:** Immunoradiometric assay for the in vitro determination of carcinoembryonic antigen (CEA) in human serum. for in vitro diagnostic use.  **IRMA CA125 antigen:** Immunoradiometric assay for the in vitro determination of ca 125 antigen in human serum and plasma. for in vitro diagnostic use.  **IRMA MUC-1 gene associated antigen (CA15-3):**immunoradiometric assay for the in vitro determination of MUC-1 gene associated antigen (CA 15-3) in human serum and plasma. For in vitro diagnostic use.  **IRMA CA 19-9 antigen:** Immunoradiometric assay for the in vitro determination of CA 19-9 antigen in human serum. For in vitro diagnostic use. | **Deferred.** The board discussed the matter at length and decided that since products are already grouped as Kits, therefore, as per para 2 of Schedule B of Medical Devices Rules, 2017 can only grouped in one of the catagories, namely, single, set, system, family, in-vitro test kit or in-vitro cluster. Reagents and articles can be grouped as clusters. Firm has applied multiple kits as CLUSTERS. Board directed the firm to apply these kits separately. The Board also decided to classify cancer marker as Class C medical device. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:**  M/s. Immunotech s.r.o. Radiova 1122/1, 10227 Praha, Czech Republic  FSC Czech Republic  Valid until 14-02-2023 | Cluster: Fertility-Pregnancy Hormone Protein.   1. **RIA ESTRADIOL**   Size: 100 tests  Code: A21854  Shelf life: 12 weeks   1. **RIA ESTRADIOL**   Size: 50 tests  Code: B89462  Shelf life: 12 weeks   1. **FREE TESTOSTERONE RIA**   Size: 100 tests  Code: DSL-4900  Shelf life: 16 weeks   1. **PROLACTIN IRMA KIT**   Size: 100 tests  Code: IM2121  Shelf life: 13 weeks   1. **PROLACTIN IRMA KIT**   Size: 400 tests  Code: IM3303  Shelf life: 13 weeks   1. **RIA TESTOSTERONE direct**   Size:100 tests  Code: IM1119  Shelf life: 12 weeks   1. **RIA PROGESTERONE kit**   Size: 100 tests  Code: IM1188  Shelf life: 12 weeks   1. **LH IRMA kit**   Size: 100 tests  Code: IM1381  Shelf life: 13 weeks   1. **LH IRMA kit**   Size: 400 tests  Code: IM3302  Shelf life: 13 weeks   1. **RIA 17α-Hydroxyprogesterone**   Size: 100 tests  Code: IM1452  Shelf life: 12 weeks   1. **hCG IRMA kit**   Size:100 tests  Code: IM2110  Shelf life: 12 weeks   1. **hCG IRMA kit**   Size: 400 tests  Code: IM2209  Shelf life: 12 weeks   1. **FSH IRMA KIT**   Size: 100 tests  Code: IM2125  Shelf life: 12 weeks   1. **FSH IRMA KIT**   Size: 400 tests  Code: IM3301  Shelf life: 12 weeks | **RIA ESTRADIOL:** Radioimmunoassay for the in vitro determination of oestradiol in human serum and plasma. For in vitro diagnostic use.  **ACTIVE FREE TESTOSTERONE RIA:** Radioimmunoassay for the quantitative measurement of free testosterone in human serum this assay is intended for in vitro diagnostic use.  **PROLACTIN IRMA KIT:** Immunoradiometric assay for the in vitro determination of prolactin in human serum and plasma. For in vitro diagnostic use.  **RIA TESTOSTERONE direct:** Radioimmunoassay for the in vitro determination of total testosterone in human serum and plasma for in vitro diagnostic use.  **RIA PROGESTERONE kit:** Radioimmunoassay for the in vitro determination of progesterone in human serum and plasma. for in vitro diagnostic use.  **LH IRMA kit:** Immunoradiometric assay for the in vitro determination of luteinizing hormone in human serum and plasma. for in vitro diagnostic use.  **RIA 17α-Hydroxyprogesterone:** Radioimmunoassay for the in vitro determination of 17α-hydroxyprogesterone in human serum and plasma. for in vitro diagnostic use.  **hCG IRMA kit:** Immunoradiometric assay for the in vitro determination of human total chorionic gonadotropin (HCG) in human serum and plasma. for in vitro diagnostic use.  **FSH IRMA kit:** Immunoradiometric assay for the in vitro determination of FSH in human serum and plasma. for in vitro diagnostic use. | **Decision: Deferred.** The board discussed the matter at length and decided that since products are already grouped as Kits, therefore, as per para 2 of Schedule B of Medical Devices Rules, 2017 can only grouped in one of the catagories, namely, single, set, system, family, in-vitro test kit or in-vitro cluster. Reagents and articles can be grouped as clusters. Firm has applied multiple kits as CLUSTERS. Board directed the firm to apply these kits separately. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:**  M/s. Immunotech s.r.o. Radiova 1122/1, 10227 Praha, Czech Republic  FSC Czech Republic  Valid until 14-02-2023  Fee submitted: Rs. 25,000/- | Cluster: Thyroid function markers   1. Thyroglobulin IRMA kit   Size: 100 tests  Code: A85726  Shelf life: 08 weeks   1. Anti-TPO RIA kit   Size: 100 tests  Code: A56719  Shelf life: 10 weeks   1. IRMA PTH   Size: 100 tests  Code: A11930  Shelf life: 08 weeks   1. IRMA PTH   Size:50 tests  Code: B89461  Shelf life: 08 weeks   1. FT4 RIA kit   Size: 100 tests  Code: IM1363  Shelf life: 11 weeks   1. FT4 RIA kit   Size: 400 tests  Code: IM3321  Shelf life: 11 weeks   1. RIA FT3 kit   Size: 100 tests  Code: M1579,  Shelf life: 12 weeks   1. RIA FT3 kit   Size: 400 tests  Code: IM3320  Shelf life: 12 weeks   1. TOTAL T3 RIA KIT   Size: 100 tests  Code: IM1699  Shelf life: 14 weeks   1. TOTAL T3 RIA KIT   Size: 400 tests  Code: IM3287  Shelf life: 14 weeks   1. Anti-hTg IRMA KIT   Size: 100 tests  Code: IM3223  Shelf life: 13 weeks   1. TSH IRMA kit   Size: 100 tests  Code: IM3712  Shelf life: 10 weeks   1. TSH IRMA kit   Size: 400 tests  Code: IM3713  Shelf life: 10 weeks   1. Total T4 RIA kit   Size: 100 tests  Code: IM1447  Shelf life: 14 weeks   1. Total T4 RIA kit   Size: 400 tests  Code: IM3286  Shelf life: 14 weeks  Class B | **Thyroglobulin IRMA kit:** Immunoradiometric assay for the in vitro determination of thyroglobulin (tg) in human serum and plasma. for in vitro diagnostic use.  **Anti-TPO RIA kit:** Radioimmunoassay for the in vitro determination of antibodies against thyroid peroxidase (anti-TPO) in human serum. for in vitro diagnostic use.  **IRMA PTH:** Immunoradiometric assay for the in vitro determination of parathyroid hormon in human serum and plasma. for in vitro diagnostic use.  **FT4 RIA kit:** Radioimmunoassay for the in vitro determination of free thyroxine in human serum and plasma. for in vitro diagnostic use.  **RIA FT3 kit:** Radioimmunoassay for the in vitro determination of free triiodothyronine in human serum and plasma. For in vitro diagnostic use.  **TOTAL T3 RIA KIT:** Radioimmunoassay for the in vitro determination of total triiodothyronine (TT3) in human serum and plasma. for in vitro diagnostic use.  **Anti-hTg IRMA KIT:** immunoradiometric assay for the in vitro determination of autoantibodies anti-hTg in human serum and plasma. for in vitro diagnostic use.  **TSH IRMA kit: I**mmunoradiometric assay for the in vitro determination of thyroid-stimulating hormone in human serum and plasma. For in vitro diagnostic use.  **Total T4 RIA kit:**Radioimmunoassay for the in vitro determination of total thyroxine (TT4) in human serum and plasma. for in vitro diagnostic use | **Decision: Deferred.** The board discussed the matter at length and decided that since products are already grouped as Kits, therefore, as per para 2 of Schedule B of Medical Devices Rules, 2017 can only grouped in one of the catagories, namely, single, set, system, family, in-vitro test kit or in-vitro cluster. Reagents and articles can be grouped as clusters. Firm has applied multiple kits as CLUSTERS. Board directed the firm to apply these kits separately. |
|  | M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi  (ELI-00273)  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland  (FSC Ireland Valid Till  14-08-2022) | Endeavor Resolute Zotarolimus Eluting Coronary Stent System  Class D  Shelf Life: 2 Years  ERES22508X Endeavor Resolute 2.25x8mm ……………..  Codes & Sizes as per FSC.  **Rs.50,000/-** | Drug Eluting Stent and Delivery System | **Approved** with cancellation as drug. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Mexico S. de R.L. de CV, Av. PAseo Cucapah 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico  (FSC Ireland Valid Till  16-08-2022) | Sprinter NC/SC RX Balloon Dilatation Catheter  Class D  Shelf Life: 2 Years  Codes & sizes as per FSC.  NCSP2006X …………..  **Rs.50,000/-** | PTCA Balloon Dilatation Catheter | **Approved** with cancellation as drug. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland  (FSC Ireland Valid Till  27-07-2022) | Resolute Onyx Zotarolimus-Eluting Coronary Stent System  Class D  Shelf Life: 2 Years  RONYX30026X 3.0x26mm ……………  Codes & sizes as per FSC.  **Rs.50,000/-** | Zotarolimus-Eluting Coronary Stent System | **Approved** with cancellation as drug. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Mexico S. de R.L. de CV, Av. PAseo Cucapah 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico  (FSC Ireland Valid Till  01-06-2023) | EuphoraTM Rapid Exchange Balloon Dilatation Catheter  Class D  Shelf Life: 2 Years  EUP 1506X …….  Codes & sizes as per FSC.  **Rs.50,000/-**  . | PTCA Balloon Dilatation Catheter product Family | **Approved** with cancellation as drug. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Vascular, 37A Cherry Hill Drive, Danvers, MA 01923, USA.  (FSC Ireland Valid Till  24-08-2021) | Export Advance TM Aspiration Catheters  Class D  Shelf Life: 2 Years  Codes & sizes as per FSC.  **Rs.50,000/-** | Aspiration Catheter | **Approved** with cancellation as drug. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Mexico S. de R.L. de CV, Av. PAseo Cucapah 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico  (FSC Ireland Valid Till  10-10-2022) | Sprinter Legend RX Balloon Dilatation Catheter  Class D  Shelf Life: 3 Years  SPL22512X ……………..  Codes & sizes as per FSC.  **Fee Submitted Rs.50,000/-** | Balloon Dilatation Catheter | **Approved** with cancellation as drug. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland  (FSC Ireland Valid Till  08-08-2022) | Resolute Integrity Zotarolimus-Eluting Coronary Stent System  Class D  Shelf Life: 3 Years  RSINT30026X Resolute Integrity 3.0x26mm ………………….  Codes & sizes as per FSC.  **Fee Submitted**  **Rs.50,000/-** | Drug Eluting Coronary Stent and Delivery Resolute Integrity Zotarolimus Eluting Rapid Exchange Coronary Stent System | **Approved** with cancellation as drug. |
|  | M/s Krestacorp, 76-C, 3rd Floor, Suit No.2, Khayaban-e-Jami, Street No.9, DHA Phase 7, Karachi  (ELI-00258) | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  (FSC UK Issuance Date  30-01-2019) | Purplex with Warming Gel Condom  Class C  Shelf Life: 05 Years  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  ((FSC UK Issuance Date  30-01-2019) | Klimax Flavored Condom  Class C  Shelf Life: 05 Years  Klimax Orange Flavored Condom  81518103016  Klimax Strawberry Flavored Condom  Klimax Banana Flavored Condom  Klimax Tutti Frutti Flavored Condom  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  (FSC UK Issuance Date  30-01-2019) | Klimax Sensual Condom  Class C  Shelf Life: 05 Years  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  ((FSC UK Issuance Date  30-01-2019) | Klimax Intense Condom  Class C  Shelf Life: 05 Years  GC81518103016  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  (FSC UK Issuance Date  30-01-2019) | Extasy Plus Condom  Class C  Shelf Life: 05 Years  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  (FSC UK Issuance Date  30-01-2019) | Klimax Extasy Condom  Class C  Shelf Life: 05 Years  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  (FSC UK Issuance Date  30-01-2019) | Klimax Ultra Condom  Class C  Shelf Life: 05 Years  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Karex Industries SDN BHD PTD. 7906 & 7907 Taman Pontian Jaya, Bt. 34, Jalan Johor, 82000, Pontian Johor Darul Takzim, Malaysia  ((FSC UK Issuance Date  30-01-2019) | Klimax Performax Condom  Class C  Shelf Life: 05 Years  **Rs.50,000/-** | Natural Rubber Latex Male Condoms | **Approved**. |
|  | **M/s Medtronic Pakistan (Private) Limited,** Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi  (ELI-00273) | **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Site:**  M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | Ensura SR MRI SureScan  Class D  Shelf Life: 18 Months (From the date of power source connection)  Model: END1SR01  **Fee Submitted Rs.50,000/-** | Single Chamber implantable pacemaker, rate-responsive | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Site:**  M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | Syncra CRT-P  Class D  Shelf Life: 18 Months (From the date of power source connection)  Model: C2TR01  **Fee submitted Rs.50,000/-** | Cardiac Resynchronization Therapy Implantable Pacemaker (Dual Chamber) | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Site:**  M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | Solara CRT-P MRI SureScan  Class D  Shelf Life: 18 Months (From the date of power source connection)  Model: W1TR06  **Fee submitted Rs.50,000/-** | Cardiac Resynchronization Therapy Implantable Pacemaker | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Facility:**  M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico  (FSC USFDA Valid Till  11-09-2019) | MiRCSP Cannulae (Minimally Invasive Retrograde Cannula)  Class D  Shelf Life: 3 Years  94113TD, 94113TDT, 94533TD, 94533TDT ……..  (**Codes as per FSC)**  **Rs.50,000/-** | Coronary Sinus Cannula | **Approved** subject to provision of stability data. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Facility:**  M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico  (FSC USFDA Valid Till  11-09-2019) | DLP® PVC RCSP Cannulae with Auto-Inflate Cuff  Class D  Shelf Life: 3 Years  94523, 94533, 94535, 94535NPL, 94835, 94845, 94885, 94885K, 94895, 94935, 94945  **Fee sumbitted Rs.50,000/-** | Retrograde Coronary Sinus Perfusion Cannula | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Facility:**  M/s Medtronic Ireland, Parkmore Business Park West Galway, Ireland  (FSC Ireland Valid Till  20-11-2022) | Sprinter Legend Over The Wire  Class D  Shelf Life: 2 Years  SPL12506WL, SPL12510WL, SPL12512WL, SPL12515WL, SPL12520WL  **Rs.50,000/-** | Balloon Dilation Catheter | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Legal Manufacturer:**  M/s Medtronic Vascular 37A, Cherry Hill Dr Danvers, MA 01923, USA  (FSC USFDAValid Till  20-09-19) | Cougar PTCA Guidewire  Class D  Shelf Life: 3 Years  CGRLS190HJ, CGRLS190HS, CGRLS190J, CGRLS190S, CGRLS300HJ, CGRLS300HS, CGRLS300J, CGRLS300S, CGRXT190HJ, CGRXT190HS, CGRXT190J, CGRXT190S, CGRXT300HJ, CGRXT300HS, CGRXT300J, CGRXT300S, LVCLS190J, LVCLS190S, LVCXT190J, LVCXT190S  **Rs.50,000/-** | PTCA Guidewires | **Approved.** |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  i)M/s Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah 10510 El Lago, C.P. 22210 Tijuana Baja California, Mexico  (FSC Ireland Valid Till  16-08-2022) | NC Euphora (Rapid Exchange Balloon Dilatation Catheter )  Class D  Shelf Life: 2 Years  NCEUP32520X, NCEUP3520X, NCEUP37520X, NCEUP4020X, NCEUP4520X, NCEUP2527X, NCEUP27527X, NCEUP3027X, NCEUP32527X, NCEUP3527X, NCEUP37527X, NCEUP4027X, NCEUP2006X, NCEUP22506X, NCEUP2506X, NCEUP27506X, NCEUP3006X, NCEUP32506X, NCEUP3506X, NCEUP37506X, NCEUP4006X, NCEUP2008X, NCEUP22508X, NCEUP2508X, NCEUP27508X, NCEUP3008X, NCEUP32508X, NCEUP3508X, NCEUP37508X, NCEUP4008X, NCEUP4508X, NCEUP5008X, NCEUP2012X, NCEUP22512X, NCEUP2512X, NCEUP27512X, NCEUP3012X, NCEUP32512X, NCEUP3512X, NCEUP37512X, NCEUP4012X, NCEUP4512X, NCEUP5012X, NCEUP2015X, NCEUP22515X, NCEUP2515X, NCEUP27515X, NCEUP3015X, NCEUP32515X, NCEUP3515X, NCEUP37515X, NCEUP4015X, NCEUP4515X, NCEUP5015X, NCEUP2020X, NCEUP22520X, NCEUP2520X, NCEUP27520X, NCEUP3020X  **Fee Submitted Rs.50,000/-** | Rapid Exchange Balloon Dilatation Catheter- Non Compliant | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland  (FSC Ireland Valid Till  24-05-2022) | IN.PACT Falcon  (Paclitaxel-eluting PTCA Balloon Catheter)  Class D  Shelf Life: 3 Years  FLC P20 014 B12,  FLC P20 020 B12,  FLC P20 030 B12,  FLC P22 014 B12,  FLC P22 020 B12,  FLC P22 030 B12,  FLC P25 014 B12,  FLC P25 020 B12 ,  FLC P25 030 B12,  FLC P25 040 B12,  FLC P27 014 B12,  FLC P27 020 B12,  FLC P27 030 B12,  FLC P30 014 B12 ,  FLC P30 020 B12,  FLC P30 030 B12,  FLC P30 040 B12,  FLC P32 014 B12,  FLC P32 020 B12,  FLC P32 030 B12,  FLC P35 014 B12,  FLC P35 020 B12,  FLC P35 030 B12,  FLC P35 040 B12,  FLC P37 014 B12,  FLC P37 020 B12,  FLC P37 030 B12,  FLC P40 014 B12,  FLC P40 020 B12,  FLC P40 030 B12,  FLC P40 040 B12,  FLC P25 014 B22,  FLC P25 020 B22,  FLC P25 030 B22,  FLC P25 040 B22,  FLC P30 014 B22,  FLC P30 020 B22,  FLC P30 030 B22,  FLC P30 040 B22,  FLC P35 014 B22,  FLC P35 020 B22,  FLC P35 030 B22,  FLC P35 040 B22,  FLC P40 014 B22,  FLC P40 020 B22,  FLC P40 030 B22,  FLC P40 040 B22  **Fee Submitted Rs.50,000/-** | Paclitaxel-eluting PTCA Balloon Catheter | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:**  M/s Medtronic CoreValve, LLC 1851 E. Deere Ave Santa Ana, CA 92705, USA  **Manufacturing Site:** M/s Medtronic Mexico S. de R.L. de CV, Av. PAseo Cucapah 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico  (FSC The Netherlands Valid Till  28-01-2020) | Core Valve Evolut R Transcatheter Aortic Valve (Bioprosthesis)  Class D  Shelf Life: 3 Years  EVOLUTR-23, EVOLUTR-26, EVOLUTR-29, EVOLUTR-34  **Fee Submitted Rs.50,000/-** | Aortic Transcatheter heart Valve bioprosthesis, stent like Framework | **Approved**. |
|  | M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Near Hill Park, Karachi  (ELI-00091) | **Manufacturer:** M/s Sofradim Production, 116 Avenue du Formans, 01600 Trevoux, France  (FSC France Issuance Date  26-11-2015)  **Fee Submitted Rs.50,000/-** | PermacolTM Collagen Paste  Class D  Shelf Life: 3 years  6000-300 | Porcine Collagen Surgical Implant | **Approved**. For Porcine the patient written consent shall be taken prior to its use according to his / her religious belief system. The Board also instructed to send an Advisory to Provincial Health Care Commissions for further passing on necessary instructuions regarding patient consent for usage of Porcine. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Sofradim Production, 116 Avenue du Formans, 01600 Trevoux, France  (FSC France Issuance Date  30-09-2016)  **Fee Submitted Rs.50,000/-** | ParietexTM Optimized Composite Mesh  Class D  Shelf Life: 3 years  PCO9X, PCO12X, PCO15X, PCO20X, PCO1510X, PCO2015X, PCO2520X, PCO3020X, PCO3728X, PCO9FX, PCO12FX, PCO15FX, PCO20FX, PCO1510FX, PCO2015FX, PCO2520FX, PCO3020FX, PCO3728FX, PCO8OSX, PCO1510OSX, PCO2015OSX, PCO2520OSX  PCO3020OSX | Composite Sterile Mesh with Absorbable Collagen Film | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Sofradim Production, 116 Avenue du Formans, 01600 Trevoux, France  (FSC France Issuance Date  30-09-2016)  **Fee Submitted Rs.50,000/-** | SymbotexTM Composite Mesh  Class D  Shelf Life: 3 years  Codes and sizes as per FSC. | Composite Sterile Mesh with Absorbable Collagen Film | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Sofradim Production, 116 Avenue du Formans, 01600 Trevoux, France  (FSC France Issuance Date  26-11-2015)  **Rs.50,000/-** | PermacolTM Surgical Implant  Class D  Shelf Life: 5 years  5000-150, 50001-150, 5000-50, 5001-50, 5033-50, 5000-100, 5110-150, 5001-100, 5220-100, 5033-100, 5033-150, 5115-150, 5110-100, 5115-100, 5120-150, 5418-100, 5230-150, 5152-150, 5240-150, 5250-150, 5063-150, 5152-100, 5120-100, 5230-100, 5284-150, 5416 100, 5616 100, 5816 100, 5210 100 | Porcine Collagen Surgical Implant | **Approved**. For Porcine the patient written consent shall be taken prior to its use according to his / her religious belief system. The Board also instructed to send an Advisory to Provincial Health Care Commissions for further passing on necessary instructuions regarding patient consent for usage of Porcine. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer:** M/s Sofradim Production, 116 Avenue du Formans, 01600 Trevoux, France  (FSC France Issuance Date  30-09-2016)  **Rs.50,000/-** | ProgipTM Laparoscopic Self-Fixating Mesh  Class D  Shelf Life: 3 years  LPG1510, LPG1612, LPG1614, LPG1309AR, LPG1309AL, LPG1510AR, LPG1510AL, LPG1612AR, LPG1612AL, LPG1510AK2, LPG1510X2 | Partially Absorbable Sterile mesh with Absorbable Collagen Film | **Approved**. |
|  | M/s. Uniplan Trade International Pvt ltd.  132/2 Quadi-e-Azam Industrial Estate, Kot Lakhpt, Lahore. | M/s. Allmed Medical GMBH Mittlebacher Str.18,  D-01896 Pulsnits, Germany.  FSC Germany  Issued on 10.04.2017  **Fee Submitted** Rs. 50,000 | POLYPURE DIALYZER (10-22) Low Flux, Medim Flux, High Flux  (HOLLOW FIBER DIALYZER)  (Codes will be provided later)  Class C  Shelf Life : Not mentioned | Allmed Hollow Fibre Hemo-Dialyzers are used for patients with acute & chronic renal failure. Hemodialyzsis ; Hemofiltration | **Approved** subject to provision of shelf life data. |
|  | M/s. Cor-Med,  2nd Floor 38/62 Rehman Plaza Bank Road Saddar,  Rawalpindi. | M/s. IBERHOSPIT EX, S.A Arda. Catalunya, 408185 Llica de Vall (Barcelona) Spain  FSC Spain  Issued on June 9, 2016  **Fee Submitted** Fee Rs. 50,000 | Crossway PTCA semi compliant Balloon  **Referencia / Reference Diámetro / Diameter(mm) Longitud / Length (mm)**   |  |  | | --- | --- | | OO64101 | OO64306 | | OO64102 | OO64307 | | OO64103 | OO64308 | | OO64104 | OO64309 | | OO64201 | OO64321 | | OO64202 | OO64322 | | OO64203 | OO64323 | | OO64204 | OO64324 | | OO64205 | OO64325 | | OO64206 | OO64326 | | OO64208 | OO64327 | | OO64221 | OO64328 | | OO64222 | OO64329 | | OO64223 | OO64351 | | OO64224 | OO64352 | | OO64225 | OO64353 | | OO64226 | OO64354 | | OO64227 | OO64355 | | OO64228 | OO64356 | | OO64229 | OO64358 | | OO64251 | OO64371 | | OO64252 | OO64372 | | OO64253 | OO64373 | | OO64254 | OO64374 | | OO64255 | OO64375 | | OO64256 | OO64376 | | OO64257 | OO64378 | | OO64258 | OO64401 | | OO64259 | OO64402 | | OO64271 | OO64403 | | OO64272 | OO64404 | | OO64273 | OO64405 | | OO64274 | OO64406 | | OO64275 | OO64408 | | OO64276 | OO64452 | | OO64277 | OO64453 | | OO64278 | OO64454 | | OO64279 | OO64455 | | OO64301 |  | | OO64302 |  | | OO64303 |  | | OO64304 |  | | OO64305 |  |   Class D  Shelflife : 03 years | PTCA semi compliant Balloon | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | M/s. IBERHOSPIT EX, S.A Arda. Catalunya, 408185 Llica de Vall (Barcelona) Spain  FSC Spain  Issued on June 9, 2016  **Fee Submitted** Rs. 50,000 | Crossway NC PTCA Dilation Catheter   |  |  | | --- | --- | | OO65201 | OO65321 | | OO65202 | OO65322 | | OO65203 | OO65323 | | OO65204 | OO65324 | | OO65205 | OO65325 | | OO65206 | OO65326 | | OO65207 | OO65327 | | OO65208 | OO65328 | | OO65209 | OO65329 | | OO65221 | OO65351 | | OO65222 | OO65352 | | OO65223 | OO65353 | | OO65224 | OO65354 | | OO65225 | OO65355 | | OO65226 | OO65356 | | OO65227 | OO65357 | | OO65228 | OO65358 | | OO65229 | OO65359 | | OO65251 | OO65371 | | OO65252 | OO65372 | | OO65253 | OO65373 | | OO65254 | OO65374 | | OO65255 | OO65375 | | OO65256 | OO65376 | | OO65257 | OO65377 | | OO65258 | OO65378 | | OO65259 | OO65379 | | OO65271 | OO65401 | | OO65272 | OO65402 | | OO65273 | OO65403 | | OO65274 | OO65404 | | OO65275 | OO65405 | | OO65276 | OO65406 | | OO65277 | OO65407 | | OO65278 | OO65408 | | OO65279 | OO65409 | | OO65301 | OO65451 | | OO65302 | OO65452 | | OO65303 | OO65453 | | OO65304 | OO65454 | | OO65305 | OO65455 | | OO65306 | OO65456 | | OO65307 | OO65457 | | OO65308 | OO65458 | | OO65309 | OO65459 |   Class D  Shelflife : 03 years | PTCA dialation Catheter -NC | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | M/s. IBERHOSPIT EX, S.A Arda. Catalunya, 408185 Llica de Vall (Barcelona) Spain  FSC Spain  Issued on June 9, 2016  Fee Submitted  Rs. 50,000/- | Iht DESing BD ( Sirolimus eluting Coronary Stent System)   |  |  | | --- | --- | | 66228 | 66304 | | 66258 | 66354 | | 66278 | 66404 | | 66308 | 66230 | | 66358 | 66260 | | 66408 | 66280 | | 66222 | 66310 | | 66252 | 66360 | | 66272 | 66410 | | 66302 | 66232 | | 66352 | 66262 | | 66402 | 66282 | | 66226 | 66312 | | 66256 | 66362 | | 66276 | 66412 | | 66306 | 66236 | | 66356 | 66266 | | 66406 | 66286 | | 66220 | 66316 | | 66250 | 66366 | | 66270 | 66416 | | 66300 | 66234 | | 66350 | 66264 | | 66400 | 66284 | | 66224 | 66314 | | 66254 | 66364 | | 66274 | 66414 |   Class D  Shelflife : 12 months | Sirolimus Eluting Coronary Stent System | **Approved**. |
|  | M/s. Bay-G Pharma 103-A, A Block Satelite Town Rawalpindi. | **Manufacturer :**  M/s. Osang Health Care, Co. Ltd.  132, Anyangcheoondong-RO, Dongan-GU Anyangi-SI, Gyenonggi-DO 14040, South Korea.  FSC South Korea  Valid till 31.01.2021  FSC Belgium  Issued on 22.01.2019  Fee Submitted  Rs. 50,000/- | Glucolab Test Strip  (Blood Monitoring Test Strip)  Codes N/A  Class C  Shelflife : 02 years | Blood Glucose testing strip | **Approved.** |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer :**  M/s. Osang Health Care, Co. Ltd.  132, Anyangcheoondong-RO, Dongan-GU Anyangi-SI, Gyenonggi-DO 14040, South Korea.  FSC South Korea  Valid till 31.01.2021  FSC Belgium  Issued on 22.01.2019  Fee Submitted  Rs. 50,000/- | EasyGluco Meter  (Blood Glucose monitor)  Codes N/A  Class C  Shelflife : N/A | Blood Glucose monitoring device | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer :**  M/s. Osang Health Care, Co. Ltd.  132, Anyangcheoondong-RO, Dongan-GU Anyangi-SI, Gyenonggi-DO 14040, South Korea.  FSC South Korea  Valid till 31.01.2021  FSC Belgium  Issued on 22.01.2019  Fee Submitted  Rs. 50,000/- | GlucoLab Meter  (Blood Glucose monitor)  Codes N/A  Class C  Shelflife : N/A | Blood Glucose monitoring device | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Manufacturer :**  M/s. Osang Health Care, Co. Ltd.  132, Anyangcheoondong-RO, Dongan-GU Anyangi-SI, Gyenonggi-DO 14040, South Korea.  FSC South Korea  Valid till 31.01.2021  FSC Belgium  Issued on 22.01.2019  Fee Submitted  Rs. 50,000/- | EasyGluco Test Strip  (Blood Glucose monitoring test strip)  Codes N/A  Class C  Shelflife : 02 years | Blood Glucose testing strip | **Approved**. |
|  | **M/s Roche Pakistan** Limited, 37-C, Bi-6, P.E.C.H.S, Karachi  (ELI-00009)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issuance Date 19-09-2016)  Fee Submitted  Rs. 50,000/- | Cobas Elecsys Total PSA  Class C  i) Cobas Elecsys Total PSA  Shelf Life: 18 Months  Size: 100 Tests  Code: 04641655190  ii) Cobas Elecsys Total PSA  Shelf Life: 18 Months  Size: 200 Tests  Code: 04491734190  iii) Cobas Elecsys Total PSA  Shelf Life: 18 Months  Size: 300 Tests  Code: 07027966190  iv) Cobas Elecsys Total PSA Calset  Shelf Life: 29 Months  Size: 4x1mL  Code: 04485220190 | Quantitative vitro diagnostic test for total (free + complexed) prostate-specific antigen (tPSA) in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issuance Date 28-01-2019)  Fee Submitted  Rs. 50,000/- | Accu-Chek Active MG/DL Blood Sugar Monitoring System  Class C  Shelf Life: not provided | The Self testing blood glucose meter | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issuance Date  Fee Submitted  Rs. 50,000/- | Accu-Chek Active DL Blood Sugar Testing Strips  Class C  Shelf Life: not provided | Blood glucose testing strips | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date22-02-2018)  (FSC Germany Issue Date19-09-2016)  (FSC Germany Issue Date15-03-2018)  Fee Submitted  Rs. 50,000/- | Cobas® Elecsys Syphilis test kit  Class C  Shelf Life: 15 Months  (i) Cobas® Elecsys Syphilis  Size: 100 Tests  Code: 06923348  (ii) Cobas® Elecsys Syphilis  Size: 200 Tests  Code: 07802960190  (iii) Cobas® Elecsys Syphilis  Size: 300 Tests  Code: 07251378190  (iv) Cobas® PreciControl Syphilis  Size: 4x2ml  Code: 06923364 | In vitro qualitative determination of total antibodies to Treponema Pallidum in human serum and plasma. The test is intended as an aid in the diagnosis of syphilis infection | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 22-02-2018)  (FSC Germany Issue Date 19-09-2016)  (FSC Germany Issue Date 15-03-2017)  Fee Submitted: Rs 50,000/- | Cobas® Elecsys AFP test kit  Class C  i) Cobas® Elecsys AFP  Size: 100 Tests  Shelf Life: 21 Months  Code: 04481798  ii) Cobas® Elecsys AFP  Size: 300 Tests  Shelf Life: 21 Months  Code: 07026706190  iii) Cobas® AFP CalSet II  Size: 4x1.0mL  Shelf Life: 29 Months  Code: 04487761  iv) Cobas® PreciControl Tumor Marker  Size: 4x3.0mL  Shelf Life: 24 Months  Code: 11776452  iv) Cobas® PreciControl Universal  Size: 4x3.0mL  Shelf Life: 24 Months  Code: 11731416 | Immunoassay for the in vitro quantitative determination of α1-fetoprotein (AFP) in human serum and plasma. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:** Roche Molecular  System Inc., 1080 US Hwy  202, South Branchburg, NJ  08876, USA.  FSC Germany Issue Date: (16-08-2018)  Fee Submitted: Rs 50,000/- | COBAS® AmpliPrep/COBAS® TaqMan® HBV Test Kit, version 2.0  Class C  Shelf Life: 25 Months  i) COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, version 2.0  Size: 72 Tests  Code: 04894570190 | In vitro nucleic acid amplification test for the quantitation of Hepatitis B Virus (HBV) DNA in human plasma and serum. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy 202, South Branchburg, NJ  08876 USA.  (FSC Germany Issue Date15-10-2018) | cobas® HBV Quantitative nucleic acid test kit.  (For use on the Cobas® 4800 System)  Class C  Shelf Life: 16 Months  i) cobas® HBV  Size: 120 Tests  Code: 06979564190  Fee Submitted: Rs 50,000/- | In vitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human  EDTA plasma or serum of HBV-infected individuals. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy 202, South Branchburg, NJ08876 USA.  (FSC Germany Issue Date 15-10-2018) | cobas® HIV-1 Quantitative nucleic acid test kit  (for use on the Cobas® 6800/8800 Systems)  Class C  Shelf Life: 27 Months  i) cobas® HIV-1  Size: 96 Tests  Code: 07000995190  Fee Submitted: Rs 50,000/- | In vitro nucleic acid amplification test for the quantitation of human immunodeficiency virus type 1  (HIV-1) in EDTA plasma. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy  202, South Branchburg, NJ  08876 USA.  (FSC Germany Issue Date 15-10-2018)  Fee submitted: Rs. 50,000/- | Cobas® HCV Quantitative nucleic acid test kit  (for use on Cobas® 6800/8800 systems)  i)Cobas® HCV  Class C  Shelf Life: 27 Months  Size: 96 Tests  Code: 06997732190  ii)Cobas® HBV/HCV/HIV-1 Control Kit  Class C  Shelf Life: 25 Months  Size: 16x0.65mL  Code: 06997767190 | In vitro nucleic acid amplification  test for both the detection & quantitation of Hepatitis C Virus (HCV) RNA genotypes 1 to 6 in human EDTA plasma or serum | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy 202, South Branchburg, NJ  08876 USA.  (FSC Germany Issue Date 15-10-2018) | Cobas® HBV Quantitative nucleic acid test kit  (for use on the Cobas® 6800/8800 Systems)  Class C  Shelf Life: 25 Months  i) Cobas® HBV  Size: 96 Tests  Code: 07000979190  Fee Submitted: Rs. 50,000/- | Invitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human  EDTA plasma or serum of HBV-infected individuals. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:** Roche Molecular  System Inc., 1080 US Hwy  202, South Branchburg, NJ  08876, USA.  FSC Germany Issue Date: (16-08-2018)  Fee Submitted: Rs. 50,000/- | COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test Kit, version 2.0  Class C  Shelf Life: 22 Months  i) COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0  Size: 48 Tests  Code: 05212294190 | In vitro nucleic acid amplification test for the quantitation of Human Immunodeficiency Virus Type 1 (HIV-1) RNA in human EDTA  plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy 202, South Branchburg, NJ  08876 USA.  (FSC Germany Issue Date 15-10-2018) | Cobas® HIV-1 quantitative nucleic acid test kit  (for use on the Cobas® 4800 System)  Class C  Shelf Life: 13 Months  i) Cobas® HIV-1  Size: 120 Tests  Code: 06979599190  Fee Submitted: Rs. 50,000/- | In vitro nucleic acid amplification test for the quantitation of human immunodeficiency virus type 1  (HIV-1) in EDTA plasma of HIV-1-infected individuals. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy 202, South Branchburg, NJ  08876 USA.  (FSC Germany Issue Date 15-10- 2018)  Fee Submitted: Rs, 50,000/- | Cobas® HCV GT test kit  (for use on the Cobas® 4800 System)  Shelf Life: 15 Months  Class C  i)Cobas® HCV GT  Size: 120 Tests  Code: 06984274190  ii) Cobas® HCV GT Control Kit  Size: 10 Sets  Code: 06984339190 | Is an In vitro nucleic acid amplification test for the qualitative identification of Hepatitis C virus (HCV) genotypes 1 subtypes a and b in human EDTA plasma or serum from individuals with chronic HCV infection. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  **Manufacturing Site:**  Roche Molecular  System Inc.,1080 US Hwy 202, South Branchburg, NJ  08876 USA.  (FSC Germany Issue Date 15-10-2018)  Fee submitted: Rs 50,000/- | Cobas® HCV quantitative nucleic acid test kit  (for use on the Cobas® 4800 System)  Class C  Shelf Life: 15 Months  i) Cobas® HCV 4800  Size: 120 Tests  Code: 06979602190  ii) Cobas® HBV/HCV/HIV-1 Control Kit  Size: 10 Tests  Code: 06979572190 | In vitro nucleic acid amplification  test for both the detection & quantitation of Hepatitis C Virus (HCV) RNA genotypes 1 to 6 in human EDTA plasma or serum. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 22-2-2018)  (FSC Germany Issue Date 19-09-2016)  Fee submitted. Rs 50,000/- | Cobas® Elecsys CA 15-3 II test kit  Class C  Shelf Life: 18 Months  i) Cobas® Elecsys CA 15-3 II  Size: 100 Tests  Code: 03045838  ii) Cobas® Elecsys CA 15-3 II  Size: 300 Tests  Code: 07027001190  iii) Cobas® Elecsys CA 15-3 II Calset  Size: 4x1ml  Code: 03045846 | Immunological in vitro assay for quantitative determination of CA 15-3 in human serum and plasma to aid in the management of breast cancer patients | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 19-09-2016)  (FSC Germany Issue Date 22-02-2018)  Fee submitted. Rs 50,000/- | Cobas® Elecsys CEA Kit  Class C  Shelf Life: 18 Months  i) Cobas® Elecsys CEA  Size: 100 Tests  Code: 11731629  ii) Cobas® Elecsys CEA  Size: 300 Tests  Code: 07027079190  iii) Cobas® Elecsys CEA Calset  Size: 4x1ml  Code: 11731645 | Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issuance Date 15-03-2017)  (FSC Germany Issuance Date 22-02-2018)  Fees submitted: Rs. 50,000/- | Cobas® Elecsys CA 125 II test kit  Class C  i) Cobas® Elecsys CA 125 II  Shelf Life: 18 Months  Size: 100 Tests  Code: 11776223  ii) Cobas® Elecsys CA 125 II  Shelf Life: 18 Months  Size: 300 Tests  Code: 07026986190  iii) Cobas® Elecsys CA 125 II Calset II  Shelf Life: 15 Months  Size: 4x1ml  Code: 070230207 | Immunoassay for the in vitro quantitative determination of OC (Ovarian Cancer) 125 reactive determinants in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issuance Date 22-02-2018)  (FSC Germany Issuance Date 24-10-2018) | Cobas Elecsys Rubella IgM Test Kit  Class C  i) Cobas Elecsys Rubella IgM  Shelf Life: 12 Months  Size: 100 Tests  Code: 04618831190  ii) Cobas Elecsys Rubella IgM  Shelf Life: 12 Months  Size: 300 Tests  Code: 07027796190  iii) Cobas Elecsys Rubella IgM PreciControl  Shelf Life: 14 Months  Size: 8x1mL  Code: 04618840  Fees submitted: Rs. 50,000/- | Immunoassay for the in vitro qualitative determination of IgM antibodies to Rubella virus in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 28-01-2019) | Accu-Chek Guide Kit mg/dL  Class C  Shelf Life: N/A  Code: 07400870  Fees submitted: Rs. 50,000/- | Self-testing blood glucose monitoring system | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 19-09-2016)  (FSC Germany Issue Date 22-02-2018)  Fee submitted Rs. 50,000/- | Cobas Elecsys free PSA test kit  Class C  Shelf Life: 18 Months  i) Cobas Elecsys free PSA  Size: 100 Tests  Code: 03289788  ii) Cobas Elecsys free PSA  Size: 300 Tests  Code: 07027320190  iii) Cobas Elecsys free PSA Calset  Size: 4x1.0mL  Code: 03289796 | Immunoassay for the in vitro quantitative determination of free prostate-specific antigen (PSA) in human serum and plasma | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 19-09-2016)  (FSC Germany Issue Date 22-02-2018)  Fee submitted: Rs. 50,000/- | Cobas Elecsys CA 19-9 test kit  Class C  i) Cobas Elecsys CA 19-9  Shelf Life: 21 Months  Size: 100 Tests  Code: 11776193  ii) Cobas Elecsys CA 19-9  Shelf Life: 21 Months  Size: 300 Tests  Code: 07027028190  iii) Cobas Elecsys CA 19-9 Calset  Shelf Life: 29 Months  Size: 4x1mL  Code: 11776215 | Immunoassay for the in vitro quantitative determination of CA 19-9 tumor associated antigen in human serum and plasma in the management of patient with cancers of the exocrine pancreas | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 24-10-2018)  (FSC Germany Issue Date 22-02-2018)  Fee submitted: Rs. 50,000/- | Cobas Elecsys Rubella IgG Test Kit  Class C  Shelf Life: 14 Months  i) Cobas Elecsys Rubella IgG  Size: 100 Tests  Code: 04618793190  ii) Cobas Elecsys Rubella IgG  Size: 300 Tests  Code: 07027770190  iii) Cobas Elecsys PreciControl Rubella IgG  Size: 16x1mL  Code: 04618807 | Immunoassay for the in vitro quantitative determination of IgG antibodies to Rubella Virus in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 30-10-2018) | Accu-Chek® Instant S mg/dL Set  Class C  Shelf Life: N/A  Code: 078194470  Fee submitted: Rs. 50,000/- | Self-testing blood glucose monitoring system | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/Manufacturing Site:** M/s Roche Diabetes Care GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 28-01-2019)  Fee submitted: Rs. 50,000/- | Accu-Chek® Performa mg/dL Kit  Class C  Shelf Life: N/A  Code: 06987788 | Self-testing blood glucose monitoring system | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 24-10-2018)  (FSC Germany Issue Date 22-02-2018)  Fee submitted: Rs.50,000/- | Cobas® Elecsys TOXO IgG Test Kit  Class C  Shelf Life: 14 Months  i) Cobas® Elecsys TOXO IgG  Size: 100 Tests  Code: 04618815190  ii) Cobas® Elecsys TOXO IgG  Size: 300 Tests  Code: 07028008190  iii) Cobas® Elecsys PreciControl TOXO IgG  Size: 16 x 1.0ml  Code: 04618823 | Immunoassay for the in vitroquantitative determination of IgG antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 24-10-2018)  Fee submitted: Rs.50,000/- | Cobas® Elecsys TOXO IgM Test Kit  Class C  Shelf Life: 14 Months  i) Cobas® Elecsys TOXO IgM  Size: 100 Tests  Code: 04618858190  ii) Cobas® Elecsys TOXO IgM  Size: 300 Tests  Code: 07028024190  iii) Cobas® Elecsys PreciControl TOXO IgM  Size: 16 x 0.67ml  Code: 04618866 | Immunoassay for the in vitro qualitative determination of IgM antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issue Date 24-10-2018)  (FSC Germany Issue Date 22-02-2018)  Fee submitted: Rs.50,000/- | Cobas® Elecsys CMV IgG Test Kit  Class C  i) Cobas® Elecsys CMV IgG  Shelf Life: 18 Months  Size: 100 Tests  Code: 04784596190  ii) Cobas® Elecsys CMV IgG  Shelf Life: 18 Months  Size: 300 Tests  Code: 07027117190  iii) Cobas® Elecsys CMV PreciControl  Shelf Life: 21 Months  Size: 16 x 1ml  Code: 04784600 | In vitro qualitative test for the detection of IgG antibodies to CMV in human serum, lithium-heparin plasma, K2-EDTA plasma and K3-EDTA plasma | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  Roche Diabetes Care GmbH,  Sandhofer Str.116, 68305  Mannheim, Germany  **Manufacturing Site:**  1. Roche Diabetes Care, Inc. 9115  Hague Road, Indianapolis IN  46250, USA  2.Roche Operations Ltd. 2875 Ponce By Pass, Ponce PR 00732, USA  (FSC Germany Issue Date 27-3-2019) | Accu-Chek® Guide Test Strips  Class C  Shelf Life: 18 Months  Size: 50 Tests  Code: 07453736020  Fee submitted: Rs. 50,000/- | Intended to be used with the Accu‐Chek Guide meter  to quantitatively measure glucose in fresh capillary whole blood from the finger,  palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control. | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  Roche Diabetes Care GmbH,  Sandhofer Str.116, 68305  Mannheim, Germany  **Manufacturing Site:**  1. Roche Diabetes Care, Inc. 9115  Hague Road, Indianapolis IN  46250, USA  2.Roche Operations Ltd. 2875 Ponce By Pass, Ponce PR 00732, USA  (FSC Germany Issue Date 27-3-2019) | Accu-Chek® Instant Test Strips  Class C  Shelf Life: 18 Months  i) Accu-Chek Instant Test Strips  Size: 10 Tests  Code: 07819366020  ii) Accu-Chek Instant Test Strips  Size: 25 Tests  Code: 07819374020  iii) Accu-Chek Instant Test Strips  Size: 50 Tests  Code: 07819382020  Fee submitted: Rs. 50,000/- | Intended to be used with the Accu‐Chek Instant and Accu-Chek Instant S meters  to quantitatively measure glucose in fresh capillary whole blood from the finger,  palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control. | **Approved.** |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  Roche Diabetes Care GmbH,  Sandhofer Str.116, 68305  Mannheim, Germany  **Manufacturing Site:**  1. Roche Diabetes Care, Inc. 9115  Hague Road, Indianapolis IN  46250, USA  2.Roche Operations Ltd. 2875 Ponce By Pass, Ponce PR 00732, USA  (FSC Germany Issue Date 27-3-2019)  Fee submitted: Rs. 50,000/- | Accu-Chek® Performa Test Strips  Class C  Shelf Life: 18 Months  i) Accu-Chek Performa Test Strips  Size: 25 Tests  Code: 06454003020  ii) Accu-Chek Performa Test Strips  Size: 50 Tests  Code: 06454011020  iii) Accu-Chek Performa Test Strips  Size: 100 Tests  Code: 06454038020 | Intended to be used with the Accu-Chek Performa and Accu-Chek Performa Nano, Accu-Chek Performa Connect, Accu-Chek Performa Expert, Accu-Check Performa Combo, Accu-Chek Performa insight blood glucose meters to quantitatively measuresglucose in fresh capillary whole blood as an aid in the monitoring the effectiveness of glucose control | **Approved**. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Manufacturer:**  Roche Diabetes Care GmbH,  Sandhofer Str.116, 68305  Mannheim, Germany  **Manufacturing Site:**  1. Roche Diabetes Care, Inc. 9115  Hague Road, Indianapolis IN  46250, USA  2.Roche Operations Ltd. 2875 Ponce By Pass, Ponce PR 00732, USA  (FSC Germany Issue Date 27-3-2019) | Accu-Chek® Inform II Test Strips  Class C  Shelf Life: 18 Months  Size:  50 tests  Code:  05942861022  Fee submitted: Rs. 50,000/- | Intended to be used with the Accu Chek Inform II, Accu Chek Performa and Accu Chek Performa Nano blood glucose meters to quantitatively measures glucose in fresh venous, neonatal, arterial and capillary whole blood from the finger as an aid in the monitoring the effectiveness of glucose control | **Approved**. |
|  | **M/s Abbott Laboratories (Pakistan) Ltd,** Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019)  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022)  Fee submitted: Rs. 50,000/- | Alinity I Rubella IgM Kit  Class C  i) Alinity I Rubella IgM Reagent Kit  Code: 08P4722  Shelf Life: 12 Months  ii) Alinity I Rubella IgM Reagent Kit  Code: 08P4732  Shelf Life: 12 Months  iii) Alinity I Rubella IgM Calibrator  Code: 08P4701  Shelf Life: 12 Months  iv) Alinity I Rubella IgM Controls  Code: 08P4710  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgM  antibodies to Rubella virus in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Standard Diagnostics, Inc. 65, Borahagai-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea  (FSC Republic of Korea Issue date 11-08-2017)  Fee submitted: Rs. 50,000/- | SD HBsAg ELISA 3.0 (01EK10)  96 Tests /Kit  Class D  Shelf Life: 12 Months | In-Vitro Diagnostic Kit for HBsAg Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Standard Diagnostics, Inc. 65, Borahagai-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea  (FSC Republic of Korea Issue date 11-08-2017)  Fee submitted: Rs. 50,000/- | SD BIOLINE Anti-HBs  Class D  (1)SD BIOLINE Anti-HBs 01FK20 (30 Test/Kit) Shelf Life: 24 Months  (2)SD BIOLINE Anti-HBs (Multi) 01FK21 (100 Test/Kit) Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Anti-HBs Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Standard Diagnostics, Inc. 65, Borahagai-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Korea  (FSC Republic of Korea Issue date 11-08-2017)  Fee submitted: Rs. 50,000/- | SD BIOLINE HBsAg  SD BIOLINE HBsAg (01FK10) (30 Test/Kits)  SD BIOLINE HBsAg (Multi) (01FK11) (100 Test/Kit)  Class D  Shelf Life: 24 Months | IVD Reagents for serotyping or patient monitoring of HIV, HBV, HCV, HTLV, Immunological method | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China  (FSC China Valid Till  04-06-2019)  Fee submitted: Rs. 50,000/- | HIV 1/2 Human Immunodeficiency Virus Rapid Test Strip (Whole Blood/Serum/Plasma)  IHI-401 (Strip:50 Test/Kit) 20163400002  Class D  Shelf Life: 25 Months | HIV 1/2 Human Immunodeficiency Virus Rapid Test Strip | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022)  Fee submitted: Rs. 50,000/- | ARCHITECT CMV IgM  Class C  i) ARCHITECT CMV IgM Calibrators  Code: 6C16-01  Shelf Life: 12 Months  ii) ARCHITECT CMV IgM Controls  Code: 6C16-10  Shelf Life: 12 Months  iii) ARCHITECT CMV IgM Reagent  (1 x 100 Tests)  Code: 6C16-25  Shelf Life: 12 Months  iv) ARCHITECT CMV IgM Reagent  (1 x 500 Tests)  Code: 6C16-30  Shelf Life: 12 Months | IVD Kit for the qualitative detection of IgM antibodies to Cytomegalovirus in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022)  Fee submitted: Rs. 50,000/- | ARCHITECT AFP  Class C  i) ARCHITECT AFP Calibrators  Code: 3P36-01  Shelf Life: 12 Months  ii) ARCHITECT AFP Controls  Code: 3P36-10  Shelf Life: 12 Months  iii) ARCHITECT AFP Reagent  Code: 3P36-20  Shelf Life: 12 Months  iv) ARCHITECT AFP Reagent  Code: 3P36-25  Shelf Life: 12 Months  v) ARCHITECT AFP Reagent  Code: 3P36-30  Shelf Life: 12 Months  vi) ARCHITECT AFP Reagent  Code: 3P36-35  Shelf Life: 12 Months | IVD Kit for the quantitative determination of alpha-fetoprotein in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022)  Fee submitted: Rs. 50,000/- | ARCHITECT Total PSA  Class C  i) ARCHITECT Total PSA Reagent  Code: 7K70-20  Shelf Life: 12 Months  ii) ARCHITECT Total PSA Reagent  Code: 7K70-25  Shelf Life: 12 Months  iii) ARCHITECT Total PSA Reagent  Code: 7K70-30  Shelf Life: 12 Months  iv) ARCHITECT Total PSA Reagent  Code: 7K70-35  Shelf Life: 12 Months  v) ARCHITECT Total PSA Calibrators  Code: 7K70-01  Shelf Life: 12 Months  vi) ARCHITECT Total PSA Controls  Code: 7K70-10  Shelf Life: 12 Months | IVD Kit used for the quantitative determination  of Total PSA (both Free PSA and PSA complexed to alpha-1-antichymotrypsin) in human serum | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022)  Fee submitted: Rs. 50,000/- | ARCHITECT CMV IgG Avidity  Class C  i) ARCHITECT CMV IgG Avidity Calibrator and Controls  Code: 3L46-11  Shelf Life: 12 Months  ii) ARCHITECT CMV IgG Avidity Reagent  Code: 3L46-25 (100 Tests)  Shelf Life: 12 Months | IVD Kit used for the determination of the avidity of IgG antibodies to Cytomegalovirus in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 26-01-2016)  Fee submitted: Rs. 50,000/- | Abbott Real Time High Risk HPV  Class C  i) Abbott Real Time High Risk HPV Control Kit  Code: 2N09-80  Shelf Life: 18 Months  ii) Abbott Real Time High Risk HPV Amplification Reagent Kit  Code: 2N09-90  Shelf Life: 18 Months | In-Vitro Diagnostic Kit for Human  papillomavirus (HPV) Testing | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 26-01-2016)  Fee submitted: Rs. 50,000/- | Abbott Real Time MTB  Class C  i) Abbott Real Time MTB Control Kit  Code: 08N15-080  Shelf Life: 18 Months  iii) Abbott Real Time MTB Amplification Reagent Kit  Code: 08N15-090 (96 Tests)  Shelf Life: 18 Months | MTB (Real Time PCR) | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Molecular, Inc. 1300 East Touhy Avenue Des Plaines, IL, 600180 USA  M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC USFDA Valid Till  10-05-2020)  (FSC Germany Issuance Date 28-01-2016)  Fee submitted: Rs. 50,000/- | Abbott RealTime MTB RIF/INH Resistance Amplification Kit  Class C  i) Abbott RealTime MTB RIF/INH Resistance Control Kit  Code: 08N28-080  Shelf Life: 18 Months  ii) Abbott RealTime MTB RIF/INH Resistance Amplification Reagent Kit  Code: 08N28-090  Shelf Life: 18 Months | In-Vitro Diagnostic Kit for RealTime PCR Testing of MTB | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostic Division, Lisnamuck, Longford, Co. Longford, Ireland  (FSC Ireland Valid Till  29-03-2023) | Alinity i STAT High Sensitive Troponin-I  Class C  (i) Alinity i STAT High Sensitive Troponin-I Reagent Kit  Code: 08P1322  Shelf Life: 06 Months    (ii) Alinity i STAT High Sensitive Troponin-I Reagent Kit  Code: 08P1332  Shelf Life: 06 Months  (iii) Alinity i STAT High Sensitive Troponin-I Calibrators  Code: 08P1301  Shelf Life: 09 Months  (iv) Alinity i STAT High Sensitive Troponin-I Controls  Code: 08P1310  Shelf Life: 06 Months | IN-VITRO DIAGNOSTIC Kit for Alinity i STAT High Sensitive Troponin-I Testing | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Legal Manufacturer:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany  **Manufacturing Site:**  M/s Abbott Molecular Inc. 1300E. Touhy Ave. Des Plaines, II 60018, USA  (FSC Germany Issuance Date 28-01-2016)  **Rs.50,000/-**  **Fee already submitted against Slip No. 0580488 dated 22-11-2016** | Abbott RealTime HIV-1  Class C  (i) Abbott RealTime HIV-1 Amplification Reagent Kit  Code: 02G31-90  Shelf Life: 18Months    (ii) Abbott RealTime HIV-1 Control Kit  Code: 02G31-80  Shelf Life: 18Months  (iii) Abbott RealTime HIV-1 Control Kit  Code: 02G31-70  Shelf Life: 18Months | IN-VITRO DIAGNOSTIC Kit for Abbott RealTime HIV-1  Testing | **Approved**. |
|  | -do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer/Distributor:** M/s Abbott Diabetes Care Ltd, Range Road, Witney, Oxon, OX29 0YL, UK  (FSC UK Issuance Date  10-04-2018)  Fee submitted: Rs. 50,000/- | Free Style Optium NEO Blood Glucose and Ketone Monitoring System  Class C  Shelf Life: Not Applicable | Glucose and Ketone Monitoring System | **Approved**. |
|  | do-  Evaluator:  Muhammad Ayub Naveed | **Manufacturer/Distributor:** M/s Abbott Diabetes Care Ltd, Range Road, Witney, Oxon, OX29 0YL, UK  (FSC UK Issuance Date  10-04-2018)  Fee submitted: Rs. 50,000/- | Free Style Optium NEO H Blood Glucose and Ketone Monitoring System  Class C  Shelf Life: Not Applicable | Glucose and Ketone Monitoring System | Approved. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated11-08-2017)  Fee Submitted: Rs.50,000/- | SD BIOLINE Malaria Ag P.f/P.v Test Kit  Class C  (1)SD BIOLINE Malaria Ag P.f/P.v  05FK80 (25 Test/Kit)  (2)SD BIOLINE Malaria Ag P.f/P.v  05FK83 (1 test/kit x 25 each)  Shelf Life: 24 Months | In-Vitro Diagnostic Kit for Malaria Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017) | SD BIOLINE Dengue IgG/IgM Test Kit  Class C  (1)SD BIOLINE Dengue IgG/IgM  11FK10 (25 Test/Kit)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Dengue Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017) | SD BIOLINE TB Ag MPT64 Rapid Test Kit  Class C  (1)SD BIOLINE TB Ag MPT64 Rapid  08FK50 (25 Test/Kit)  Shelf Life: 18 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Detection of M. Tuberculosis Complex | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 18-08-2018) | SD BIOLINE Troponin I Test Kit  Class C  (1)SD BIOLINE Troponin I  90FK10 (25 Test/Kit)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Troponin I Testing (cardiac marker) | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017  WHO-PreQualified) | SD BIOLINE Malaria Ag P.f/Pan Test Kit  Class C  (1)SD BIOLINE Malaria Ag P.f/Pan  05FK60 (25 Test/Kit)  (2)SD BIOLINE Malaria Ag P.f/Pan  05FK63 (1 test/kit x 25each)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Malaria Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017) | SD BIOLINE Dengue IgG/IgM,WB Test Kit  Class C  (1)SD BIOLINE Dengue IgG/IgM,WB  11FK20 (25 Test/Kit)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Dengue Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017) | SD BIOLINE Syphilis 3.0 Test Kit  Class C  (1)SD BIOLINE Syphilis 3.0  06FK10 (30 Test/Kit)  (2)SD BIOLINE Syphilis 3.0  06FK11 (Multi) (100 Test/Kit)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Syphilis Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017) | SD BIOLINE Dengue Duo Test Kit  Class C  (1)SD BIOLINE Dengue Duo  11FK45 (10 Test/Kit)  (2) SD BIOLINE Dengue Duo  11FK46 (25 Test/Kit)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Dengue Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | -do-  Evaluator:  Unum Zia Shamsi | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc.,65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.  (FSC Korea Dated 11-08-2017) | SD BIOLINE Dengue NS1 Ag Test Kit  Class C  (1)SD BIOLINE Dengue NS1 Ag  11FK50 (25 Test/Kit)  Shelf Life: 24 Months  Fee Submitted: Rs.50,000/- | In-Vitro Diagnostic Kit for Dengue Testing | **Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of product if the manufacturing plant is approved by the panel of experts. |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022) | ARCHITECT CEA  Class C  i) ARCHITECT CEA Reagent  Code: 7K68-22  Shelf Life: 18 Months  ii) ARCHITECT CEA Reagent  Code: 7K68-27  Shelf Life: 18 Months  iii) ARCHITECT CEA Reagent  Code: 7K68-32  Shelf Life: 18 Months  iv) ARCHITECT CEA Reagent  Code: 7K68-35  Shelf Life: 18 Months  v) ARCHITECT CEA Calibrators  Code: 7K68-02  Shelf Life: 26 Months  vi) ARCHITECT CEA Controls  Code: 7K68-12  Shelf Life: 26 Months | IVD Kit for the quantitative determination of  Carcinoembryonic Antigen (CEA) in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022)  Fee submitted: Rs. 50,000/- | ARCHITECT Free PSA  Class C  i) ARCHITECT Free PSA Calibrators  Code: 7K71-01  Shelf Life: 12 Months  ii) ARCHITECT Free PSA Controls  Code: 7K71-10  Shelf Life: 12 Months  iii) ARCHITECT Free PSA Reagent  Code: 7K71-20  Shelf Life: 12 Months  iv) ARCHITECT Free PSA Reagent  Code: 7K71-25  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of  free prostate specific antigen (PSA) in human serum | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT Methotrexate  Class C  i) ARCHITECT Methotrexate Calibrators  Code: 2P49-01  Shelf Life: 18 Months  ii) ARCHITECT Methotrexate Controls  Code: 2P49-10  Shelf Life: 18 Months  iii) ARCHITECT Methotrexate Extended Range Controls  Code: 2P49-15  Shelf Life: 18 Months  iv) ARCHITECT Methotrexate Reagent Kit  Code: 2P49-25  Shelf Life: 18 Months | IVD Kit used for the quantitative determination of methotrexate in  human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT HE4  Class C  i) ARCHITECT HE4 Calibrators  Code: 2P54-01  Shelf Life: 12 Months  ii) ARCHITECT HE4 Controls  Code: 2P54-10  Shelf Life: 12 Months  iii) ARCHITECT HE4 Reagent Kit  Code: 2P54-25  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of HE4 antigen in human serum | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT HAV Ab-IgG  Class C  i) ARCHITECT HAV Ab-IgG Calibrators  Code: 6C29-01  Shelf Life: 12 Months  ii) ARCHITECT HAV Ab-IgG Controls  Code: 6C29-10  Shelf Life: 12 Months  iii) ARCHITECT HAV Ab-IgG Reagent Kit (4x100 Tests)  Code: 6C29-22  Shelf Life: 12 Months  iv) ARCHITECT HAV Ab-IgG Reagent Kit (1x100 Tests)  Code: 6C29-27  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human serum and  plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT iGentamicin  Class C  i) ARCHITECT iGentamicin Calibrators  Code: 1P31-01  Shelf Life: 12 Months  ii) ARCHITECT iGentamicin Reagent Kit  Code: 1P31-25  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of gentamicin, an antibiotic drug,  in human serum or plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT Toxo IgG Avidity  Class C  i) ARCHITECT Toxo IgG Avidity Calibrator & Controls  Code: 6L37-11  Shelf Life: 12 Months  ii) ARCHITECT Toxo IgG Avidity Reagent Kit  Code: 6L37-25  Shelf Life: 12 Months | IVD Kit used for the determination of the avidity of IgG antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT EBV VCA IgM  Class C  i) ARCHITECT EBV VCA IgM Calibrator  Code: 3P66-01  Shelf Life: 18 Months  ii) ARCHITECT EBV VCA IgM Controls  Code: 3P66-10  Shelf Life: 18 Months  iii) ARCHITECT EBV VCA IgM Reagent Kit (1x100 Tests)  Code: 3P66-25  Shelf Life: 18 Months  iv) ARCHITECT EBV VCA IgM Reagent Kit (1x500 Tests)  Code: 3P66-35  Shelf Life: 18 Months | IVD Kit used for the qualitative detection of IgM antibodies to  Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA) in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT iVancomycin  Class C  i) ARCHITECT iVancomycin Calibrator  Code: 1P30-01  Shelf Life: 12 Months  ii) ARCHITECT iVancomycin Reagent Kit (1x100 Tests)  Code: 1P30-27  Shelf Life: 18 Months | IVD Kit used for the quantitative measurement of vancomycin in human serum or plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)3  Fee submitted: Rs. 50,000/- | ARCHITECT HAV Ab-IgM  Class C  i) ARCHITECT HAV Ab-IgM Calibrator  Code: 6C30-22  Shelf Life: 12 Months  ii) ARCHITECT HAV Ab-IgM Controls  Code: 6C30-11  Shelf Life: 12 Months  iii) ARCHITECT HAV Ab-IgM Reagent Kit (4x100 Tests)  Code: 6C30-22  Shelf Life: 12 Months  iv) ARCHITECT HAV Ab-IgM Reagent Kit (1x100 Tests)  Code: 6C30-27  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human serum and  plasma. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT CYFRA 21-1  Class C  i) ARCHITECT CYFRA 21-1 Calibrator  Code: 2P55-01  Shelf Life: 12 Months  ii) ARCHITECT CYFRA 21-1 Controls  Code: 2P55-10  Shelf Life: 12 Months  iii) ARCHITECT CYFRA 21-1 Reagent Kit  Code: 2P55-25  Shelf Life: 12 Months | IVD Kit used for the quantitative determination  of human cytokeratin 19 fragments in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 30-10-2017)  Fee submitted: Rs. 50,000/- | ARCHITECT CA 15-3  Class C  i) ARCHITECT CA 15-3 Reagent Kit  Code: 2K44-21  Shelf Life: 12 Months  ii) ARCHITECT CA 15-3 Reagent Kit  Code: 2K44-27  Shelf Life: 12 Months  iii) ARCHITECT CA 15-3 Reagent Kit  Code: 2K44-37  Shelf Life: 12 Months  iv) ARCHITECT CA 15-3 Calibrators  Code: 2K44-02  Shelf Life: 12 Months  v) ARCHITECT CA 15-3 Controls  Code: 2K44-11  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of DF3 defined antigen in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT EBV EBNA-1 IgG  Class C  i) ARCHITECT EBV EBNA-1 IgG Calibrator  Code: 3P67-01  Shelf Life: 18 Months  ii) ARCHITECT EBV EBNA-1 IgG Controls  Code: 3P67-10  Shelf Life: 18 Months  iii) ARCHITECT EBV EBNA-1 IgG Reagent Kit (1x100 Tests)  Code: 3P67-25  Shelf Life: 18 Months  iv) ARCHITECT EBV EBNA-1 IgG Reagent Kit (1x500 Tests)  Code: 3P67-35  Shelf Life: 18 Months | IVD Kit used for the qualitative detection of  IgG antibodies to Epstein-Barr Nuclear Antigen-1 (EBNA-1) in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT Galectin-3  Class C  i) ARCHITECT Galectin-3 Calibrator  Code: 5P03-01  Shelf Life: 18 Months  ii) ARCHITECT Galectin-3 Controls  Code: 5P03-10  Shelf Life: 18 Months  iii) ARCHITECT Galectin-3 Reagent Kit (100 test)  Code: 5P03-25  Shelf Life: 18 Months | IVD Kit used for the quantitative determination of galectin-3 in human serum and EDTA plasma. | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT EBV VCA IgG  Class C  i) ARCHITECT EBV VCA IgG Calibrator  Code: 3P-65-01  Shelf Life: 18 Months  ii) ARCHITECT EBV VCA IgG Controls  Code: 3P-65-10  Shelf Life: 18 Months  iii) ARCHITECT EBV VCA IgG Reagent Kit (1x100 Tests)  Code: 3P-65-25  Shelf Life: 18 Months  iv) ARCHITECT EBV VCA IgG Reagent Kit (1x500 Tests)  Code: 3P-65-35  Shelf Life: 18 Months | IVD Kit used for the qualitative detection of IgG antibodies to  Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA) in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT Toxo IgG  Class C  i) ARCHITECT Toxo IgG Calibrator  Code: 6C19-01  Shelf Life: 12 Months  ii) ARCHITECT Toxo IgG Controls  Code: 6C19-10  Shelf Life: 12 Months  iii) ARCHITECT Toxo IgG Reagent Kit (1x100 Tests)  Code: 6C19-25  Shelf Life: 12 Months  iv) ARCHITECT Toxo IgG Reagent Kit (1x500 Tests)  Code: 6C19-35  Shelf Life: 12 Months | IVD Kit for the quantitative determination of IgG antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | Alinity I CA 19-9 XR  Class C  i) Alinity I CA 19-9 XR Calibrator  Code: 08P3201  Shelf Life: 12 Months  ii) Alinity I CA 19-9 XR Controls  Code: 08P3210  Shelf Life: 12 Months  iii) Alinity I CA 19-9 XR Reagent Kit (2x100 Tests)  Code: 08P3220  Shelf Life: 12 Months  iv) Alinity I CA 19-9 XR Reagent Kit (2x500 Tests)  Code: 08P3230  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of  1116-NS-19-9 reactive determinants in human serum or plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 26-01-2016)  Fee submitted: Rs. 50,000/- | Alinity I BNP  Class C  i) Alinity I BNP Calibrators  Code: 08P2401  Shelf Life: 12 Months  ii) Alinity I BNP Controls  Code: 08P2410  Shelf Life: 12 Months  iii) Alinity I BNP Reagent Kit (2x100 Tests)  Code: 08P2420  Shelf Life: 12 Months  iv) Alinity I BNP Reagent Kit (2x500 Tests)  Code: 08P2430  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of  human B-type natriuretic peptide (BNP) in human EDTA plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 26-01-2016)  Fee submitted: Rs. 50,000/- | ARCHITECT iCarbamazepine  Class C  i) ARCHITECT iCarbamazepine Calibrators  Code: 1P36-01  Shelf Life: 12 Months  ii) ARCHITECT iCarbamazepine Reagent Kit  Code: 1P36-25  Shelf Life: 12 Months | IVD Kit used for the quantitative measurement  of carbamazepine, an anticonvulsant drug, in human serum or plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT iTheophylline  Class C  i) ARCHITECT iTheophylline Calibrators  Code: 1P29-01  Shelf Life: 18 Months  ii) ARCHITECT iTheophylline Reagent Kit  Code: 1P29-01  Shelf Life: 18 Months | IVD Kit used for the quantitative measurement  of theophylline in human serum or plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 30-10-2017)  Fee submitted: Rs. 50,000/- | ARCHITECT BNP  Class C  i) ARCHITECT BNP Reagent Kit  Code: 8K28-28  Shelf Life: 12 Months  ii) ARCHITECT BNP Reagent Kit  Code: 8K28-36  Shelf Life: 12 Months  iii) ARCHITECT BNP Calibrators  Code: 8K28-03  Shelf Life: 12 Months  iv) ARCHITECT BNP Controls  Code: 8K28-12  Shelf Life: 12 Months | IVD Kit for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 30-05-2017)  Fee submitted: Rs. 50,000/- | ARCHITECT i Toxo IgG  Class C  i) ARCHITECT i Toxo IgG Reagent Kit (2x100 Test)  Code: 07P4522  Shelf Life: 12 Months  ii) ARCHITECT i Toxo IgG Reagent Kit (2x500 Test)  Code: 07P4532  Shelf Life: 12 Months  iii) ARCHITECT i Toxo IgG Calibrators  Code: 07P4501  Shelf Life: 12 Months  iv) ARCHITECT i Toxo IgG Controls  Code: 07P4510  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of IgG antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT Toxo IgM  Class C  i) ARCHITECT Toxo IgM Reagent Kit (1x100 Tests)  Code: 6C20-25  Shelf Life: 12 Months  ii) ARCHITECT Toxo IgM Reagent Kit (1x500 Tests)  Code: 6C20-35  Shelf Life: 12 Months  iii) ARCHITECT Toxo IgM Calibrators  Code: 6C20-01  Shelf Life: 12 Months  iv) ARCHITECT Toxo IgM Controls  Code: 6C20-10  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgM  antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | ARCHITECT i Toxo IgM  Class C  i) ARCHITECT i Toxo IgM Calibrator  Code: 07P4701  Shelf Life: 09 Months  ii) ARCHITECT i Toxo IgM Controls  Code: 07P4710  Shelf Life: 12 Months  iii) ARCHITECT i Toxo IgM Reagent Kit (2x100 Tests)  Code: 07P4722  Shelf Life: 12 Months  iv) ARCHITECT i Toxo IgM Reagent Kit (2x500 Tests)  Code: 07P4732  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgM  antibodies to Toxoplasma gondii in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 12-04-2017)  Fee submitted: Rs. 50,000/- | ARCHITECT CA 19-9 XR  Class C  i) ARCHITECT CA 19-9 XR Reagent Kit  Code: 2K91-24  Shelf Life: 12 Months  ii) ARCHITECT CA 19-9 XR Reagent Kit  Code: 2K91-32  Shelf Life: 12 Months  iii) ARCHITECT CA 19-9 XR Reagent Kit  Code: 2K91-39  Shelf Life: 12 Months  iv) ARCHITECT CA 19-9 XR Calibrators  Code: 2K91-03  Shelf Life: 12 Months  v) ARCHITECT CA 19-9 XR Controls  Code: 2K91-12  Shelf Life: 12 Months | IVD Kit used for the quantitative determination  of 1116-NS-19-9 reactive determinants in human serum or plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2017)  Fee submitted: Rs. 50,000/- | ARCHITECT i HAV Ab-IgG  Class C  i) ARCHITECT i HAV Ab-IgG Calibrator  Code: 08P2601  Shelf Life: 12 Months  ii) ARCHITECT i HAV Ab-IgG Controls  Code: 08P2610  Shelf Life: 12 Months  iii) ARCHITECT i HAV Ab-IgG Reagent Kit (2x100 Tests)  Code: 08P2622  Shelf Life: 12 Months  iv) ARCHITECT i HAV Ab-IgG Reagent Kit (2x100 Tests)  Code: 08P2632  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgG antibody to hepatitis A virus (IgG anti-HAV) in human serum and  plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 12-04-2017)  Fee submitted: Rs. 50,000/- | Alinity i CA 15-3  Class C  i) Alinity I CA 15-3 Calibrators  Code: 08P5101  Shelf Life: 12 Months  ii) Alinity I CA 15-3 Controls  Code: 08P5110  Shelf Life: 12 Months  iii) Alinity I CA 15-3 Reagent Kit (2x100 Tests)  Code: 08P5120  Shelf Life: 12 Months  iv) Alinity I CA 15-3 Reagent Kit (2x500 Tests)  Code: 08P5130  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of DF3 defined antigen in human serum and plasm | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | Alinity i CA 125 II  Class C  i) Alinity i CA 125 II Calibrators  Code: 08P4901  Shelf Life: 08 Months  ii) Alinity i CA 125 II Controls  Code: 08P4910  Shelf Life: 08 Months  iii) Alinity i CA 125 II Reagent Kit (2x100 Tests)  Code: 08P4920  Shelf Life: 12 Months  iv) Alinity i CA 125 II Reagent Kit (2x500 Tests)  Code: 08P4930  Shelf Life: 12 Months | IVD Kit used for the quantitative determination of OC 125 defined antigen in human serum and Plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | Alinity i HAV Ab-IgM  Class C  i) Alinity i HAV Ab-IgM Calibrators  Code: 02R2801  Shelf Life: 12 Months  ii) Alinity i HAV Ab-IgM Controls  Code: 02R2810  Shelf Life: 12 Months  iii) Alinity i HAV Ab-IgM Reagent Kit (2x100 Tests)  Code: 02R2822  Shelf Life: 12 Months  iv) Alinity i HAV Ab-IgM Reagent Kit (2x500 Tests)  Code: 02R2832  Shelf Life: 12 Months | IVD Kit used for the qualitative detection of IgG  antibody to hepatitis A virus (IgG anti-HAV) in human serum and plasma | **Approved**. |
|  | -do-  Evaluator:  Hafiz Muhammad Asif Iqbal | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany  (FSC Germany Issuance Date 19-07-2018)  Fee submitted: Rs. 50,000/- | Alinity i Homocysteine  Class C  i) Alinity i Homocysteine Calibrators  Code: 09P2801  Shelf Life: 15 Months  ii) Alinity i Homocysteine Controls  Code: 09P2810  Shelf Life: 80 Weeks  iii) Alinity i Homocysteine Reagent Kit (2x100 Tests)  Code: 09P2820  Shelf Life: 12 Months | IVD Kit used for the quantitative  determination of total L-homocysteine in human serum or plasma | **Approved**. |

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