**Government of Pakistan**

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

**Drug Regulatory Authority of Pakistan**

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**MINUTES OF THE 11TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 01-02-2019**

11th 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 1st February, 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. Abdul Haleem Khan, member MDB to preside over the meeting as Chairman. Subsequently meeting was chaired by Dr. Abdul Haleem Khan, Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore and was attended by the following:-

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| **S.No**. | **Name and Designation / Department** | **Position in the MDB** |
|  | Dr. Abdul Haleem Khan, Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore. | Member / Chairman |
|  | Mr. Rafiq Ahmed, Director Health Services, Rawalpindi Division (Nominee of Director General Health, Punjab). | Member |
|  | Mr. Imranullah, Senior Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa). | Member |
|  | Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar. | Member |
|  | Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi. | Member |
|  | Mr. Muhammad Asghar, CEO, Cyber Soft Technologies, Lahore. | Member |
|  | Dr. Muhammad Farid Khan, Director Emergency Services, District Kasur. | Member |
|  | Professor Dr. Ejaz Hassan Khan, Principal North West School of Medicine, Peshawar. | Member |
|  | Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad. | Secretary / Member |

The meeting started with the recitation of the Holy Quran. The Chairman MD&MC welcomed all the participants. Secretary MDB presented the agenda of the meeting.

**Item No.I**. **CONFIRMATION OF MINUTES OF 10TH MEDICAL DEVICS BOARD MEETING**.

**Decision:** The Board confirmed the minutes of the 10th meeting of MDB.

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

Secretary MDB informed the Board that the following applications for grant of Establishment License to import medical devices under Medical Devices Rules, 2017 were received in the Division. The establishments were inspected by the panels constituted by the Chairman MDB. The inspections were conducted according to the checklist.

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

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| **S.No** | **Name of Establishment** | **Director/Proprietor/**  **partners** | **Name of panel Inspector (s)** | **Cold Chain**  **(Yes/No)** | **Decision** |
|  | M/s Endo-Kare, 14-A, Aibak Block, New Garden town Lahore. | Sardar Hassan Kamran Asif | Hafiz Muhammad Asif Iqbal, AD-V (MDMC), DRAP, Islamabad.  Miss Hira Bhutto, AD-I (MD&MC), DRAP, Islamabad. | No. | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Amtronech, 560, A Block Faisal Town, Lahore. | Mr. Abid Ali.  Mr. Maqsood Alam. | -do- | No. | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Servier Research and Pharmaceuticals Pakistan Pvt Ltd, 65 Main Boulevard Gulberg Lahore. | Nicolas Charles Marie  Pierre Albert Paul Dussaud | -do- | No. | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Medi-Serv International, GF 28 Jinnah Plaza, Defence Chowk, Main Boulevard Lahore Cantt. | Rana Bashir Ahmad  Mrs. Sakina Bashir. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Biosorin, 533 Shadman -1, Main Shadman Road Lahore. | Muhammad Murtaza Khan | -do- | Yes | **Approved** for cold chain facility only. |
|  | M/s Neutro Health Care, 22-M, Gulberg-III, Lahore | Amjad Iqbal  Shabir Ahmad | -do- | No. | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Suafa Traders, 11 Model Town,  R.Y.Khan.  **Godown**:  **5-Canal View, Bukhari Street, Rahim Yar Khan.** | Mr. Syed Farjad Ali Bukhari  Mr. Syed Shamshad Ali.  Ms. Uroosa Shamshad . | Mr. Muhammad Ayub Naveed, AD-II (MDMC), DRAP, Islamabad.  Hafiz Muhammad Asif Iqbal, AD-V (MDMC),DRAP, Islamabad | No | **Approved** for room temperature medical devices without cold chain facility  Godown Address added. |
|  | M/s Care and Cure International,  65-B, Satellite Town, Rahim Yar Khan. | Raja Anwar Ur Rehman | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Oscartech Pakistan,  Kotla Arab Ali, Kharian,  Distt Gujrat. | Shabir Ahmad Bhatti | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s. Shaheen Aerotraders, Air Port Road, Opposite Benazir Bhutto Road International, Chaklala Rawalpindi. | Wg Cdr ® Ejaz Ahmad Khan | Hafiz Muhammad Asif Iqbal, AD-V (MDMC), DRAP, Islamabad.  Miss Hira Bhutto, AD-I (MD&MC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Biowel Sciences.  Head office: Office No 202, 2nd Floor, Gulistan Khan Plaza, Fazal-e-Haq Road, Blue Area Islamabad.  Godown address: Same as above | Dr Nasir Mehmood Malik  Dr Waseem Mirza | Mrs.Unum Zia Shamsi, AD-IV (MDMC), DRAP, Islamabad.  Hafiz Muhammad Asif Iqbal, AD-V (MDMC), DRAP, Islamabad | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Flowtronix Systems.  Head office: Flat No. 02, 1st Floor Al-Ashraf Plaza, Range Road, Rawalpindi. Godown address: Same as above | Muhammad Shahzad Akram | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s F.W Distributors.  Head office:  Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi  Godown address: Same as above | Muhammad Yunus  Muhammad Faisal Ali | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Mediniche International.  Head office:  113, 2nd Floor, China Town Plaza, Gordon College Road, Rawalpindi.  Godown address: Same as above | Nadeem Iqbal Khokhar | -do- | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Life-Tec.  Head office:  Unit B, 1st Floor, Block 20D, G-8 Markaz Islamabad. Godown address: Same as above | Sana Ur Rehman.  Khalid Mehmood Zia. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Shahbaz Scientific Corporation.  Head office:  House No.201, Gillani Street No.5 East, Shabbir Lane, Near Rescue 1122 Office, Peshawar Road, Rawalpindi.  Godown address: Same as above | Muhammad Shahbaz | -do- | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Nimrall Farma.  Head office:  Flat no. E-15, Aziz Bhatti Road, 2nd Floor, Lal Kurti, Distt, Rawalpindi.  Godown address: Same as above | Shahzad Saeed  Muhammad Kashif  Kalsoom Mubashir | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s 3J Diagnostics, Flat No 7-B, 2nd Floor Liberty Plaza Opp. RGH Muree Road, Rawalpindi. | Johnson John | Mr. Muhammad Ayub Naveed, Assistant Director-II (MDMC),DRAP, Islamabad.  Ms. Hira Bhutto, Assistant Director-I (MDMC), DRAP, Islamabad | Yes | **Approved** for limited cold chain facility. |
|  | M/s Miraj Corporation, office No 13-14 2nd Floor, Jinnah Business Center, Chadni Chowk Rawalpindi. | Ch Mushtaq Ahmed. | -do- | Yes | **Approved** for cold chain facility only. |
|  | M/s NSONs Group Pvt Ltd, House No CB 1-7, Lane No.7, Peshawar Road Rawalpindi. | Mr. Ahtesham Nawaz.  Mrs. Myda Ahtesham | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Pak Glorious Enterprises, Flat No 305, Muhammadia Plaza, Gordon Collage Road Rawalpindi. | Shabbir Ahmed  Umer Shabbir | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Bilal Enterprises, 8- Commercial Complex, Safari Villas 2, Bahria Town Phase 7, Islamabad. | Mrs. Shagufta Naz | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Zaidi Traders, D-417, Satellite Town, Rawalpindi.  Godown Address:  F-263, Satellite Town, Rawalpindi. | Syed Masood Akhtar Zaidi | -do- | No | **Approved** for room temperature medical devices without cold chain facility.  Godown Address added. |
|  | M/s K.R International, Kr House No 210 CB No 988 Street No 5, East Shabbir LanePeshwar Road Pir Wadhai Mor Rawalpindi | Mr Muhammad Akhtar | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Curative Pharmaceuticals Pvt Ltd. 500, 5th Floor, Plaza No 54, Block B, Civic Center, Phase-IV, Bahria Town, Rawalpindi/ Islamabad. | Mr.Shafqat Hussain  Mr.Adnan Shafqat  Mr.Zeshan Shafqat  Mrs.Gul Nargis | -do- | No | **Approved** for limited storage facilaity for room temperature medical devices without cold chain facility. |
|  | M/s Mira Khan & Co., H No 12/14, Swati gate, Hakim abad, Peshawar. | Masood Parvaiz Khan | Mr. Muhammad Ayub Naveed, AD-II (MDMC),DRAP, Islamabad.  Mr. Arslan Tariq, Assistant Director (QA&LT), DRAP, Islamabad | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Tahir Scientific Supplies, 13-Karachi Market Khyber Bazar Peshawar.  **Godown:**  **33 Ground Floor, Karachi Market, Khyber Bazar, Peshawar.** | Muhammad Tahir Shah. | -do- | No | **Approved** for room temperature medical devices without cold chain facility.  Godown Address added. |
|  | M/s Zafar Enterprises, House No 444, Near Jamal Medicos New dabgari Garden Peshawar. | Malik Saeed Khan Afridi. | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Zaidi Chemist, 15 Soekarno Square, Khyber Bazar, Peshawar. | Zahid Ahmed | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s I-Care Health, 512, Pak Medical Center Khyber Bazar, Peshawar.  **Godown:**  87, ground floo**r,** Pak Medical Center Khyber Bazar, Peshawar. | Ahmad Saeed. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Umar & Co., MC Plaza Shop No B13 Bank Road Mardan.  **Godown:**  Shamsi Road, Near GGHS, Mardan. | Mr. Khalil Mohammad | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Safi Brothers, Room No -22-23, 2nd Floor Clock Tower Shamsi Road, Mardan, Khyber Pukhtunkhwa. | Muhammad Aamir Khan Safi.  Ibrar Ali.  Muhammad Asad Khan.  .Muhammad Umar Khan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Pharmatronics Pvt Ltd. S-11.2nd Floor, Clock Tower Shamsi Road Mardan.  **Godown:**  **S-16-17, Second Floor, Clock Tower Shamsi Road Mardan.** | Syed Saeed Ullah Shah.  Syed Babar Saeed | -do- | No | **Approved** for room temperature medical devices without cold chain facility.  Godown Address added. |
|  | M/s Unity Brands Associates Pvt Ltd, Haji Manaz Plaza, R.A Bazar Nowshera | Abdur Rehman | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s. Parazelsus Pakistan Private Limited.  Head office: No 201-204, 2nd Floor, Park Towers, Shahrah-e-Firdousi, Clifton, Karachi.  **Godown Address:**  Shed No. F-9, Plot S1, Survey No 230, Sec No. 02, Road 4000, Korangi Industrial Area, Karachi | Markus Haefeli  Mujtaba Rahim  Zia Shams (CEO) | Mrs. Unum Zia Shamsi, AD-IV (MD&MC), DRAP, Islamabad.  Hafiz Muhammad Tayyab, Assistant Director (RRR), DRAP, Islamabad. | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Bionta Pharma.  Head office: Suit No. A-1, Plot No. B-10, Gulshan-e-Iqbal Karachi. **Godown Address:** Suit No. A-10, Plot No. B-10, Gulshan-e-Iqbal Karachi. | Bu Amjad Raza Ur Rehman  Muhammad Hashim Ali Khan | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s EngItech. Head office: C-59/1 Block-B Gulshan-e-Jamal, Karachi. Godown Address: Same as above | Adnan Karamat  Sami Ullah Khan | -do- | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Waseem Brothers.  Head office: Plot No B-45, Block 5, Gulshan-e-Iqbal, Karachi. Godown Address: Same as above | Abdul Waseem | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Diagnostic Systems.  Head office: 1st Floor, A-21, Block 13-D-1, Rufi Cottages, Sehba Akhtar Rd, Gulshan-e-Iqbal, Karachi.  Godown Address: Same as above | Ayaz Aleem | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Chohan and Company.  Head office:21 Bahadurabad Block 3, Karachi.  Godown Address: Same as above | Abdul Waheed Chohan | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Reagnchem Scientific.  Head office: 2nd Floor, A-21, Block 13-D-1, Rufi Cottages, Sehba Akhtar Rd, Gulshan-e-Iqbal, Karachi.  Godown Address: Same as above | Mufti Sarmad Aleem | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Saru International.  Head office:B-194/1, Block-12, Gulistan-e-Jauhar, Karachi.  Godown Address: Same as above | Saleem Iqbal | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Innovate Medical Technologies (Pvt) Ltd.  Head office: House No. A-7, Baloch Goth Block No 13-D-3 Gulshan-e-Iqbal, Karachi.  Godown Address: Same as above | Waqas Jawaid  Maroof Ali Mohyuddin | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Zedco.  Head office: Office No 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e- Faisal, Karachi. Godown Address: Same as above | Shujaat Hussain | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Biologic Medical Systems,  Head office:166E Annexe B, Block-3, PECHS, Off Khalid Bin Waleed Road, Karachi.  Godown Address: Same as above | Kamran Tahir | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s A.J Mirza Pharma Pvt Ltd. Head office: 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi Godown Address: 2nd Floor, Shafi Court, Merewether Road, Civil Lines, Karachi | Mr. Ali Abbas  Syed Shahab Balkhi  Mr. Adnan Hussain (CEO) | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (Private) Limited.  Head office: D-2, 2nd Floor, Westland Trade Centre, Plot No.C-5, Block 7/8 KCHSU, Shaheed -E- Millat Road, Karachi.  Godown Address: Same as above | Qinghua Yang (CEO)  Zahid Moeen Uddin Qureshi  Shahid Moin Qureshi | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s FY Diagnostic & Surgicals,  Head office:Suit No. 203. Anum Blessing, 2nd Floor, KCHSU, Shahrah-e-Faisal Karachi.  Godown Address: Suit No. 115, Anum Blessing, 2nd Floor, KCHSU, Shahrah-e-Faisal Karachi. | Younus Ali Khan  Farha Younus | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility. |
|  | M/s Jafri Medical.  Head office:  Suit No. 104C/11, Maryam Heights, Block 7/8, KCHS, PECHS, Shaheed e Millat Road, Karachi.  Godown Address: Same as above | Mrs. Salma Zaidi | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Mehran International.  Head office:  498/C, Feroz Shah Mehta Road, Karachi.  Godown Address: Same as above | Mrs Zainab Usman | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Aftab Life Care Impex, 1st floor Al - Falah Chambers Tilak Road, Hyderabad.  Godown Address:  Plot No.B-10, Employees Cooperative Housing Society, Phase-II, Kohsar, Latifabad, Hyderabad. | Attiquue Ahmad Aftab | Hafiz Muhammad Tayyab, Assistant Director (RRR), DRAP, Islamabad.  Mr. Arslan Tariq, Asistant Director (QA&LT), DRAP, Islamabad | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Cosmos Enterprises.A-49/1, Anees Ahmed Square, Hirabad, Hyderabad.  Godown Address: Same as above. | Hassan Dhanani | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility with limited capacity. |
|  | M/s Imran & Faizan Brothers & Trading co. 15-Patel Road Quetta. | Imran Mushtaq.  Jibran Mushtaq. | Mr. Muhammad Ayub Naveed, AD-II (MDMC), DRAP, Islamabad.  Hafiz Muhammad Asif Iqbal, A-V (MDMC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Green Care Trading Pvt Ltd, Zarghoon Medical Store, Opp Bolan Medical Complex Hospital, Brewery Road, Chilton Town, Quetta. | Syed Noor Ullah  Syed Muhammad Ismail | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Hitec Corporation  Office No, 2, Ist Floor Ali Complex Plaza No 77, Fazal-e- Haq Road Islamabad  **Godown:**  Basement No.2, Ali Complex Plaza No.77, Fazal-e-Haq Road, Islamabad. | Ahad Maqbool Ahmed.  Maqbool Ahmed Bhatti. | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Focus Surgicals, 58-Kacha Lawrance Road, Near Drugs Control Wing Lahore. | Tariq Ahmed,  M. Zahid Sheikh, | Hafiz Muhammad Asif Iqbal, A-V (MDMC), DRAP, Islamabad.  Ms. Hira Bhutto, AD-I (MDMC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Meditech Pvt Ltd. 114G/1 M.A Johar Town, Lahore. | 1.M. Saleem Sheikh  2.Roofia Saleem  3.Khurram Saleem  4.Maria Saleem  5.Khalid Sheikh  6.Nadia Khurram | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s ANZ Healthcare Technologies, 112-A, Comm. Area, Sec.-C. Bahria Town Lahore. | Zafar ud din  Asim Majeed | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Akram Brother & Co, 89-D Jail Road Lahore. | Rana Muhammad  Akram Khan | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Ahmad Care International, 2nd Floor, 7- Shahrah e Tajbagh, Main Market,  phase 1, Tajbag housing schem, Lahore | Mr Amir Ijaz Butt | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s De Khon, 11-C, Old FCC Ferozpur Road, Lahore. | Dr Faisal Q. Khokar | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s AK Pharma Pvt Ltd, Building No Zone 2557 Adjacent Total Petrol Pump Firduos Market Gulberg III, Lahore. | Khalida Aziz | -do- | No | **Approved** for room temperature medical devices without cold chain facility  Address corrected. |
|  | M/s Muslim Trading Agencies, Ground Floor 3-Syed Moj Dary Road, Lahore.  **Godwon Address: 4 Lake Road, Near Jamia Masjid Qadsia, Chouburji, Lahore.** | Rafi Ullah Sheikh,  Shafi Ullah Shaikh,  Sami Ullah Sheikh, | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility subject to submission of DSL.  Godown Address added. |
|  | M/s Medequips Smc Pvt Ltd, 30, Shahrah e Quaid e Azam, Lahore. | Mr Umer Farooq | -do- | No | **Approved** for room temperature medical devices without cold chain facility subject to submission of DSL. |
|  | M/s Three Stars Medical Supplies, M 17-M18, Mezanine Floor Saith Center Syed Mouj Darya Road Lahore. | Zafar Ullah Alvi | -do- | Yes | **Approved** for room temperature medical devices and cold chain facility. |
|  | M/s Bio Pharma International, 3 D 2nd Floor, Chuburji Center, Multan Road, Lahore. | Muhammad Abbas | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s RHS International, 1st Floor of Building, 34-Mozang Road, Opp. Total Petrol Pump, Lahore.  **Godown Address: 2nd Floor, S 60-R 34, Mozang Road, Lahore.** | Shoaib Rafi | -do- | No | **Approved** for room temperature medical devices without cold chain facility.  Godown Address added. |
|  | M/s Azad Scientific, Office No 3/B Mouj Darya Road Near AG Office Lahore. | Khalid Mahmood Malik | -do- | Yes | **Approved** for cold chain facility. |
|  | M/s Linkers Asia, 96-H-3, Johar Town Lahore. | Akhtar Abbas  Qumar Abbas | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Inventus Medical Technologies, 63/3 First Floor, Street 9, Block-C, Phase 8, DHA, Lahore. | Khalid Luqman Chaudhry  Shakila Khalid Chaudhry | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Muslim Medical Services 1st Floor Sky Star Travels, 3- Syed Moj Darya Road Lahore.  **Godown Address:** **Basement,** **S 60-R 34, Mozang Road, Lahore.** | Haroon Rafi | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Qadri Healthco, Azeem House Ground Floor, 4-A Mozang Road Lahore | Sheikh Sohail Sabir | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Digionics Pvt Ltd, 15 Shadman, Jail Road, Lahore. | .Riaz Masood Abbasi  Qasim Masood | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Moon Enterprises, 5/6 Rabani Road, Old Anarkali, Lahore. | Muhammad Afzal  Muhammad Murslin  Zaeema Murslin | -do- | Yes | **Approved** for room temperature medical devices with cold chain facility.  Address Corrected. |
|  | M/s Bajwa Sons, 13- Muslim Street, House No 3, 1st and 2nd Floor, Mayo Hospital Road, Lahore. | Mr. Farhat Munawar Bajwa  Mr. Usman Ahmed Bajwa | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s M & N Health Care,  House No 40, Block-A Satellite Town,  Gujranwala. | Ahmed Usman Amin  Ali Zain Amin | -do- | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Fresenius Medical Care Pakistan (Pvt) Ltd., TAMC,First Floor, 27C 111, M.M. Alam Road Gulberg-III, Lahore. | .Javeed Nasir Qureshi.  KWONG LEUNG TSANG  JAN WALTER.  ANDREAS HENDRIK DE WIT. | Mr. Muhammad Ayub Naveed, Assistant Director-II(MDMC),DRAP, Islamabad.  Ms. Hira Bhutto, Assistant Director-I (MDMC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Maxims Medical Lahore Pakistan, 210 2nd Floor Land Mark Plaza Jail Road Lahore. | Syed Salim Javeed.  Yasmin Salim. | Miss Hira Bhutto, Assistant Director-I (MDMC),DRAP, Islamabad.  Hafiz Muhammad Tayyab, Assistant, DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility |
|  | M/s Johnson & Johnson Pakistan (Pvt) Ltd, Office No, 806, 8th Floor Horizon Towers,  Block 3, Scheme No 5, Clifton,  Karachi. | Khalid Shabban Mansour  Ramez Ezzat Aziz Louca | Dr. Najam Us Saqib, Additional Director, DRAP, Karachi.  Dr. Farman Ali Bozdar, Assistant Director, DRAP, Karachi. | No | **Approved** for room temperature medical devices without cold chain facility subjce to agreement for storage area. |
|  | M/s Arizona Healthcare Products, Plot No. 14, chuburji Park road near chowk Chuburji, Lahore. | Mr. Zahoor Ellahi.  Mr.Rashida Ishrat | Hafiz Muhammad Asif Iqbal, Assistant Director-V (MD&MC), DRAP, Islamabad.  Hafiz Muhammad Jawad Ali, Assistant Director (EC), DRAP, Islamabad | No | **Approved** for room temperature medical devices without cold chain facility |

**Item No.III. 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 under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:

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|  | **EVALUATOR: MRS. HIRA BHUTTO, AD, MDMC** | | | | | | | | | | | | | | | |
| **Sr No.** | **Name of Importer** | **Name of Manufacturer** | | | **Name of Medical Device** | | | | **Brief Description** | | | | **Decision** | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC USFDA  valid till 05-08-2020) | | | PT GraphixTM Guidewire with ICETM Hydrophilic Coating  Class D  Shelf Life: 24Month  H74914902011  08714729254928  0.014", 182cm, Straight  H74914902012  08714729141723  0.014", 182cm, Straight, 5 pk  H7491490201J1  08714729254935  0.014", 182cm, J Tip  H7491490201J2  08714729141730  0.014", 182cm, J Tip, 5 pk  H74914903011  08714729254942  0.014", 182cm, Straight  H74914903012  08714729188469  0.014", 182cm, Straight, 5 pk  H7491490301J1  08714729254959  0.014", l82cm, J Tip  H7491490301J2  08714729141754  0.014", 182cm, J Tip, 5 pk  H74914905011  08714729254966  0.014", 182cm, Straight  H74914905012  08714729141785  0.014", 182cm, Straight, 5 pk  H7491490501J1  08714729254973  0.014", 182cm, J Tip  H7491490501J2  08714729188476  0.014", 182cm, J Tip, 5 pk  H74914914011  08714729255017  0.014", 300cm, Straight  H74914914012  08714729141969  0.014", 300cm, Straight, 5 pk  H7491491401J1  08714729255024  0.014", 300cm, J Tip  H7491491401J2  08714729141976  0.014", 300cm, J Tip, 5pk | | | | The Boston Scientific ChoICE Magnet, Mailman Magnet, Luge Magnet, ChoICE PT Magnet, and PT Graphix Magnet Guidewires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. | | | | **Approved** subject to valid Agency Agreement. | | | |
|  | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore  (ELI-00094) | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA **Manufacturing Sites:** M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland  (FSC Ireland valid till 09-11-2022) | | | XIENCE Sierra Everolimus Eluting Coronary Stent System  Class D  Shelf Life: 3Year  Diameter(mm) Length (mm)  2.0 x 8,12,15,18,23,28,33,38  2.25 x 8,12,15,18,23,28,33,38  2.50 x 8,12,15,18,23,28,33,38  2.75 x 8,12,15,18,23,28,33,38  3.0 x 8,12,15,18,23,28,33,38  3.25 x 8,12,15,18,23,28,33,38  3.50 x 8,12,15,18,23,28,33,38  4.0 x 8,12,15,18,23,28,33,38 | | | | Everolimus Eluting Coronary Stent System | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA **Manufacturing Sites:** (1) M/s Abbott Vascular Road # 2, km 58.0, Cruce Davila, Barceloneta, PR 00617, USA  (2) M/s Abbott Vascular 26531, Ynez Rd., Temecula, CA 92591, USA  (FSC USFDA valid till 16-05-2020) | | | Hi-Torque Progress PTCA Guide Wire  Class D  Shelf Life: 2Year  1011836, 1011837, 1011838, 1011839, 1011840, 1011841, 1011842, 1011843, 1011844, 1011845  Fee: 50000/- | | | | PTCA Guide Wire | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA **Manufacturing Sites:** M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland  (FSC Ireland valid till 17-08-2020) | | | Perclose ProGlide Suture-Medicated Closure System  Class C  Shelf Life: 2Year | | | | Suture-Medicated Closure System | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA **Manufacturing Sites:** (i) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA (ii) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA  (FSC USFDA Valid Till  16-05-2020) | | | Hi-Torque® Cross-ITTM Guide Wire with Hydrocoat Hydrophilic Coating  Class D  Shelf Life: 2 Years  1003308H, 1003308HJ, 1003309H, 1003309HJ  1003310H, 1003310HJ, 1003311H, 1003311HJ  1003312H, 1003312HJ, 1003313H, 1003313HJ  1003314H, 1003314HJ, 1003315H, 1003315HJ  1003316H, 1003316HJ, 1003317H, 1003317HJ  1003318H, 1003318HJ  1003319H, 1003319HJ  Fee: 50,000/- | | | | PTCA Guide Wire | | | | **Approved.** | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Issue 19-07-2018 Germany) | | | Alinity i Syphilis TP Kit  Class D  (1) Alinity i Syphilis TP Calibrator  07P6001  Shelf Life: 12 Months  (2) Alinity i Syphilis TP Controls  07P6010  Shelf Life: 12 Months  (3) Alinity i Syphilis TP Reagent Kit  07P6022  Shelf Life: 12 Months  (2x100 tests)  (4) Alinity i Syphilis TP Reagent Kit  07P6032  Shelf Life: 12 Months  (2x600 tests)  Fee: 50000/- | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i Syphilis TP Testing | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany Issue 19-07-2018 ) | | | Alinity i Anti-HBe Kit  Class D  (1) Alinity i Anti-HBe Calibrator 07P6301  Shelf Life: 15 Months  (2) Alinity i Anti-HBe Controls  07P6310  Shelf Life: 12 Months  (3) Alinity i Anti-HBe Reagent Kit  07P6322  Shelf Life: 11 Months  Fee: 50000/- | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i Anti-HBe Testing | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany Issue  19-07-2018 ) | | | Alinity i Anti-HBc II Kit  Class D  (1) Alinity i Anti-HBc II Calibrator  07P8701  Shelf Life: 12 Months  (2) Alinity i Anti-HBc II Controls 07P8710  Shelf Life: 12 Months  (3) Alinity i Anti-HBc II Reagent Kit 07P8722  Shelf Life: 12 Months  (4) Alinity i Anti-HBc II Reagent Kit 07P8732  Shelf Life: 12 Months | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i Anti-HBc II Testing | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott ireland Diagnostic Division Finisklin Business Par, Sligo, Ireland  (FSC Ireland valid till  26-05-2022 ) | | | Alinity s HBsAg Confirmatory Kit  Class D  (1) Alinity s HBsAg Confirmatory Reagent Kit 06P0357  Shelf Life: 12 Months  (2) Alinity s HBsAg Calibrator Kit 06P0202  Shelf Life: 12 Months  (3) Alinity s HBsAg Assay Control Kit 06P0210  Shelf Life: 12 Months  (4) Alinity s HBsAg Release Control Kit 06P0212  Shelf Life: 12 Months | | | | IN-VITRO DIAGNOSTIC Kit for Alinity s HBsAg Confirmatory Testing | | | | **Approved.** | | | |
|  | M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi  (ELI-00090) | **Manufacturer:**  M/s Changzhou Chunguang Medical Equipment Co., Ltd., Shijiaqiao Dongqing Zhenlu Town, Changzhou City, Jiangsu Province, China  (FSC China Valid Till 01-04-2019) | | | Perfect +  Disposable Infusion Set  Class B  Shelf Life: 5 Years  Fee: 25000/- | | | | Disposable Infusion Set, Sterile with Needle | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017. | | | |
|  | -do- | **Manufacturer:** M/s Evereast Medical Products Group Co., Ltd., No.1 Wangzhuang Village, Shejia Town, Changyuan County, Henan 453400, China  (FSC China Valid Till22-05-2023) | | | K&K Zenith Disposable  Endotracheal Tube, Sterile With Cuff  Class B  Shelf Life: 5 Years  Codes as per Free Sale Certificate | | | | Disposable Trachea Cannula | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017. | | | |
|  | -do- | **Manufacturer:** M/s Evereast Medical Products Group Co., Ltd., No.1 Wangzhuang Village, Shejia Town, Changyuan County, Henan 453400, China  (FSC China Valid Till22-05-2023) | | | Disposable Urethral Catheter  (Disposable Foley Catheter)  Class B  Shelf Life: 5 Years  Sizes: (2way) 6fr, 8fr, 10fr, 12fr, 14fr, 16fr, 18fr, 20fr, 22fr, 24fr  (3way) 16fr, 18fr, 20fr, 22fr, 24fr | | | | Disposable Latex Foley Balloon Catheter, Sterile | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017. | | | |
|  | M/s Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi  (ELI-000109) | **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, Cludad Juarez, Chihuahua, CP 32574, Mexico  (FSC USFDA Valid Till  30-08-2019) | | | Avanti + Sheath Introducers  Class B  Shelf Life: 3Year  402604A,402604P,402604R  402604T,402604X,402605A  402605P,402605R,402605T  402605X,402606A,402606P  402606R,402606T,402606X  402607A,402607P,402607R  402607T,402607X,402608A  402608P,402608T,402608X  402609A,402609T,402609X  402610A,402610T,402610X  402611T,402611X,402655P  402655X,402656P,402656T  402656X,402657P,402658A  402658P,504504S,504604P  504604S,504604T,504605P  504605S,504605T,504606D  504606P,504606S,504606T  504606V,504607D,504607T  504607V,504607X,504608D  504608T,504608V,504608X  504609D,504609T,504609X  504610T,504610X,504611T  504611X,504614Z,504615Z  504616Z,504617Z,504624Z  504625Z,504626Z,504627Z  504655T,504655X,504656T  504656X,504657T,504657X  504658T,504658X | | | | Catheter Sheath Introducer | | | | **Approved.** | | | |
|  | M/s Roche Pakistan Limited. 37-C, Block 6, P.E.C.H.S, Karachi.  (ELI-00009) | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  FSC Germany Issuance Data  (19-09-2016) | | | Cobas® Elecsys Anti HBc Kit  Class D  (i) Cobas®Elecsys Anti-HBc  Shelf Life: 13 Months  **Size:**  100 Tests  **Code:**  11820559122  (ii)Cobas®Elecsys PreciControlAnti-HBc  Shelf Life: 29 Months  **Size:**  16x1.3mL  **Code:**  11876325122  (iii) Cobas®Elecsys Anti-HBc II  Shelf Life: 15 Months  **Size:**  100 Tests  **Code:**  07374160190  (iv) Cobas®Elecsys Anti-HBc II  Shelf Life: 15 Months  **Size:**  200 Tests  **Code**:  07394764190  (v) Cobas®ElecsysAnti-HBc II  Shelf Life: 15 Months  **Size:**  300 Tests  **Code:**  07026790190  (vi) Cobas®Elecsys PreciControl Anti-HBc II  Shelf Life: 24 Months  **Size:**  16x1.3mL  **Code:**  04927931190 | | | | In vitro qualitative determination of IgG and IgM  antibodies to the hepatitis B core antigen in human serum and plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  FSC Germany Issuance Data  (19-09-2016) | | | Cobas® 6800/8800 MPX Kit  Class D  (i) Cobas® MPX - 96  Shelf Life: 25 Months  **Size:**  96 Tests  **Code:**  06997708190  (ii)Cobas® MPX - 480  Shelf Life: 25 Months  **Size:**  480 Tests  **Code:**  06997716190  (iii) Cobas® MPX Control Kit  Shelf Life: 25 Months  **Size:**  4x1mL  **Code:**  06997724190  (iv) Cobas® NHP Negative Control Kit  Shelf Life: 26 Months  **Size:**  16x1mL  **Code:**  07002220190 | | | | Qualitative in vitro test for the direct detection of HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in human plasma and serum. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  FSC Germany Issuance Data  (19-09-2016) | | | Cobas®Elecsys Anti-HBe Kit  Class D  (i) Cobas®Elecsys Anti-HBe  Shelf Life: 24 Months  **Size:**  100 Tests  **Code:**  11820613122  (ii)Cobas®Elecsys Anti-HBe  Shelf Life: 24 Months  **Size:**  300 Tests  **Code:**  07026838190  (iii) Cobas®Elecsys PreciControl Anti-HBe  Shelf Life: 21 Months  **Size:**  16 x 1.3 mL  **Code:**  11876384122 | | | | Immunoassay for the in vitro qualitative determination of  human antibodies to the  hepatitis B e antigen (HbeAg) in human serum & plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  FSC Germany Issuance Data  (16-08-2018) | | | Cobas® AmpliPrep/ Cobas® TaqMan® HIV-1 Qualitative Test, v2.0  Class D  Shelf Life: 22 Months  **Size**:  72 Tests  **Code**:  06693083190 | | | | In vitro diagnostic, total nucleic acid amplification  test for the qualitative detection of HIV-1 DNA and RNA (or total nucleic acid, TNA) in human  plasma or dried blood spots. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Molecular System Inc.,  1080 US Hwy 202,  South Branchburg, NJ 08876  USA.  FSC USFDA Valid Till  (03-06-2020) | | | Cobas® AmpliPrep/ Cobas ® TaqMan® HCV Qualitative Test, v2.0  Class D  Shelf Life: 10 Months  **Size:**  72 Tests  **Code:**  05480477190 | | | | Qualitative in vitro nucleic acid  amplification test for the detection of HCV RNA genotypes 1 to 6 in human EDTA plasma or  serum. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Molecular System Inc., 1080 US Hwy 202, South Branchburg, NJ 08876  USA.  FSC USFDA Valid Till  (07-11-2018) | | | Cobas® TaqScreen Kit  Class D  (i) Cobas® TaqScreen MPX Test, v2.0  Shelf Life: 24 Months  **Size**:  96Tests  **Code**:  05969492190  (ii) Cobas® TaqScreen MPX Control Kit, v2.0  Shelf Life: 24 Months  **Size**:  6 Sets  **Code**:  05965411190 | | | | Qualitative in vitro test for the direct detection of HIV-1, Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA and HBV DNA in human plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,Sandhofer Str.116, 68305 Mannheim, Germany  FSC Germany Issuance Data  (19-09-2016) | | | Cobas®Elecsys Anti-HBc IgM Kit  Class D  (i) Cobas®Elecsys Anti-HBc IgM  Shelf Life: 15 Months  **Size:**  100 Tests  **Code:**  11820567122  (ii) Cobas®Elecsys Anti-HBc IgM II  Shelf Life: 15 Months  **Size:**  300 Tests  **Code:**  07026811190  (iii) Cobas®ElecsysPreciControl Anti-HBc IgM  Shelf Life: 24 Months  **Size**:  16x1.0mL  **Code**:  11876333122 | | | | Immunoassay for the in vitro qualitative determination of IgM antibodies to  the hepatitis B core antigen in human serum and plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  FSC Germany Issuance Data  (19-09-2016) | | | Cobas®Elecsys HBeAg Kit  Class D  (i) Cobas®Elecsys HBeAg  Shelf Life: 24 Months  **Size:**  100 Tests  **Code:**  11820583 122  (ii) Cobas®Elecsys HBeAg  Shelf Life: 24 Months  **Size:**  300 Tests  **Code:**  07027427190  (iii) Cobas®Elecsys PreciControl HBeAg  Shelf Life: 21 Months  **Size**:  16x1.3mL  **Code**:  11876376122 | | | | Immunoassay for the in vitro qualitative determination of hepatitis B e antigen (HbeAg) in human serum & plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  FSC Germany Issuance Data  (19-09-2016) | | | Cobas®Elecsys Anti-HBs Kit  Class D  (i) Cobas®Elecsys Anti-HBs  Shelf Life: 15 Months  **Size:**  100 Tests  **Code:**  11820524122  (ii) Cobas®ElecsysAnti-HBs II  Shelf Life: 15 Months  **Size:**  100 Tests  **Code:**  05894816190  (iii) Cobas®ElecsysAnti-HBs II  Shelf Life: 15 Months  **Size**:  200 Tests  **Code**:  06771823190  (iv) Cobas®Elecsys Anti-HBs II  Shelf Life: 15 Months  **Size:**  300 Tests  **Code:**  07026854190  (v) Cobas®Elecsys PreciControl Anti-HBs  Shelf Life: 23 Months  **Size:**  16x1.3mL  **Code:**  11876317122 | | | | Immunoassay for the in vitro qualitative determination of hepatitis B e antigen (HbeAg) in human serum & plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  (FSC Germany Issuance Date  19-09-2016) | | | Cobas Elecsys Troponin I IVD Test Kit  (i) Cobas® Elecsys Troponin I  Class C  Shelf Life: 15 Months  Size: 300 Tests  Code: 07028059190  (ii) Cobas® Elecsys CalSet Troponin I  Class C  Shelf Life: 18 Months  Size: 4x1.0ml  Code: 07439547190  (iii) Cobas® Elecsys Troponin I Stat  Class C  Shelf Life: 15 Months  Size: 100 Tests  Code: 05094798  (iv) Cobas® Elecsys Troponin I Stat Calset  Class C  Shelf Life: 18 Months  Size: 4x1.0ml  Code: 05094801  (v) Cobas® Elecsys Troponin I  Class C  Shelf Life: 15 Months  Size: 100 Tests  Code: 05094810  (vi) Cobas® Elecsys Troponin I CalSet  Class C  Shelf Life: 18 Months  Size: 4x1.0ml  Code: 05094828 | | | | Immunoassay for the in Vitro Quantitative Determination of Cardiac Troponin I in Human Serum and Plasma  (IVD Test Kit) | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  (FSC Germany Issuance Date  19-09-2016) | | | Cobas® Elecsys Troponin / Cobas Roche Cardiac Assay  (i) Cobas® Elecsys Troponin T hs Stat  Class C  Shelf Life: 18 Months  Size: 100 Tests  Code: 05092728190  (ii) Cobas® Elecsys Troponin T hs Stat CalSet  Class C  Shelf Life: 18 Months  Size: 4x1.0ml  Code: 05092736190  (iii) Cobas® Elecsys Troponin T hs  Class C  Shelf Life: 18 Months  Size: 200 Tests  Code: 05092744190  (iv) Cobas® Elecsys Troponin T hs Calset  Class C  Shelf Life: 18 Months  Size: 4x1.0ml  Code: 05092752190  (v) Cobas® Elecsys Troponin T hs  Class C  Shelf Life: 18 Months  Size: 300 Tests  Code: 07028075190  (vi) Cobas® Elecsys Troponin T hs CalSet  Class C  Shelf Life: 18 Months  Size: 4x1.0ml  Code: 07401671190  (vii) Cobas® Elecsys PreciControl Troponin  Class C  Shelf Life: 18 Months  Size: 4x2.0ml  Code: 05095107190  (viii) Cobas® TROPT Sensitive  Class C  Shelf Life: 21 Months  Size: 10 Tests  Code: 11621904193  (ix) Cobas® Roche Cardiac T Quantitative  Class C  Shelf Life: 18 Months  Size: 10 Tests  Code: 04877772190  (x) Cobas® Roche Cardiac Control Troponin T  Class C  Shelf Life: 18 Months  Size: 2x1.0ml  Code: 04890515190  (xi) Cobas® Roche Cardiac POC Troponin T  Class C  Shelf Life: 18 Months  Size: 10 Tests  Code: 07007302190  (xii) Cobas® Roche Cardiac POC Troponin T Control  Class C  Shelf Life: 18 Months  Size: 2x1.0ml  Code: 07089643190 | | | | Immunoassay for the in Vitro Quantitative Determination of Cardiac Troponin I in Human Serum and Plasma  (IVD Test Kit) | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  (FSC Germany Issuance Date  19-09-2016) | | | Cobas® Elecsys CK MB Kits  Class C  (i) Cobas® Elecsys CK-MB STAT  Code: 05957648  Size: 100 Tests  Shelf Life: 18 Months  (ii) Cobas® Elecsys CK-MB  Size: 100 Tests  Code: 07027087190  Shelf Life: 18Months  (iii) Cobas® CK-MB STAT CalSet  Size: 4x1mL  Code: 05957656  Shelf Life: 18Months  (iv) Cobas® Roche Cardiac CK-MB  Size: 10 Tests  Code: 04877900  Shelf Life: 12Months  (v) Cobas® Roche Cardiac Control CK-MB  Size: 2x1mL  Code: 04890426  Shelf Life: 12Months  (vi) Cobas® Elecsys CKMB  Size: 2x50 Tests  Code: 07442050190  Shelf Life: 12Months  (vii) Cobas® CKMB  Size: 100 Tests  Code: 07190808190  Shelf Life: 12Months  (viii) Cobas® C.f.a.s. CK-MB  Size: 3x1mL  Code: 11447394  Shelf Life: 24Months | | | | Immunoassay for the in vitro Quantitative Determination of the  MB isoenzyme of Creatine Kinase in human serum and plasma. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116,  68305 Mannheim, Germany  (FSC Germany Issuance Date  19-09-2016) | | | Cobas® CK Kits  Class C  (i) Cobas® CK  Code: 07442017190  Size: 2x100 Tests  Shelf Life: 12 Months  (ii) Cobas® CK  Size: 200 Tests  Code: 07190794190  Shelf Life: 12Months | | | | In vitro test for the quantitative determination of Creatine Kinase (CK) in  human serum and plasma on the cobas c 111 system. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Diagnostics GmbH,  Sandhofer Str.116, 68305 Mannheim, Germany  (FSC Germany Issuance Date  19-09-2016) | | | Cobas Roche Cardiac ProBNP Kit  Class C  (i) Cobas® Elecsys ProBNP II  Size: 100 Tests  Code: 04842464  Shelf Life:18 Months  (ii) Cobas® Elecsys ProBNP II CalSet  Size: 4x1mL  Code: 04842472  Shelf Life: 18Months  (iii) Cobas® Elecsys ProBNP II STAT  Size: 100 Tests  Code: 05390109  Shelf Life: 18Month  (iv)Cobas® Elecsys proBNP II STAT CalSet  Size: 4x1mL  Code: 05390117  Shelf Life: 18Month  (v) Cobas® Elecsys proBNP II  Size: 300 Tests  Code: 07027664190  Shelf Life: 18Month  (vi) Cobas® CalSet proBNP II  Size:4x1mL  Code:07360886190  Shelf Life: 18 Months  (vii) Cobas® Elecsys PreciControl Cardiac II  Size:4x2mL  Code:04917049  Shelf Life: 18 Months  (viii) Cobas® Elecsys Roche Cardiac pro BNP+  Size: 10 Tests  Code: 05533643  Shelf Life: 09 Months  (ix) Cobas® Elecsys Roche Cardiac proBNP  Size:2x1mL  Code:04890493  Shelf Life: 12 Months | | | | Cardiac Probe BNP Kit. | | | | **Approved**. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Roche Molecular System Inc., 1080 US Hwy 202, South Branchburg, NJ 08876, USA  (FSC USFDA Valid Till  03-06-2020) | | | Cobas AmpliPrep/Cobas Taqman HCV Quantitative Test, v2.0  Class: C  Size: 72 Tests  Shelf Life: 18 Months  Code: 05532264190 | | | | In vitro nucleic acid amplification test for the quantitation of Hepatitis C Virus (HCV) RNA genotypes 1 to 6 in human EDTA Plasma or Serum | | | | **Approved**. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | ProtectaTM XT VR  Class D  Shelf Life: 18Months  Model: D354VRG | | | | Single Chamber Implantable Defibrillator | | | | **Approved** subject to fresh Agency Agreement and add in label whether the product is MRI safe and combatible or not. | | | |
|  | -do- | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | ProtectaTM XT DR  Class D  Shelf Life: 18Months from the date of coonection of power source  Model: D354DRG | | | | Dual-Chamber Implantable Defibrillator | | | | **Approved** subject to fresh Agency Agreement and add in label whether the product is MRI safe and combatible or not. | | | |
|  | -do- | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | Evera MRITM XT VR SureScanTM  Class D  Shelf Life: 18Months  Model: DVMB2D4 | | | | Single Chamber Implantable Defibrillator | | | | **Approved** subject to fresh Agency Agreement and add in label whether the product is MRI safe and combatible or not. | | | |
|  | -do- | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | BravaTM Quad CRT-D  Class D  Shelf Life: 18Months after attachment with power supply  Model: DTBC2QQ | | | | Cardiac Resynchronization Therapy Implantable Defibrillator | | | | **Approved** subject to fresh Agency Agreement and add in label whether the product is MRI safe and combatible or not. | | | |
|  | -do- | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | ReliaTM IPG  Class D  Shelf Life: 18Months  Model: REVDD01 | | | | Dual Chamber Implantable pacemaker | | | | **Approved** subject to fresh Agency Agreement, stability data and add in label whether the product is MRI safe and combatible or not. | | | |
|  | -do- | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | BravaTM Quad CRT-D  Class D  Shelf Life: 18Months  Model: DTBC2Q1 | | | | Cardiac Resynchronization Therapy Implantable Defibrillator | | | | **Approved** subject to fresh Agency Agreement and add in label whether the product is MRI safe and combatible or not. | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020) | | | ADVIA Centaur EHIV Kit  (i) ADVIA Centaur HIV 1/O/2 Enhanced  Class D  Shelf Life: 10 Months  SMN: 10309022  (ii) ADVIA Centaur HIV 1/O/2 Enhanced Quality Control Material  Class D  Shelf Life: 12 Months  SMN: 10309010 | | | | Human Immunodeficiency Virus Type 1 and Type 2 Detection of Antibody (EHIV) Assay | | | | **Approved.** | | | |
|  | M/s Tek Enterprises, Office No. MZ-9, Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore  (ELI-00189) | **Marketed By:** M/s Asahi Intecc Co., Ltd., 1703 Wakita-cho, Moriyama-ku, Nagoya, Aichi, 463-0024, Japan  **Manufacturing Site:**  (i) M/s Asahi Intecc Co., Ltd., 3-100 Akatsuki-Cho, 489-0071 Seto, Aichi, Japan  (ii) M/s Asahi Intecc (Thailand) Co., Ltd., 158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 12000 Thailand  (FSC Japan Issuance Date  07-03-2017) | | | ASAHI PTCA Guide Wire  Class D  Shelf Life: 3 Years  (AG145000 ASAHI PTCA Guide Wire Light  AG141000 ASAHI PTCA Guide Wire Soft  AG142000 ASAHI PTCA Guide Wire Intermediate  AG141002 ASAHI PTCA Guide Wire Grand Slam  AG14M050 ASAHI PTCA Guide Wire Miracle 3  AG14M045 ASAHI PTCA Guide Wire Miracle 4.5  AG14M060 ASAHI PTCA Guide Wire Miracle 6  AG14M070 ASAHI PTCA Guide Wire Miracle 12  AG143090 ASAHI PTCA Guide Wire Conquest  AGH146000 ASAHI PTCA Guide Wire Rinato  AGP140001 ASAHI PTCA Guide Wire Fielder FC  AGP140002 ASAHI PTCA Guide Wire Fielder XT  AGH143090 ASAHI PTCA Guide Wire Conquest Pro  AGH143091 ASAHI PTCA Guide Wire Conquest Pro 12  AHW14S003S  ASAHI PTCA Guide Wire ULTIMATEbros 3  AHW14R001S  ASAHI PTCA Guide Wire ASAHI SION  AHW14R004S  ASAHI PTCA Guide Wire ASAHI SION blue  AHW14R017S  ASAHI PTCA Guide Wire ASAHI SION blue ES 190cm  APW14R010S ASAHI PTCA Guide Wire ASAHI SION black 190cm  AHW14R013S  ASAHI PTCA Guide Wire ASAHI SUOH 03 190cm  APW14R009S ASAHI Fielder XT-A  APW14R005S  ASAHI Fielder  XT-R  AHW10S302S ASAHI RG3  AHW14R007S  ASAHI Gaia First  AHW14R008S  ASAHI Gaia Second  AHW14R011S  ASAHI Gaia Third)  Fee: **Rs.50,000/-** | | | | Guide Wire | | | | **Approved.** | | | |
|  | -do- | **Marketed By:** M/s Asahi Intecc Co., Ltd., 1703 Wakita-cho, Moriyama-ku, Nagoya, Aichi, 463-0024, Japan  **Manufacturing Site:**  (i) M/s Asahi Intecc Co., Ltd., 3-100 Akatsuki-Cho, 489-0071 Seto, Aichi, Japan  (ii) M/s Asahi Intecc (Thailand) Co., Ltd., 158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 1200 Thailand  (FSC Japan Issuance Date  07-03-2017)  **Fee Rs.50,000/-** | | | ASAHI Corsair Microcatheter  Class D  Shelf Life: 3 Years  (CSW135-26N ASAHI Corsair Microcatheter, 2.6 Fr, Straight, 135cm  CSW150-26N ASAHI Corsair Microcatheter, 2.6 Fr, Straight, 150cm) | | | | Microcatheter | | | | **Approved.** | | | |
|  | -do- | **Marketed By:** M/s Asahi Intecc Co., Ltd., 1703 Wakita-cho, Moriyama-ku, Nagoya, Aichi, 463-0024, Japan  **Manufacturing Site:**  (i) M/s Asahi Intecc Co., Ltd., 3-100 Akatsuki-Cho, 489-0071 Seto, Aichi, Japan  (ii) M/s Asahi Intecc (Thailand) Co., Ltd., 158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 1200 Thailand  (FSC Japan Issuance Date  01-03-2017) | | | ASAHI ZenyteEX PTCA Guiding Catheter  Class D  Shelf Life: 3 Years  W6JL35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 3.5cm  W6JL40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.0cm  W6JL45-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.5cm  W6JL50-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 5.0cm  W6JL35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 3.5cm, Side Hole  W6JL40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.0cm, Side Hole  W6JL45-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.5cm, Side Hole  W6JL50-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 5.0cm, Side Hole  W6JL35-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 3.5cm, Short Tip  W6JL40-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.0cm, Short Tip  W6JL45-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.5cm, Short Tip  W6JL50-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 5.0cm, Short Tip  W6JL35-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 3.5cm, Short Tip, Side Hole  W6JL40-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.0cm, Short Tip, Side Hole  W6JL45-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 4.5cm, Short Tip, Side Hole  W6JL50-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Left 5.0cm, Short Tip, Side Hole  W6JR35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 3.5cm  W6JR40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.0cm  W6JR45-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.5cm  W6JR50-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 5.0cm  W6JR35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 3.5cm, Side Hole  W6JR40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.0cm, Side Hole  W6JR45-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.5cm, Side Hole  W6JR50-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 5.0cm, Side Hole  W6JR35-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 3.5cm, Short Tip  W6JR40-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.0cm, Short Tip  W6JR45-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.5cm, Short Tip  W6JR50-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 5.0cm, Short Tip  W6JR35-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 3.5cm, Side Hole  W6JR40-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.0cm, Side Hole  W6JR45-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 4.5cm, Side Hole  W6JR50-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Judkins Right 5.0cm, Side Hole  W6HS00-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Hockey Stick  W6HS00-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Hockey Stick, Side Hole  W6SA35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Shepherd Crook 3.5cm  W6SA40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Shepherd Crook 4.0cm  W6SC35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Special Curve 3.5cm  W6SC40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Special Curve 4.0cm  W6SC35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Special Curve 3.5cm, Side Hole  W6SC40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Special Curve 4.0cm, Side Hole  W6IM00-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Internal Mammary  W6IM00-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Internal Mammary, Side Hole  W6PB30-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Power Backup 3.0cm  W6PB35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Power Backup 3.5cm  W6PB40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Power Backup 4.0cm  W6PB30-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Power Backup 3.0cm, Side Hole  W6PB35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Power Backup 3.5cm, Side Hole  W6PB40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Power Backup 4.0cm, Side Hole  W6SP30-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 3.0cm  W6SP35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 3.5cm  W6SP37-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 3.75cm  W6SP40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 4.0cm  W6SP30-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 3.0cm, Side  Hole  W6SP35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 3.5cm, Side  Hole  W6SP37-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 3.75cm, Side Hole  W6SP40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Super Power Backup 4.0cm, Side Hole  W6MP01-0-X100  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Multi Purpose 1.0cm  W6MP02-0-X100  ASAHI ZenyteEX PTCA GUIDING CATHETER, 6Fr, Multi Purpose 2.0cm  W7JL35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 3.5cm  W7JL40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.0cm  W7JL45-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.5cm  W7JL50-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 5.0cm  W7JL35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 3.5cm, Side Hole  W7JL40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.0cm, Side Hole  W7JL45-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.5cm, Side Hole  W7JL50-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 5.0cm, Side Hole  W7JL35-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 3.5cm, Short Tip  W7JL40-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.0cm, Short Tip  W7JL45-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.5cm, Short Tip  W7JL50-0-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 5.0cm, Short Tip  W7JL35-2-X100S  ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 3.5cm, Short Tip, Side Hole  W7JL40-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.0cm, Short Tip, Side Hole  W7JL45-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 4.5cm, Short Tip, Side Hole  W7JL50-2-X100S ASAHI  ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Left 5.0cm, Short Tip, Side Hole  W7JR35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 3.5cm  W7JR40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.0cm  W7JR45-0-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.5cm  W7JR50-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 5.0cm  W7JR35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 3.5cm, Side Hole  W7JR40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.0cm, Side Hole  W7JR45-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.5cm, Side Hole  W7JR50-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 5.0cm, Side Hole  W7JR35-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right  3.5cm, Short Tip  W7JR40-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.0cm, Short Tip  W7JR45-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.5cm, Short Tip  W7JR50-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 5.0cm, Short Tip  W7JR35-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 3.5cm, Short Tip, Side Hole  W7JR40-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.0cm, Short Tip, Side Hole  W7JR45-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 4.5cm, Short Tip, Side Hole  W7JR50-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Judkins Right 5.0cm, Short Tip, Side Hole  W7HS00-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Hockey Stick  W7HS00-2-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 7Fr, Hockey Stick, Side Hole  W7SA35-0-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 7Fr, Shepherd Crook 3.5cm  W7SA40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Shepherd Crook 4.0cm  W7SC35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Special Curve 3.5cm  W7SC40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Special Curve 4.0cm  W7SC35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Special Curve 3.5cm, Side Hole  W7SC40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Special Curve 4.0cm, Side Hole  W7IM00-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Internal Mammary  W7IM00-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Internal Mammary, Side Hole  W7PB30-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Power Backup 3.0cm  W7PB35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Power Backup 3.5cm  W7PB40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Power Backup 4.0cm  W7PB30-2-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 7Fr, Power Backup 3.0cm, Side Hole  W7PB35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Power Backup 3.5cm, Side Hole  W7PB40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Power Backup 4.0cm, Side Hole  W7SP30-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 3.0cm  W7SP35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 3.5cm  W7SP37-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 3.75cm  W7SP40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 4.0cm  W7SP30-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 3.0cm, Side Hole  W7SP35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 3.5cm, Side Hole  W7SP37-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 3.75cm, Side Hole  W7SP40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Super Power Backup 4.0cm, Side Hole  W7MP01-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Multi Purpose 1.0cm  W7MP02-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 7Fr, Multi Purpose 2.0cm  W8JL35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 3.5cm  W8JL40-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.0cm  W8JL45-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.5cm  W8JL50-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 5.0cm  W8JL35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 3.5cm, Side Hole  W8JL40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.0cm, Side Hole  W8JL45-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.5cm, Side Hole  W8JL50-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 5.0cm, Side Hole  W8JL35-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left  3.5cm, Short Tip  W8JL40-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.0cm, Short Tip  W8JL45-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.5cm, Short Tip  W8JL50-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 5.0cm, Short Tip  W8JL35-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 3.5cm, Short Tip, Side Hole  W8JL40-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.0cm, Short Tip, Side Hole  W8JL45-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 4.5cm, Short Tip, Side Hole  W8JL50-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Left 5.0cm, Short Tip, Side Hole  W8JR35-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 3.5cm  W8JR40-0-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.0cm  W8JR45-0-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.5cm  W8JR50-0-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 8Fr, Judkins Right 5.0cm  W8JR35-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 3.5cm, Side Hole  W8JR40-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.0cm, Side Hole  W8JR45-2-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.5cm, Side Hole  W8JR50-2-X100 ASAHI ZenyteEX  PTCA GUIDING CATHETER, 8Fr, Judkins Right 5.0cm, Side Hole  W8JR35-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 3.5cm, Short Tip  W8JR40-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.0cm, Short Tip  W8JR45-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.5cm, Short Tip  W8JR50-0-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 5.0cm, Short Tip  W8JR35-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 3.5cm, Short Tip, Side Hole  W8JR40-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.0cm, Short Tip, Side Hole  W8JR45-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 4.5cm, Short Tip, Side Hole  W8JR50-2-X100S ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Judkins Right 5.0cm, Short Tip, Side Hole  W8MP01-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Multi Purpose 1.0cm  W8MP02-0-X100 ASAHI ZenyteEX PTCA GUIDING CATHETER, 8Fr, Multi Purpose 2.0cm | | | | PTCA Guiding Catheter | | | | **Approved.** | | | |
|  | M/s Sakuf Trading, 2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Baltacci (Selective and Hyperselective Catheter)  Class D  Shelf Life: 5 Years  BALTACCI 1,2F  BALTACCI 1,2FP  BALTACCI 1,5F  BALTACCI 1,8F  BALTACCI 1,8FP  BALTACCI B1  BALTACCIBDPE - BALTACCIBDPE100  Fee: 50,000/- | | | | Selective and Hyperselective Catheter | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Spirales (SPI) Flow Coils  Class D  Shelf Life: Five years  SPIøXLP18 –  SPIøXLP37 –  SPIF2, 5XLP10 | | | | Flow Coils | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | RYVA (Connection Device)  Class B  Shelf Life: Not Mention  Fee: 25000 submitted (25000 submitted earlier | | | | Connection Device | | | | **Approved** subject to provision of stability data and real time aging data. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Fargo (Guiding Catheters)  Class D  Shelf Life: 5 Years  Fee: 25000 submitted (25000 submitted earlier  FRGMIN4.2F120 FRGMIN4.2F120MP FRGMIN4.2F135 FRGMIN4.2F135MP  FRG6F115\_8  FRG6F105\_8MP  FRG6F115\_8  FRG6F115\_8MP  FRG6F125\_8  FRG6F125\_8MP  FRG6F135\_8  FRG6F135\_8MP  FRGMAX6F95\_8 FRGMAX6F95\_8MP FRGMAX6F105\_8 FRGMAX6F105\_8MP FRGMAX6F115\_8 FRGMAX6F115\_8MP FRGMAX6F125\_8 FRGMAX6F125\_8MP | | | | Guiding Catheters | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Gold Balloon (Embolization Latex Detachable Balloons)  Class D  Shelf Life: Not Mentioned  GOLDBAL1-  GOLDBAL2  GOLDBAL3  GOLDBAL4  GOLDBAL5  GOLDBAL12X13SP  Fee: 25000 submitted (25000 submitted earlier | | | | Embolization Latex Detachable Balloons | | | | **Approved** subject to provision of stability data and real time aging data. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | LEO+ / LEO+ Baby stent auto-expansible  Class D  Shelf Life: 5 years  LEO.3,5X12 - LEO.3,5X12\_SV - LEO.3,5X18 - LEO.3,5X18\_SV - LEO.3,5X25 - LEO.3,5X25\_SV - LEO.3,5X30 - LEO.3,5X30\_SV - LEO.3,5X35 - LEO.3,5X35\_SV - LEO.3,5X50 - LEO.3,5X50\_SV - LEO.4,5X15 - LEO.4,5X15\_SV - LEO.4,5X20 - LEO.4,5X20\_SV - LEO.4,5X25 - LEO.4,5X25\_SV - LEO.4,5X30 - LEO.4,5X30\_SV - LEO.4,5X40 - LEO.4,5X40\_SV - LEO.4,5X50 - LEO.4,5X50\_SV - LEO.4,5X75 - LEO.4,5X75\_SV - LEO.5,5X25 - LEO.5,5X25\_SV - LEO.5,5X30 - LEO.5,5X30\_SV - LEO.5,5X35 - LEO.5,5X35\_SV - LEO.5,5X50 - LEO.5,5X50\_SV - LEO.5,5X60 - LEO.5,5X60\_SV - LEO.5,5X75 - LEO.5,5X75\_SV - LEO.6,5X30 - LEO.6,5X30\_SV - LEO.6,5X35 - LEO.6,5X35\_SV - LEO.6,5X40 - LEO.6,5X40\_SV - LEO.6,5X60 - LEO.6,5X60\_SV - LEO.6,5X80 - LEO.6,5X80\_SV - LEO.7,5X35 - LEO.7,5X35\_SV-LEO.7,5X50 - LEO.7,5X50\_SV - LEO.7,5X70 - LEO.7,5X70\_SV - LEO.7,5X95 - LEO.7,5X95\_SV.LEO.2,0X8 - LEO.2,0X12 - LEO.2,0X15 - LEO.2,0X18 - LEO.2,0X25 - LEO.2,5X12 - LEO.2,5X18 - LEO.2,5X25 - LEO.2,5X30 - LEO.2,5X35 - LEO.3,0X12 - LEO.3,0X18 - LEO.3,0X25 - LEO.3,0X35.  Fee: 25000 submitted (25000 submitted earlier | | | | LEO+ / LEO+ Baby stent auto-expansible | | | | **Approved.** | | | |
|  | M/s Asto Life Sciences (Pvt). Ltd., 44/1, Block K, Model Town, Lahore  (ELI-00103) | **Legal Manufacturer/ Manufacturing Site:** M/s Becton Dickinson, S.A Camino de Valdeoliva, s/n 28750 San Agustin del Guadalix Madrid, Spain  (FSC Spain Valid Till  24-05-2020) | | | BD Spinal Needle  Class D  Shelf Life: 5 years  18G3.51N  20G 3.51N  22G 3.51N  23G 3.51N  25G 3.51N  26G 3.51N  27G 3.51N  Fee: 50,000/- | | | | Spinal Needle Quincke Type Point | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Legal Manufacture/ Manufacturer:** M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  **Manufacturer:** (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (FSC USFDA Valid Till  15-02-2019) | | | Endurity MRI (CRT-Ps)  Implantabale Cardiac Pulse Generators (Pacemakers) and  Class D  Shelf Life: 18 Months  Model: PM1172, PM2172 | | | | Pacemaker | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Manufacturer:**  (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (iii) St. Jude Medical  Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA  (FSC USFDA Valid Till  13-03-2019) | | | Endurity Core CRT-Ps  Implantabale Cardiac Pulse Generators (Pacemakers) and  Class D  Shelf Life: 18 Months  Model: PM1152, PM2152 | | | | Pacemaker | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Legal Manufacture/ Manufacturer:** M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  **Manufacturer:** (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (FSC USFDA Valid Till  15-02-2019) | | | Fortify AssuraTM DR  Class D  Shelf Life: 02 Years  Model:CD2359-40Q, CD2359-40QC, MR Conditional | | | | Implantable Cardioverter Defibrillator | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Legal Manufacture/ Manufacturer:** M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  **Manufacturer:** (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (FSC Belgium issued on 21-04-2017) | | | Ellipse TM VR  Class D  Shelf Life: 02 Years  Model:CD1377-36Q, CD1377-36QC | | | | Tiered Therapy Cardioverter / Defibrillator | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Manufacturer:**  (i) M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  (ii) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St KM 67.5, Santana Industrial Park Arecibo, PR 00612, USA  (iii) M/s St. Jude Medical Operations (M) SDN BHD Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang 11900, Malaysia  (FSC USFDA Valid Till  13-03-2019) | | | Quadra Allure MP RF CRT-P)  Class D  Shelf Life: 02 Years  Model:PM 3262 | | | | Implantable Cardiac Pulse Generators (Pacemakers) and CRT-Ps  Cardiac Resynchronization Therapy Pacemaker | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Manufacturer:**  (i) M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  (ii) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St KM 67.5, Santana Industrial Park Arecibo, PR 00612, USA  (iii) M/s St. Jude Medical Operations (M) SDN BHD Plot 102, Lebuhraya Kampung Jawa Bayan Lepas Industrial Zone Penang, Pulau Pinang 11900, Malaysia  (FSC USFDA Valid Till  13-03-2019) | | | Tendril STS  Implantable Cardiac Pacing Leads (Bradycardia and Left Heart Leads)  Class D  Shelf Life: 02 Years  Model:2088TC | | | | Implantable Cardiac Pacing Leads | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Legal Manufacture/ Manufacturer:** M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  **Manufacturing Sites:** (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (FSC Belgium Issuance Date  23-10-2018) | | | Quadra AssuraTM  Class D  Shelf Life: 02 Years  Model: CD3367-40,  CD3367-40C | | | | Cardiac Resynchronization Device, Tiered-Therapy Cardioverter/ Defibrillator | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Legal Manufacture/ Manufacturer:** M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  **Manufacturing Sites:** (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (FSC Belgium Issuance Date  23-10-2018) | | | Durata TM  Class D  Shelf Life: 36 Months  Model: 7121Q-58, 7120Q-65 | | | | Implantable Defibrillator Lead | | | | **Approved.** | | | |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road, Saddar, Rawalpindi  (ELI-00199) | **Legal Manufacture/ Manufacturer:** M/s St. Jude Medical, Cardiac Rhythm Management Division, 15900 Valley View Ct Sylmar, CA 91342, USA  **Manufacturing Sites:** (i) M/s St. Jude Medical, Puerto Rico, LLC Lot a Interior No.2, St 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 Penang, Pulau Pinang 11900, Malaysia  (FSC Belgium Issuance Date  23-10-2018) | | | Quartet TM  Class D  Shelf Life: 03 Years  Model:1456Q-75 | | | | Left Heart Leads | | | | **Approved.** | | | |
|  | M/s SES Associates, 148-Ejaz Park Model Town Link Road, Lahore  (ELI-00041) | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical Mepro GmbH Am Soterberg 4 66620 Nonweiler-Otzenhausen, Germany  (FSC Germany issued on  28-05-2018) | | | Nit-Occlud® PDA-R  Class D  Shelf Life: 3 Years  Ref: 160102, 160103, 160104, 160105, 160106, 160107, 160108, 160112, 160113, 160114, 160115, 160116, 160117, 160118, 160119, 160120  Fee: 50000/- | | | | Cardiac Occluder | | | | **Approved** subject to provision of notarized Design Examination Certificate. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical Mepro GmbH Am Soterberg 4 66620 Nonweiler-Otzenhausen, Germany  (FSC Germany issued on  28-05-2018) | | | Nit-Occlud® ASD-R  Class D  Shelf Life: 3 Years  Ref: 160120, 160208, 160210, 160212, 160214, 160216, 160218, 160220, 160222, 160224, 160226, 160228, 160230  Fee: 50000/- | | | | Cardiac Occluder | | | | **Approved** subject to provision of notarized Design Examination Certificate. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical Mepro GmbH Am Soterberg 4 66620 Nonweiler-Otzenhausen, Germany  (FSC Germany Valid Till  27-05-2019) | | | Multi Snare®  Class B  Shelf Life: 3 Years  Ref: 147015, 147015V3, 147302, 147302V3, 147304, 147304V3, 147305,147305V3, 147310, 147310V3, 147315, 147315V3, 147320, 147320V3, 147330, 147330V3 | | | | Vascular Snare Catheter | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical Mepro GmbH Am Soterberg 4 66620 Nonweiler-Otzenhausen, Germany  (FSC Germany Valid Till  27-05-2019) | | | Angiographic Catheter  Class D  Shelf Life: 5 Years  Ref: 147401, 147411, 147431, 147440, 147471, 147481  Fee: 50000/- | | | | Angiographic Catheter, Single Use | | | | **Approved** subject to provision of translation of stability data in Englishlanguage. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical Mepro GmbH Am Soterberg 4 66620 Nonweiler-Otzenhausen, Germany  (FSC Germany Valid Till  27-05-2019) | | | Nit-Occlud® Implantation Sheath  Class B  Shelf Life: 3 Years  Ref: 600080, 700080  Fee: 25000/- | | | | Catheter Introducer | | | | **Approved** subject to provision of Notarized Design Examination Certificate and complete  Stability data. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical AG Wankelstrabe 60 50996 Koln, Germany  (FSC Germany Issuance Date  26-04-2018) | | | Nit-Occlud® PFO: Double Umbrella System for Interventional Closure of PFO (Patent Foramen Ovale)  Class D  Shelf Life: 3 Years  Ref: 182020, 182026, 182030  Fee: 50000/- | | | | Cardiac Occluder | | | | **Approved** subject to provision of Notarized Design Examination Certificate and complete  Stability data. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical AG Wankelstrabe 60 50996 Koln, Germany  (FSC Germany Issuance Date  26-04-2018) | | | Nit-Occlud® Le VSD  Class D  Shelf Life: 3 Years  Ref: 149086, 149106, 149126, 149128, 149148, 149168  Fee: 50000/- | | | | Cardiac Occluder | | | | **Approved** subject to provision of Notarized Design Examination Certificate. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s pfm medical AG Wankelstrabe 60 50996 Koln, Germany  (FSC Germany Issuance Date  26-04-2018) | | | Nit-Occlud® PDA Spiral System For Interventional Closure of PDA (Patent Ductus Arteriosus)  Class D  Shelf Life: 3 Years  Ref: 143106, 143126, 143146, 145044, 145054, 145065, 145076, 145096, 145116  Fee: 50000/- | | | | Cardiac Occluder | | | | **Approved** subject to provision of Notarized Design Examination Certificate and complete  Stability data. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s QualiMed Innovative Medizinproduket GmbH, BoschstraBe 16 D-21423 Winsen, Germany  (FSC Germany Issuance Date  13-08-2013) | | | MAGMA  Rapamycin-Eluting Coronary Stent System  Class D  Shelf Life: 18 months  Fee: 50000/- | | | | Drug eluting Coronary Stent System | | | | **Approved** subject to provision of Embassy atteseted Free Sale Certificate and Esential Priniciple of Safety and Performance. | | | |
|  | M/s Lab Link Enterprises, M-203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi  (ELI-00007) | **Legal Manufacturer:**  M/s Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-Ku, Osaka-shi, Osaka, Japan  **Manufacturer:** M/s Nipro Corporation Odate Factory 8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5974, Japan  (FSC JAPAN Issuance Date  07-01-2013) | | | Nipro Safelet Cath  Class B  Shelf Life: 5 Years  Sizes: G-14, G- 16, G-18, G-20, G-22, G-24 | | | | IV Catheter | | | | **Approved** subject to provision of Embassy attested Free Sale Certificate. | | | |
|  | M/s Allmed Solutions, A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi  (ELI-00029) | **Manufactured By:** M/s Ameco Medical Industries, Industrial Zone B4-Part 119 East 10th of Ramadan City, Egypt  (FSC Egypt Issuance Date  10-06-2018) | | | Sterile Long Term Hemodialysis Catheters Kits and Accessories  Class D  Shelf Life: 36 Months  Codes as per Free Sale Certificate Applied | | | | Dialysis Catheters Kits and Accessories | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | M/s Mira Khan and Co., Correspondence Office (Flat No.414, 4th Floor Park Tower, F-10/3, Islamabad  Godown: House No.12/4, Swati Gate Hakimabad, Peshawar | **Manufacturer:** M/s RAYS S.p.A Via Francesco Crispi 26 – 60027 Osimo (AN) Italy  (FSC Italy Issuance Date  07-0-2018) | | | Rays Cotton Guaze  (Sterile/Non Sterile Cotton Guaze)  Class B  Shelf Life: 5 Years | | | | Cotton Gauze Swab | | | | **Approved.** | | | |
|  | M/s Noesis (Pvt) Ltd., SCB Main Annexe, I.I Chundrigar Road, Karachi  (ELI-00048) | **Manufacturer:** M/s Q-Med AB, Seminariegatan 21, SE-752 28 Uppsala, Sweden  (FSC Sweden Valid Till  01-03-2023) | | | Restylane Lidocaine  Class D  Shelf Life: 36 Months | | | | Sodium Hyaluronate (20mg) | | | | **Approved** for use as derma filler**.** | | | |
|  | -do- | **Manufacturer:** M/s Q-Med AB, Seminariegatan 21, SE-752 28 Uppsala, Sweden  (FSC Sweden Valid Till  01-03-2023) | | | Restylane Skinboosters Vital Lidocaine  Class D  Shelf Life: 36 Months | | | | Sodium Hyaluronate | | | | **Approved** for use as derma filler**.** | | | |
|  | -do- | **Manufacturer:** M/s Q-Med AB, Seminariegatan 21, SE-752 28 Uppsala, Sweden  (FSC Sweden Valid Till  01-03-2023) | | | Restylane Lyft Lidocaine  Class D  Shelf Life: 36 Months | | | | Sodium Hyaluronate | | | | **Approved** for use as derma filler**.** | | | |
|  | M/s Ghazi Brothers, Ghazi House, D-35, KDA Scheme No.1, Miran Muhammad Shah Road, Karachi  (ELI-00002) | **Legal Manufacturer/ Manufacturing Site:** M/s LG Chem Ltd., 129, Seokam-ro, Iksan-si, Jeollabuk-do, 54588, Korea  (FSC Korea Issuance Date  27-04-2017) | | | YVOIRE Contour  Class D  Shelf Life: 24 Months | | | | Dermal Filler, Dermal Tissue Reconstructive Material, Microbe-Derived | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s LG Chem Ltd., 129, Seokam-ro, Iksan-si, Jeollabuk-do, 54588, Korea  (FSC Korea Issuance Date  27-04-2017) | | | YVOIRE Classic Plus  Class D  Shelf Life: 24 Months | | | | Dermal Filler, Synthetic-Fluid Tissue Reconstructive Material, Anaesthetic | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s LG Chem Ltd., 129, Seokam-ro, Iksan-si, Jeollabuk-do, 54588, Korea  (FSC Korea Issuance Date  27-04-2017) | | | YVOIRE Volume Plus  Class D  Shelf Life: 24 Months | | | | Dermal Filler, Synthetic-Fluid Tissue Reconstructive Material, Anaesthetic | | | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | M/s Medinostic Healthcare (Pvt) Limited, B-18, SITE, Karachi  (ELI-00012) | **Manufacturer:** M/s Medimark Scientific Limited, 4 East Point, Seal High Street, Sevenoaks, Kent TN15 0EG, UK  (FSC UK issued on 21/06/2017) | | | Reprodis, Model: HLD4i  (Disinfectant for non-surgical invasive medical devices)  Class C  Shelf Life: 3 Years  Fee: 50,000/-  Codes as per Free Sale Certificate Applied | | | | Reprodis HLD4i High Level Instrument Disinfectant | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s Medimark Scientific Limited, 4 East Point, Seal High Street, Sevenoaks, Kent TN15 0EG, UK  (FSC UK issued on 21/06/2017) | | | Chemgene, Model: HLD4H Concentrate, Ready to use Spray, Wipes  (Disinfection of non-invasive medical devices)  Class B  Shelf Life: 3 Years  Fee: **Rs.50,000/-**  Codes as per Free Sale Certificate Applied | | | | Chemgene HLD4H High Level Medical Surface Disinfectant | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s Medimark Scientific Limited, 4 East Point, Seal High Street, Sevenoaks, Kent TN15 0EG, UK  (FSC UK issued on 21/06/2017) | | | Chemgene, Model: HLD4L Concentrate  Class C  Shelf Life: 3 Years  Fee:50,000  Codes as per Free Sale Certificate Applied | | | | Chemgene HLD4L High Level Disinfectant | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s PAL International Limited, of Bilton Way Lutterworth Leicestershire LE17 4JA, UK  (FSC UK Issuance Date  06-08-2018) | | | Medipal® 2% Chlorhexidine in 70% Alcohol non-Invasive Medical Devices Wipes  (Non-Invasive medical devices disinfectant)  Class: B  Shelf Life: 3 Years  Codes as per Free Sale Certificate Applied | | | | Chlorhexidine Digluconate 2% Propan-2ol 70% Water 28% | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s PAL International Limited, of Bilton Way Lutterworth Leicestershire LE17 4JA, UK  (FSC UK Issuance Date  06-08-2018) | | | Medipal® 2% Chlorhexidine in 70% Alcohol Skin Wipes  Class B  (Non-Invasive medical devices disinfectant)  Shelf Life: 3 Years  Codes as per Free Sale Certificate Applied | | | | Chlorhexidine Digluconate 2% Propan-2ol 70% Water 28% | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s PAL International Limited, of Bilton Way Lutterworth Leicestershire LE17 4JA, UK  (FSC UK Issuance Date  06-08-2018) | | | Medipal® Disinfectant Wipes  (Non-Invasive medical devices disinfectant)  Class B  Shelf Life: 3 Years  Fee: Rs.50,000/-  Codes as per Free Sale Certificate Applied | | | | N, N Didecyl-N, N-Dimethylammonium Chloride (contains 10% Propan-2-ol) 0.640%  N-(3-Aminopropyl)-N-dodecylpropane-1,3-Diamine 0.531%  Ethoxylate 0.555%  MGDA; Alanine, N, N Bis (carboxymethyl) – Trisodium salt 0.240%  Monoethanolamine 0.800%  Water 97.234% | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s PAL International Limited, of Bilton Way Lutterworth Leicestershire LE17 4JA, UK  (FSC UK Issuance Date  06-08-2018) | | | Medipal® Cholrine Disinfectant Wipes  (Non-Invasive medical devices disinfectant)  Class B  Shelf Life: 3 Years  Fee: **Rs.50,000/-**  Codes as per Free Sale Certificate Applied | | | | Sodium Hypochlorite 0.5% Sodium Cholride 4% Sodium Hydroxide 0.05% Water 95.45% | | | | **Approved.** | | | |
|  | -do- | **Manufacturer:** M/s PAL International Limited, of Bilton Way Lutterworth Leicestershire LE17 4JA, UK  (FSC UK Issuance Date  06-08-2018) | | | Medipal® Alcohol Disinfectant Wipes  (Non-Invasive medical devices disinfectant)  Class B  Shelf Life: 3 Years  Codes as per Free Sale Certificate Applied | | | | Propan-2-ol 70% & Water 30% | | | | **Approved.** | | | |
|  | M/s UDL Distribution (Pvt) Limited, 1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  (i) M/s Arrow International De Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panacericana Chihuahua, Chihuahua, CP 31200, Mexico  (ii) M/s Arrow International Inc., 312 Commerce Place Asheboro, NC 27203, USA  (iii) M/s Arrow International C.R. a.s. Jamska 2359/47 Zdar NAD Sazavou, Vysocina 591 01, Czech Republic  (iv) M/s Arrow International de Chihuahua S.A. de C.V. Ave. Washington 3701, Edificios 4 and 36 Colonia Complejo Industrial Las Americas Chihuahua, Chihuahua CP 31114, Mexico  (FSC USFDA Valid Till  10-07-2020) | | | Arrow Two Lumen You-Bend Hemodialysis Catheterization  Class D  Shelf Life: 5 Years  CU-13122-F, CV12122-UF,  CV-12142-UF, CV-13122-UF,  CV-15122-UF, CV-15142-UF | | | | Catheter | | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  (i) M/s Arrow International De Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panacericana Chihuahua, Chihuahua, CP 31200, Mexico  (ii) M/s Arrow International Inc., 312 Commerce Place Asheboro, NC 27203, USA  (iii) M/s Arrow International C.R. a.s. Jamska 2359/47 Zdar NAD Sazavou, Vysocina 591 01, Czech Republic  (iv) M/s Arrow International de Chihuahua S.A. de C.V. Ave. Washington 3701, Edificios 4 and 36 Colonia Complejo Industrial Las Americas Chihuahua, Chihuahua CP 31114, Mexico  (FSC USFDA Valid Till  10-07-2020) | | | Arrow Two Lumen Central Venous Catheters  Class D  Shelf Life: 5 Years  CS-12702-E,CS-12802,CS-15802-E,CS-16702,CS-16702-E,CS-17702,CS-17702-E, CV-12702,CV-16702,CV-16702-E,CV-17702,CV-17702-E,ES-14702  **Fee: Rs.50,000/-** | | | | Central Venous Catheters | | | | **Approved.** | | | |
|  | M/s Advance Cardiology System, 12, Al-Sehat Centre, Rafique H.J. Shaheed Road, Hotel Regent Plaza, Karachi  (ELI-00074) | **Legal Manufacturer:**  M/s BrosMed Medical B.V. Hogebrinkerweg 31 3871KM Hoevelaken, The Netherlands  **Manufacturer:** M/s BrosMed Medical Co., Ltd., 3F, 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan City, Guangdong Province, China  (FSC The Netherlands Valid Till  20-10-2023) | | | Apollo Balloon Dilatation Catheter  Class D  Shelf Life: 2 Years  802-2008 802-2010  802-2012 802-2015  802-2018 802-2208  802-2210 802-2212  802-2215 802-2218  802-2508 802-2510  802-2512 802-2515  802-2518 802-2708  802-2710 802-2712  802-2715 802-2718  802-3008 802-3010  802-3012 802-3015  802-3018 802-3208  802-3210 802-3212  802-3215 802-3218  802-3508  802-3510  802-3512  802-3515  802-3518  802-3708  802-3710  802-3712  802-3715  802-3718  802-4008  802-4010  802-4012  802-4015  802-4018  802-4508  802-4510  802-4512  802-4515  802-4518  802-5008  802-5010  802-5012  802-5015  802-5018  Fee: 50000/- | | | | PTCA Coronary Dilatation Balloon Catheter | | | | **Approved.** | | | |
|  | M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore  (ELI-00147) | **Authorized Representative:** M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20537 Hamburg, Germany  **Manufacturer:**  M/s Biosensors International Pte Ltd., 36 Jalan Tukang 619266, Singapore  (FSC Germany Issuance Date  22-07-2018) | | | Embolectomy Catheter  Class B  Shelf Life: 3 Years  Model: EL1440, EL1480, EL14100, EL1540, EL1580, EL1640, EL1680, EL1740, EL1780, EL3260, EL3280, EL13340, EL3380 | | | | Biosensors Embolectomy Catheter | | | | **Approved.** | | | |
|  | -do- | **Authorized Representative:** M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20537 Hamburg, Germany  **Manufacturer:**  M/s Biosensors International Pte Ltd., 36 Jalan Tukang 619266, Singapore  (FSC Germany Issuance Date  22-07-2018) | | | Pressure Monitoring Systems and Kits – Accutarans  Class B  Shelf Life: 3 Years  Model: AT 12-3, AT 24-30, AT 2448-3, AT 4812, AT 4812-3, AT 4812-30, AT 6008-3, AT 6012, AT 6012-3, AT 6024-30, AT 7212-3, AT 8004-30, AT 8006-3, AT 8008-3, AT 8406-3, AT2 2448-3, AT2 4812-3, AT2 6012-3, AT2 7212-3, AT2 8006-3, AT3 4812-3, AT3 6012-3, AT3 7212-3, AT BC-248A, AT2 BC-248A, AT2 BC 180-30, AT 2448-3-BP2, AT2 2448-3-BP2, AMT 12-3, AMT 24-30, AMT 2448-3, AMT 4812, AMT 4812-3, AMT 4812-30, AMT 6008-3, AMT 6012, AMT 6012-3, AMT 7212-3, AMT 8006-3, AMT 8008-3, AMT 8406-3, AT, AT-3, AT-30 AT 12-3, AT 24-30, AT 2448-3, AT 4812, AT 4812-3, AT 4812-30, AT 6008-3, AT 6012, AT 6012-3, AT 6024-30, AT 7212-3, AT 8004-30, AT 8006-3, AT 8008-3, AT 8406-3, AT2 2448-3, AT2 4812-3, AT2 6012-3, AT2 7212-3, AT2 8006-3, AT3 4812-3, AT3 6012-3, AT3 7212-3, AT BC-248A, AT2 BC-248A, AT2 BC 180-30, AT 2448-3-BP2, AT2 2448-3-BP2, AMT 12-3, AMT 24-30, AMT 2448-3, AMT 4812, AMT 4812-3, AMT 4812-30, AMT 6008-3, AMT 6012, AMT 6012-3, AMT 7212-3, AMT 8006-3, AMT 8008-3, AMT 8406-3, AT, AT-3, AT-30 | | | | Blood Pressure Monitoring System (Pressure Transducer) | | | | **Approved.** | | | |
|  | M/s Hospicare Systems, Mezzanine Floor, Rabbiya Garden, Block 3, MCHS, Shaheed-e-Millat Road, Karachi  (ELI-00274) | **Manufacturer:**  M/s Grifols Diagnostic Solutions Inc., 4560 Horton St, Emerville, CA 94608, USA  **Manufacturing Site**: 10808 willow court, San zdiego, CA 92127, USA  (FSC USFDA Valid Till  14-05-2020) | | | Procleix Ultrio Elite Assay (1000 and 5000 Test Kits)  Class D  Shelf Life: 24 Months  Fee: 50,000/-  REAGENTS:  Procleix Ultrio Elite Assay Kits (Internal Control Reagent,Amplification Reagent, Enzyme Reagent, Probe Reagent, Target Capture Reagent, Selection Reagent);  Procleix Ultrio Elite Assay Target Enhancer Reagent Kit (Target Enhancer Reagent):  Procleix Ultrio Elite Assay Calibrators Kit (Negative Calibrator, HIV Positive Calibrator, HCV Positive Calibrator, HBV Positive Calibrator);  Procleix Ultrio Elite Assay HIV, HCV, and HBV Discriminatory Probe Reagents Kit (HIV Discriminatory Probe Reagent, HCV Discriminatory Probe Reagent, HBV Discriminatory Probe Reagent);  Procleix Assay Fluids Kit (Wash Solution, Oil, Buffer for Deactivation Fluid);  Procleix Auto Detect Reagents Kit (Auto Detect 1, Auto Detect2);  ProcleixUltrioEliteAssayNegativeCalibrators NegativeCalibrators;ProcleixUltrioEliteAssayPositive Calibrators. | | | | Procleix Ultrio Elite Assay (Qualitative Test Kit) | | | | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | **Legal Manufacture:** M/s Lepu Medical (Europe) Cooperatief UA Abe Lenstra Boulevard 36 8448 JB Heerenveen, The Netherlands  **Manufacturer:** M/s Shanghai Shape Memory Alloy Co., Ltd 1F and 5F, Tower 41, No. 258 Xinzhuan Development District Shanghai 201612, China  (FSC Netherlands Valid Till  23-11-2021) | | | MemoPartTM Occluder Delivery System  Class D  Shelf Life: 3 Years  Fee: 50000/-  Sizes: | | | | MemopartTM Delivery System | | | | **Approved** subject to the specifications / codes available on Free Sale Certificate of Netherland**.** | | | |
| ODS-A-I-5F ODS-P/V-II-5F  ODS-A-I-6F ODS-P/V-II-6F  ODS-A-I-7F ODS-P/V-II-7F  ODS-A-I-8F ODS-P/V-II-8F  ODS-A-I-9F ODS-P/V-II-9F  ODS-A-I-10F ODS-P/V-II-10F  ODS-A-I-12F ODS-P/V-II-12F  ODS-A-I-14F ODS-P/V-II-14F  ODS-A-III-5F ODS-P/V-IV-5F  ODS-A-III-6F ODS-P/V-IV-6F  ODS-A-III-7F ODS-P/V-IV-7F  ODS-A-III-8F ODS-P/V-IV-8F  ODS-A-III-9F ODS-P/V-IV-9F  ODS-A-III-10F ODS-P/V-IV-10F  ODS-A-III-12F ODS-P/V-IV-12F  ODS-A-III-14F ODS-P/V-IV-14F | | | | | | | |
|  | -do- | **Legal Manufacture:** M/s Lepu Medical (Europe) Cooperatief UA Abe Lenstra Boulevard 36 8448 JB Heerenveen, The Netherlands  **Manufacturer:** M/s Shanghai Shape Memory Alloy Co., Ltd 1F and 5F, Tower 41, No. 258 Xinzhuan Development District Shanghai 201612, China  (FSC Netherlands Valid Till 23-11-2021) | | | MemoPartTM Patent Ductus Arterious (PDA) Occluder  Class D  Shelf Life: 3 Years | | | | | MemopartTM Occluder System | | | **Approved** subject to the specifications / codes available on Free Sale Certificate of Netherland**.** | | | |
| WBFDQ- II 06 WTWBFDQ- II 06  WBFDQ- II 08 WTWBFDQ- II 08  WBFDQ- II 10 WTWBFDQ- II 10  WBFDQ- II 12 WTWBFDQ- II 12  WBFDQ- II 14 WTWBFDQ- II 14  WBFDQ- II 16 WTWBFDQ- II 16  WBFDQ- II 18 WTWBFDQ- II 18  WBFDQ- II 20 WTWBFDQ- II 20  WBFDQ- II 22 WTWBFDQ- II 22  WBFDQ- I 04 WTWBFDQ- I 04  WBFDQ- I 05 WTWBFDQ- I 05  WBFDQ- I 06 WTWBFDQ- I 06  WBFDQ- I 07 WTWBFDQ- I 07  WBFDQ- I 08 WTWBFDQ- I 08  WBFDQ- I 09 WTWBFDQ- I 09  WBFDQ- I 10 WTWBFDQ- I 10  WBFDQ- I 11 WTWBFDQ- I 11  WBFDQ- I 12 WTWBFDQ- I 12  WBFDQ- I 13 WTWBFDQ- I 13  WBFDQ- I 14 WTWBFDQ- I 14  WBFDQ- I 16 WTWBFDQ- I 16  WBFDQ- I 18 WTWBFDQ- I 18  WBFDQ- I 20 WTWBFDQ- I 20  WBFDQ- I 22 WTWBFDQ- I 22 | | | | | | | |
|  | M/s Atco Pharma International (Private) Limited, B-18, S.I.T.E., Karachi  (ELI-00106) | **Manufactured By:** M/s CID S.p.A Strade per Crescentino s/n, 13040 Saluggia (VC), Italy  (FSC Italy Issuance Date  02-05-2018) | | | Cre8 EVO Amphilimus Eluting Coronary Stent  Class D  Shelf Life: 24 Months  Stent Length (mm):  9, 13,16,20,26,33,40 & 46  Stent Dia (mm):  2.25, 2.25, 2.75, 3.00, 3.50, 4.00 & 4.50 | | | | | Drug Eluting Stent | | | **Approved.** | | | |
|  | -do- | **Manufactured By:** M/s CID S.p.A Strada per Crescentino s/n, 13040 Saluggia (VC), Italy  **Manufacturer:** ALVIMEDICA TIBBI URUNLER SAN. VE DIS TIKARET A.S Istanbul Trakya Serbest Bolgesi Ferhatpasa Mah. Ataturk Bulv. Manolya Sok. No 7, 34540 Catalca-Istanbul Turkey  (FSC Italy Issuance Date  02-05-2018) | | | Fluydo Pegaso PTCA Balloon Catheter  Class D  Shelf Life: 3 Years  Balloon Length (mm):  10,15,20 & 30  Balloon Dia (mm):  1.5,2.0,2.5,3.0,3.5 & 4.0 | | | | | Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Balloon Catheter | | | **Approved.** | | | |
|  | M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi  (ELI-00011) | **Manufacturer:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  (FSC Germany Issuance Date  23-10-2018) | | | Cutimed® Gel  Class C  Shelf Life: 3 Years  72610-00 8g 10tubes  72610-01 15g 10tubes  72610-02 25g 10tubes  72610-03 15g 1tube | | | | | Cutimed® Gel is a transparent, amorphous hydrogel for wound bed preparation of dry or necrotic secondary healing wounds. | | | **Approved.** | | | |
|  | -do- | **Manufacturer:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  (FSC Germany Issuance Date  23-10-2018) | | | Cutimed® Cavity  Class C  Shelf Life: 3 Years  72621-00 5cmx6cm 10pounches  72621-01 10cmx10cm 10pounches  72621-00 15cmx2cm 10pounches  72621-00 15cmx15cm 5pounches | | | | | Cutimed® Cavity  Does a sterile wound dressing pad comprise polyurethane hydrophilic open-cell foam It is available in different sizes | | | **Approved.** | | | |
|  | M/s Matrix Medical Care, Flat No. 55/5, First Floor, Shadman, Lahore  (ELI-00124) | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till  28-05-2020) | | | Qraymed Syringe for Insulin  Class B  Shelf Life: 5 Years  QR06-0401, QR06-0402,  QR06-0403, QR06-0404,  QR06-0405, QR06-0406 | | | | | Insulin Syringe | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till  28-05-2020) | | | Qraymed Sterile Heparin Caps for single Use  Class B  Shelf Life: 5 Years  QR05-2001, QR05-2002 | | | | | Heparin Caps | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed I.V Cannula for single use  Class B  Shelf Life: 5 Years  Codes as per Free Sale Certificate Applied | | | | | IV Cannula | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Sterile Safety Auto Disable Syringe for single use  Class B  Shelf Life: 5 Years  QR06-0108, QR06-0109,  QR06-0110, QR06-0111,  QR06-0112, QR06-0113,  QR06-0114 | | | | | Auto Disable Syringe | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Stomach Tube  Class B  Shelf Life: 5 Years  QR08-501, QR08-502,  QR08-503, QR08-504, QR08-505  QR08-506, QR08-507, QR08-508  QR08-509 | | | | | Stomach Tube | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Feeding Tube  Class B  Shelf Life: 5 Years  QR08-0401, QR08-0402,  QR08-0403, QR08-0404 | | | | | Feeding Tube | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Nebulizer with Mask  Class B  Shelf Life: 5 Years  QR08-1301, QR08-1302,  QR08-1303, QR08-1304,  QR08-1305 | | | | | Nebulizer Mask | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Nelaton Catheter  Class B  Shelf Life: 5 Years  QR08-901, QR08-902, QR08-903  QR08-904, QR08-905, QR08-906  QR08-907, QR08-908, QR08-909  QR08-910, QR08-911, QR08-912  QR08-913, QR08-914, QR08-915  QR08-916, QR08-917,  QR08-1001, QR08-1002,  QR08-1003, QR08-1004,  QR08-1005, QR08-1006,  QR08-1007, QR08-1008,  QR08-1009, QR08-1010,  QR08-1011, QR08-1012,  QR08-1013, QR08-1014 | | | | | Nelaton Catheter | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Transfusion Sets for single use  Class B  Shelf Life: 5 Years  QR02-0101, QR02-0102,  QR02-0103, QR02-0104,  QR02-0105, QR02-0106 | | | | | Transfusion Set | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Scalp Vein Sets for single use  Class B  Shelf Life: 5 Years  QR07-0201, QR07-0202,  QR07-0203, QR07-0204,  QR07-0205, QR07-0206,  QR07-0207, QR07-0208,  QR07-0209, QR07-0210 | | | | | Scalp Vein Sets | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Suction Catheter  Class B  Shelf Life: 5 Years  QR08-0101, QR08-0102,  QR08-0103, QR08-0104,  QR08-0105, QR08-0106,  QR08-0107, QR08-0201,  QR08-0202, QR08-0203,  QR08-0204, QR08-0205,  QR08-0206, QR08-0207,  QR08-0301, QR08-0302,  QR08-0303, QR08-0304,  QR08-0305, QR08-0306,  QR08-0307 | | | | | Suction Catheter | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Three Way Stopcock and Extension Tube  Class B  Shelf Life: 5 Years  QR04-0201, QR04-0202,  QR04-0301, QR04-0302,  QR04-0401 , QR04-0402 | | | | | Three Way Stopcock and Extension Tube | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Sterile Hypodermic Needles for single use  Class B  Shelf Life: 5 Years  QR07-0101, QR07-0102,  QR07-0103, QR07-0104,  QR07-0105, QR07-0106,  QR07-0107, QR07-0108,  QR07-0109, QR07-0110,  QR07-0111, QR07-0112,  QR07-0113, QR07-0114,  QR07-0115, QR07-0116 | | | | | Hypodermic Needles | | | The product is **deferred** till the decision regarding assesment of potential of spread of blood borne diseases by hypodermic needle. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Sterile Hypodermic Syringes for single use  Class B  Shelf Life: 5 Years  QR06-0201, QR06-0202,  QR06-0203, QR06-0204,  QR06-0205, QR06-0206,  QR06-0207, QR06-0301,  QR06-0302, QR06-0303,  QR06-0304, QR06-0305,  QR06-0306, QR06-0307,  QR06-0308, QR06-0309,  QR06-0310 | | | | | Hypodermic Syringes | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Simple Oxygen Mask  Class B  Shelf Life: 5 Years  QR08-1201, QR08-1202,  QR08-1203, QR08-1204,  QR08-1205, QR08-1206,  QR08-1207, QR08-1208 | | | | | Oxygen Mask | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Infusion Sets with Burette  Class B  Shelf Life: 5 Years  QR03-100, QR03-150 | | | | | Infusions Sets | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till28-05-2020) | | | Qraymed Infusion Sets for single use  Class B  Shelf Life: 5 Years  QR01-0101, QR01-0102,  QR01-0103, QR01-0104,  QR01-0105, QR01-0106,  QR01-0107, QR01-0108,  QR01-0109, QR01-0201,  QR01-0202, QR01-0203,  QR01-0204, QR01-0205,  QR01-0301, QR01-0302,  QR01-0303, QR01-0304,  QR01-0401, QR01-0402,  QR01-0403, QR01-0501,  QR01-0502, QR01-0503 | | | | | Infusions Sets | | | **Approved.** The firm has provided the required documents. | | | |
|  | -do- | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till 28-05-2020) | | | Qraymed Nasal Cannula  Class B  Shelf Life: 5 Years  QR08-1101, QR08-1102,  QR08-1103, QR08-1104,  QR08-1105, QR08-1106,  QR08-1107, QR08-1108 | | | | | Nasal Cannula | | | **Approved.** The firm has provided the required documents. | | | |
|  | **Evaluator: Muhammad Ayub Naveed, AD, MDMC** | | | | | | | | | | | | | | | |
|  | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore  (ELI-00094) | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA **Manufacturing Sites:**  (1) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA  (2) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA  (FSC USFDA valid till 16-05-2020)  Fee Rs.50,000/- | | | Hi-Torque Power Turn Guide Wire  Class D  Shelf Life: 2Year | | | | | PTCA Guide Wire | | | **Approved.** | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC USFDA  valid till 05-08-2020)  Fee Rs.50,000/- | | | ChoICETM PT Guidewire with ICETM Hydrophilic Coating  Class D  Shelf Life: 24Months  H74912154011  08714729252467  0.014", 300cm, Straight  H74912154012  08714729150633  0.014", 300cm, Straight, 5 pk  H7491215401J1  08714729252474  0.014", 300cm, J Tip  H7491215401J2  08714729193708  0.014", 300cm, J Tip, 5 pk  H74912155011  08714729303039  0.014", 300cm, Straight  H74912155012  08714729177012  0.014", 300cm. Straight, 5 pk  H7491215501J1  08714729252498  0.014", 300cm, J Tip  H7491215501J2  08714729176947  0.014", 300cm, J Tip, 5 pk  H74912160011  08714729252504  0.014", 182cm, Straight  H74912160012  08714729150626  0.014", 182cm, Straight, 5 pk  H7491216001J1  08714729252511  0.014", 182cm, J Tip  H7491216001J2  08714729193715  0.014", 182cm, J Tip, 5 pk  H74912161011  08714729252528  0.014", 182cm, Straight  H74912161012  08714729176992  0,014", 182cm, Straight, 5 pk  H7491216101JI  08714729252535  0.014", 182cm, J Tip  H7491216101J2  08714729177005  0.014", 182cm, J Tip, 5 pk | | | | | Guidewires intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature. | | | **Approved** subject to valid Agency Agreement.  (Existing expired on 31st Dec, 2018). | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC USFDA  valid till 05-08-2020)  Rs. 50000/- | | | ChoiceTM PT Magnet Guidewire with ICETM Hydrophilic Coating  Class D  Shelf Life: 24Months  H7491216001M2  08714729877264  0.014', 182cm, Straight, 5 pk  H7491216001MJ2  08714729877271  0.014", 182cm, J Tip, 5 pk  H7491216101M2  08714729877288  0.014", 182cm, Straight, 5 pk  H7491216101MJ2  08714729877295  0.014', 182cm, J Tip, 5pk | | | | | Intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature. They are available with a nominal diameter of 0.014 in (0.37 mm) and in nominal lengths of 182 or 300 cm. These CV Guidewires contain a 304 stainless steel core wire. The proximal section of the core wire of all models is coated with polytetrafluoroethylene (PTFE) for lubricity. The distal end of the core wire is formed (flattened) to allow for shaping. | | | **Approved** subject to valid Agency Agreement (Existing expired on 31st Dec, 2018). | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | **Manufacturer:** M/s Shenzhen Shineyard  Medical Device Co., Ltd.  3F/Changfeng Industrial Block, No.3, LiuXian Road, Xin’an, Baoan District, ShenZhen, Guangdong, 518000, China  (FSC UK MHRA)  Fee Rs.100,000/- | | | PBMV Balloon Catheters Sets  Class D  Shelf Life: 2 Year  Codes Sizes  PBMV-14  PBMV-16  PBMV-18  PBMV-20  PBMV-24  PBMV-26  PBMV-28  PBMV-30 | | | | | Percutaneous Balloon Mitral Valvuloplasty  Balloon Catheter Set is  intended to dilate the mitral stenosis  using percutaneous balloon mitral  valvuloplasty (PBMV) technique,  which offers minimal invasive  therapy for patients with mitral stenosis. | | | **Approved**. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany  Issue 19-07-2018 )  Fee Rs.50,000/- | | | Alinity i rHTLV-I/II Kit  Class D  (1) Alinity i rHTLV-I/II Calibrator  07P6101  Shelf Life: 12 Months  (2) Alinity i rHTLV-I/II Controls 07P6110  Shelf Life: 12 Months  (3) Alinity i rHTLV-I/II Reagent Kit 07P6122 (2x100 Tests)  Shelf Life: 12 Months  (4) Alinity i rHTLV-I/II Reagent Kit 07P6132 (2 x 500 Test)  Shelf Life: 12 Month | | | | | In-vitro diagnostic Kit for the human T-lymphotropic virus Type I & II | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany  Issue 15-10-2018 )  Fee Rs.50,000/- | | | Alinity s HTLV I/II Kit  `  Class D  (1) Alinity s HTLV I/II Reagent Kit,  06P0755  Shelflife : 9 Months  Alinity s HTLV I/II Calibrator Kit,  06P0702  Shelflife : 9 Months  Alinity s HTLV I/II Assay Control Kit  06P0710  Shelflife : 9 Months  Alinity s HTLV I/II Release Control Kit  06P0712  Shelflife : 9 Months | | | | | In-vitro diagnostic Kit for the human T-lymphotropic virus Type I & II | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany  Issue 15-10-2018 )  Fee Rs.50,000/- | | | Alinity s Syphilis Kit,  Class D  Alinity s Syphilis Reagent Kit,  06P0955  Shelflife : 12 Months  Alinity s Syphilis Calibrator Kit  06P0902  Shelflife : 12 Months  ,  Alinity s Syphilis Assay Control Kit  06P0910  Shelflife : 12 Months  Alinity s Syphilis Release Control Kit  06P0912  Shelflife : 12 Months | | | | | In-vitro diagnostic Kit for qualitative detection of antibodies to treponema pallidum in Human Serum & Plasma. | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany  Issue 15-10-2018 )  Fee Rs.50,000/- | | | Alinity s Chagas Kit,  Class D  Alinity s Chagas Reagent Kit,  06P0845  Shelflife : 12 Months  Alinity s Chagas Calibrator Kit  06P0802  Shelflife : 12 Months  Alinity s Chagas Assay Control Kit  06P0810  Shelflife : 12 Months  Alinity s Chagas Release Control Kit  06P0812  Shelflife : 12 Months | | | | | In-vitro diagnostic Kit for detection of antibodies to trypanosome cruzi  ( Chagas Disease) | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany  Issue 19-07-2018 )  Fee Rs.50,000/- | | | Alinity s Anti-HCV Kit,  *(1) Alinity s Anti-HCV Reagent Kit,*  06P0455  Shelflife : 12 Months  *(2)Alinity s Anti-HCV Calibrator Kit,*  06P0402  Shelflife : 12 Months  *(3)Alinity s Anti-HCV Assay Control Kit*  06P0410  Shelflife : 12 Months  *Alinity s Anti-HCV Release Control Kit*  06P0412  Shelflife : 12 Months | | | | | In-vitro diagnostic Kit for qualitative detection of antibodies to Hepatitis C Virus | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany Issue 19-07-2018 )  Fee Rs.50,000/- | | | Alinity i HIV Ag/Ab Combo Kit  Class D  (1) Alinity i HIV Ag/Ab Combo Calibrators 08P0701  Shelf Life: 10 Months  (2) Alinity i HIV Ag/Ab Combo Controls 08P0710  Shelf Life: 10 Months  (3) Alinity i HIV Ag/Ab Combo Reagent Kit 08P0722 (2 x 100 Tests)  Shelf Life: 10 Months  (4) Alinity i HIV Ag/Ab Combo Reagent Kit 08P0732  Shelf Life: 10 Months | | | | | In-vitro diagnostic Kit for qualitative detection of HIV P24Ag/Ab to Human Immuno Deficiency Virus | | | **Approved.** | | | |
|  | M/s UDL DISTRIBUTION (PVT) LTD.  1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | **Legal Manufacturer:-**  Arrow International, Inc. 16 Elizabeth Drive, Chelmsford, MA 01824. USA  **Manufacturing Facility:-**  Arrow International, 312, commerce Place Asheboro, NC 27203,USA  (FSC USFDA validity  15-04-2020)  Fee Rs. 50,000/- | | | Wedge Pressure Balloon Catheter  Class D  Shelf Life : 2 years  I-07121,  AI-07122,  AI-07123,  AI-07124,  AI-07125,  AI-07126,  AI-07126-j,  AI-07127,  AI-07127-stc,  AI-07128A | | | | | The Balloon Wedge Pressure catheter is used in sampling blood to determine oxygen levels, and in measuring central venous, right ventricular, pulmonary artery, and pulmonary artery wedge pressures. The Double Wedge Pressure catheter also allows solution infusion with simultaneous measurement of pressure. | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:-**  Arrow International, Inc. 16 Elizabeth Drive, Chelmsford, MA 01824. USA  **Manufacturing Facility:-**  Arrow International, 312, commerce Place Asheboro, NC 27203,USA  (FSC USFDA validity  15-04-2020)  Fee Rs. 50,000/- | | | Arrow Berman Angiographic Balloon Catheters.  Class D  Shelf Life : 2 years  AI-07134,  AI-07130,  AI-07130-j,  AI-07130-j,  AI-07135,  AI-07131,  AI-07136,  AI-07132,  AI-07137,  AI-07138, | | | | | Angiographic Balloon catheters consist of radiopaque polyvinyl chloride (PVC) extruded tubing with internal lumens extending throughout its length. The catheters are marked in 10cm increments along the length of the tubing to indicate distance from the distal end and to aid in proper catheter placement. Catheter contains distinct balloon inflation and media injection lumens, which are situated parallel to each other within the catheter bodies. | | | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | **Legal Manufacturer:** M/s Microvention Europe: 30 bis rue du Vieil Abreuvior, 78100 Saint Germain en Laye, France  **Design & Development/ Production Site:** (1) M/s MicroVention, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA  (2) M/s MicroVention Costa Rica S.R.L Edificio B33 Zona Franca Coyol Alajuela, Costa Rica  (FSC France Issuance Date  08-09-2016)  Fee Rs.50,000/- | | | CASPERTM RX  Carotid Artery Stent System  Class D  Shelf Life: 3 Years  CPR-0520-143RX,  CPR-0530-143RX,  CPR-0540-143RX,  CPR-0616-143RX,  CPR-0625-143RX,  CPR-0630-143RX,  CPR-0718-143RX,  CPR-0725-143RX,  CPR-0730-143RX,  CPR-0820-143RX,  CPR-0825-143RX,  CPR-0830-143RX,  CPR-0840-143RX,  CPR-0920-143RX,  CPR-0930-143RX,  CPR-1020-143RX,  CPR-1030-143RX, | | | | | Carotid Artery Stent System | | | **Approved.** | | | |
|  | M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi  (ELI-00090) | **Manufacturer:**  M/s Changzhou Chunguang Medical Equipment Co., Ltd., Shijiaqiao Dongqing Zhenlu Town, Changzhou City, Jiangsu Province, China  (FSC China Valid Till  01-04-2019)  Fee Rs.25,000/- | | | Perfect + Disposable Surgical Hypodermic Needle  Class B  Shelf Life: 5 Years  Sizes: 21G, 22G, 23G, 24G, 26G, 27G) | | | | | Disposable Sterile Surgical Hypodermic Needle | | | **Approved**  subject to inspection of manufac-turer abroad under Rule 71 of MDR 2017. | | | |
|  | -do- | **Manufacturer:**  M/s Changzhou Chunguang Medical Equipment Co., Ltd., Shijiaqiao Dongqing Zhenlu Town, Changzhou City, Jiangsu Province, China  (FSC China Valid Till  01-04-2019)  Fee Rs.25,000/- | | | Perfect + Disposable Syringes  Class B  Shelf Life: 5 Years  Sizes: 30ml, 50ml | | | | | Disposable Syringes, Sterile with Needle | | | **Approved**  subject to inspection of manufac-turer abroad under Rule 71 of MDR 2017. | | | |
|  | -do- | **Manufacturer:** M/s Evereast Medical Products Group Co., Ltd., No.1 Wangzhuang Village, Shejia Town, Changyuan County, Henan 453400, China  (FSC China Valid Till22-05-2023) | | | K&K Zenith Disposable Endotracheal Tube, Sterile Wihtout Cuff  Class B  Shelf Life: 5 Years | | | | | Disposable Trachea Cannula | | | **Approved**  subject to inspection of manufac-turer abroad under Rule 71 of MDR 2017. | | | |
|  | M/s OBS Pakistan (Pvt) Limited., C-14, Manghopir Road, SITE, Karachi  (ELI-00003) | **Legal Manufacturer:** M/s Saten- Batiment Genavenir IV -1 rue Pierre Fontaine -9100 EVRY - France  **Manufacturing Site:** M/s Laboratories Pharmaster, Z.I, de Kraft – 67150 ERSTEIN - France  (FSC France Issuance Date  09-11-2015)  Fee Rs.100,000/- | | | Cationorm® Cationic Emulsion for Ophtalmic Use  Class C  Shelf Life: 3 Years | | | | | Cationic Emulsion for Ophtalmic Use | | | **Approved.** | | | |
|  | M/s  S. Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078) | **Manufactured By:** M/s JMS Healthcare PHL, Inc., Lot 2-B-1, Phase 1B, First Philippine Industrial Park, Special Economic Zone, 4232 Tanauan City, Batangas, Philippines  (FSC Philippines Valid Till  14-08-2023)  Fee Rs.50,000/- | | | JMS Blood Bag CPDA-1 (Q) 500+300ml x 3, 17G  (Quadruple Bag)  Class C  Shelf Life: 3Years  Size: Quadruple Bag | | | | | Blood Bag | | | **Approved**  subject to inspection of manufac-turer abroad under Rule 71 of MDR 2017. | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | Atellica IM HBct Kit  (i) Atellica IM Anti Hepatitis B Core Total  Class D  Shelf Life: 12 Months  SMN:10995597  (ii) Atellica IM Anti Hepatitis B Core Total Control (HBcT QC)  Class D  Shelf Life: 18 Months  SMN:10995598 | | | | | In-vitro diagnostic kit for detection of Total Antibodies to Hepatitis B Core (HBcT) Assay | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | Versant HIV-1 RNA 1.5 Kit  (i) Versant HIV-1 RNA 1.5 Assay (kPCR) 1 of 2  Class D  Shelf Life: 20 Months  SMN: 10729727  (ii) Versant HIV-1 RNA 1.5 Assay (kPCR) 2 of 2  Class D  Shelf Life: 20 Months  SMN: 10729728  (iii) Versant Sample Preparation 1.0 Reagents 1 of 2  Class D  Shelf Life: 25 Months  SMN: 10286026  (iv) Versant Sample Preparation 1.0 Reagents 2 of 2  Class D  Shelf Life: 25 Months  SMN: 10286027 | | | | | In-vitro diagnostic kit for detection of Human Immunodeficiency Virus Type 1 (HIV-1) | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | ADVIA Centaur HBeAg Kit  (i) ADVIA Centaur Hepatitis B e Antigen  Class D  Shelf Life: 24 Months  SMN:10291295  (ii) ADVIA Centaur HBe AG QC Material  Class D  Shelf Life: 19 Months  SMN:10291296 | | | | | In-vitro diagnostic kit for detection of Hepatitis B e Antigen (HBeAg) | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | Atellica IM aHBs2 Kit  (i) Atellica IM Anti-Hepatitis B Surface Antigen 2 (aHBs2)  Class D  Shelf Life: 24 Months  SMN: 10995453  (ii) Atellica IM Anti-Hepatitis B Surface Antigen 2 Quality Control (aHBs2 QC)  Class D  Shelf Life: 12 Months  SMN: 10995454 | | | | | In-vitro diagnostic kit for detection of antibodies to Hepatitis B Surface Antigen (aHBs2) Assay | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | ADVIA Centaur Anti-HBs2 Kit  (i) ADVIA Centaur Anti-HBs2  Class D  Shelf Life: 24 Months  SMN: 10286268  (ii) ADVIA Centaur Anti-HBs2 Quality Control Material  Class D  Shelf Life: 12 Months  SMN: 10283088 | | | | | Antibodies to Hepatitis B Surface Antigen (aHBs2) Assay | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till  31-12-2020)  Fee Rs.50,000/- | | | Atellica IM aHBcM Kit  (i) Atellica IM Hepatitis B Core Antigen (aHBcM)  Class D  Shelf Life: 18 Months  SMN:10995449  (ii) Atellica IM Hepatitis B Core Antigen Quality Control (aHBcM QC)  Class D  Shelf Life: 18 Months  SMN:10995450 | | | | | IgM Antibodies to Hepatitis B Core Antigen (aHBcM) Assay | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | Versent HBV DNA 1.0 (kPCR) Kit  (i) Versent HBV DNA 1.0 Assay (kPCR) Box 1 of 2  Class D  Shelf Life: 25 Months  SMN: 10282480  (ii) Versent HBV DNA 1.0 Assay (kPCR) Box 2 of 2  Class D  Shelf Life: 25 Months  SMN: 10282481  **(iii) Versant Sample Preparation 1.2 Box 1of 2**  **Class D**  **Shelf Life: 25 Months**  **SMN: 10629800**  **(iv) Versant Sample Preparation 1.2 Box 2 of 2**  **Class D**  **Shelf Life: 25 Months**  **SMN: 10629801** | | | | | Hepatitis B Virus (HBV) DNA Assay | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Issuance Date  27-04-2017)  Fee Rs.50,000/- | | | Atellica IM aHCV Kit  (i) Atellica IM Hepatitis C (aHCV)  Class D  Shelf Life: 12 Months  SMN:10995456  (ii) Atellica IM Hepatitis C (aHCV) Quality Control (aHCV QC)  Class D  Shelf Life: 12 Months  SMN:10995457 | | | | | The assay is an in vitro diagnostic immunoassay for the qualitative determination of immunoglobulin G (IgG) antibodies to hepatitis C virus (HCV) in human serum or plasma | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs.50,000/- | | | Versant HCV RNA 1.0 Kit  (i) Versant HCV RNA 1.0 Assay (kPCR) Box 1 of 2  Class D  Shelf Life: 25 Months  SMN:10469013  (ii) Versant HCV RNA 1.0 Assay (kPCR) Box 2 of 2  Class D  Shelf Life: 25 Months  SMN:10469014  (iii) Versant Sample Preparation 1.0 Reagents Box 1 of 2  Class D  Shelf Life: 25 Months  SMN:10286026  (iv) Versant Sample Preparation 1.0 Reagents Box 2 of 2  Class D  Shelf Life: 25 Months  SMN:10286027 | | | | | The assay for the quantitation of Hepatitis C virus (HCV) RNA in serum and plasma of HCV-infected individuals | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020) | | | ADVIA Centaur HBsAg Conformity  Class D  Shelf Life: 24 Months  SMN: 10309058 | | | | | Hepatitis B Surface Antigen (HBsII) Conformity Assay | | | **Approved.** | | | |
|  | -do- | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020) | | | Atellica IM HBs II Conformity  Class D  Shelf Life: 24 Months  SMN: 10995603 | | | | | Hepatitis B Surface Antigen (HBsII) Conformity Assay | | | **Approved.** | | | |
|  | M/s Sakuf Trading, 2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018)  Fee Rs.50,000/- | | | Sonic (Selective and Hyperselective Catheters)  Class D  Shelf Life: 18 Months  SONIC1,2F15 - SONIC1,2F25 - SONIC1,2F25.190 - SONIC1,2F35 - SONIC1,2F15SG - SONIC1,2F25SG - SONIC1,2F25.190SG - SONIC1,2F35SG - SONIC1,5F15 - SONIC1,5F25 - SONIC1,5F35 - SONIC1,5F45 - SONIC1,5F25 - SONIC1,5F15SG - SONIC1,5F25SG - SONIC1,5F35SG - SONIC1,5F45SG. | | | | | Selective and Hyperselective Catheters | | | **Approved.** | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site/ Manufacturer:**  M/s Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA  (FSC USFDA Valid Till  08-05-2020)  Fee Rs.50,000/- | | | Comet Pressure Guidewire  Class D  Shelf Life: 9 Months  GTIN  08714729875758  08714729904397 | | | | | Intravascular Haemodynamic Monitoring System Guidewire | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Manufacturing Site/ Manufacturer:**  M/s Hemoteq AG Adenauerstrabe 15 52146 Wurselen Germany  (FSC Germany Issuance Date  21-08-2018)  Fee Rs.50,000/- | | | Ranger TM SL Over-The-Wire Paclitaxel-Coated PTA Balloon Catheter  Class D  Shelf Life: 20 Months  (Codes and sizes as per FSC) | | | | | Catheter, Anioplasty, Balloon Dilatation | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer:** M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site/ Manufacturer:**  M/s Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA  (FSC Ireland Valid Till  05-03-2023)  Fee Rs.50,000/- | | | AngioJet TM Spiroflex TM VG Monorail TM Thrombectomy Set  Class D  Shelf Life: 2 Years  106608-002  106608-003  106608-004  106608-005  106608-006  106608-007 | | | | | Embolectomy / thrombectomy Suction Catheter | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Manufacturing Site/ Manufacturer:**  M/s Hemoteq AG Adenauerstrabe 15 52146 Wurselen Germany  (FSC Germany Issuance Date  21-08-2018)  Fee Rs.50,000/- | | | Ranger TM Over-the-Wire Paclitaxel-Coated PTA Balloon Catheter  Class D  Shelf Life: 20 Months  (Codes and sizes as per FSC) | | | | | Catheter, Anioplasty, Balloon Dilatation | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer:**  M/s Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA  (FSC USFDA Valid Till  03-05-2020)  Fee Rs.25,000/- | | | Rubicon TM 14 Support Catheter  Class B  Shelf Life: 3 Years  135 cm, 150 cm | | | | | Vascular Guide Catheter, Singel-Use | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer:**  M/s Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA  (FSC USFDA Valid Till  03-05-2020)  Fee Rs.25,000/- | | | Rubicon TM 18 Support Catheter  Class B  Shelf Life: 3 Years  90 cm, 135 cm, 150 cm | | | | | Vascular Guide Catheter, Singel-Use | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer:**  M/s Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311, USA  (FSC USFDA Valid Till  03-05-2020)  Fee Rs.25,000/- | | | Guidezilla TM Guide Extension Catheter  Class B  Shelf Life: 24 Months  Guidezilla:  145 cm, 5F-in-6F | | | | | Vascular Guide Catheter, Singel-Use | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer/ Contract Manufacturer:**  M/s AvailMed S.A. De C.V. C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A, Col. Cd. Industrial Tijuana, Baja California 22444, Mexico  (FSC USFDA Valid Till  25-12-2019)  Fee Rs.50,000/- | | | RunWay TM Guide Catheter  Class D  Shelf Life: 3 Years  Codes and sizes as per FSC of USFDA) | | | | | Guide Catheters are intended for use in general intravascular, coronary and peripheral applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature. | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer:**  M/s Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland  (FSC Ireland Valid Till  10-08-2020)  Fee Rs.25,000/- | | | XXL TM Vascular Balloon Dilatation Catheter  Class B  Shelf Life: 36 Months  XXL/12-2/5.8/75  XXL/12-2/5.8/120  XXL/12-4/5.8/75  XXL/12-4/5.8/120  XXL/14-2/5.8/75  XXL/14-2/5.8/120  XXL/14-4/5.8/75  XXL/14-4/5.8/120  XXL/12-6/5.8/75  XXL/14-6/5.8/75 | | | | | Catheter, Angioplasty, Balloon, Dilatation | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer/ Manufacturing Site:**  M/s Boston Scientific Corporation, 2546 First Street, Propark El Coyol, Alajuela 20904, Costa Rica  (FSC Ireland Valid Till  10-08-2020)  Fee Rs.50,000/- | | | OptiCross TM 40 MHz Coronary Imaging Catheter  Class D  Shelf Life: 07 Months  GTIN  08714729890393  08714729841351 | | | | | Ultrasound System, Imaging, Cardiovascular | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer/ Contract Manufacturer:**  M/s Boston Scientific Corporation, 2546 First Street, Propark El Coyol, Alajuela COSTA Rica 20904  **Name of Distributor:**  M/s Boston Scientific Corp., Marina Bay Cust, Fulfillment Center, 500 Commander Shea Boulevard Quincy, MA 02171, USA  (FSC USFDA Valid Till  19-12-2019)  Fee Rs.50,000/- | | | FilterWire EZ TM Embolic Protection System (3.5mm-5.5mm)  Class D  Shelf Life: 25 Months  (3.5 mm-5.5 mm) System , 190 cm  (3.5 mm-5.5 mm) System , 300 cm | | | | | Emboli Capture Guidewire | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer/ Manufacturing Site:**  M/s Boston Scientific Corporation, 2546 First Street, Propark El Coyol, Alajuela 20904, Costa Rica  (FSC USFDA Valid Till  08-05-2020)  Fee Rs.50,000/- | | | Ultra ICE Plus 9  MHz Intracardiac Echo Catheter  Class D  Shelf Life: 2.5 Years  UPN  M00499100  GTIN  08714729904373 | | | | | Ultrasound System, Imaging, Cardiovascular | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer/ Owner Operator:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer:**  M/s Boston Scientific Corporation, 302 Parkway, Global Park La Aurora, Heredia, Costa Rica  **Name of Distributor:**  M/s Boston Scientific Corp., Marina Bay Cust, Fulfillment Center, 500 Commander Shea Boulevard Quincy, MA 02171, USA  (FSC USFDA Valid Till  05-08-2020)  Fee Rs.25,000/- | | | V-14 TM Control Wire TM Guidewire with ICE TM Hydrophilic Coating  Class B  Shelf Life: 2 Years  V-14 Short Taper 182 Straight Tip  V-14 Short Taper 182 Angled Tip  V-14 Short Taper 300 Straight Tip  V-14 Short Taper 300 Angled Tip  V-14 Long Taper 182 Straight Tip  V-14 Long Taper 182 Angled Tip  V-14 Long Taper 300 Straight Tip  V-14 Long Taper 300 Angled Tip | | | | | Peripheral Vascular Guidewire, Manual | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | -do- | **Legal Manufacturer:**  M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturer:**  M/s Boston Scientific Limited, Ballybrit Business Park Galway, Ireland  (FSC Ireland Valid Till  12-04-2023)  Fee Rs.50,000/- | | | Carotid Wallstent TM Monorail TM Closed Cell Self-Expanding Stent  Class D  Shelf Life: 43 Months  5 mm x 30mm  7 mm x 30mm  7 mm x 40mm  7 mm x 50mm  9 mm x 30mm  9 mm x 40mm  9 mm x 50mm | | | | | Carotid Artery Stent | | | **Approved** subject to valid Agency Agreement. (Existing expired on 31st Dec, 2018). | | | |
|  | M/s Hashir Surgical Services  (i) Office No. 16, Street No.1, F-2, Phase 6, Hayatabad, Peshawar  (ii) Office No. 5, 2nd Floor, Syed's Tower, University Road, Peshawar  (iii) House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar  (ELI-00075) | **Legal Manufacture:**  M/s Jiangxi Fenglin Medical Appliances Co., Ltd., Fulin Road, Fuzhou City, Jiangxi 344100 Province China  (FSC Chnia Valid Till  01-01-2020)  **Fee Rs. 100,000/-** | | | Bio Soft Sterile Infusion Sets for Single Use  Class B  Shelf Life: 5 Years  Model:  A1, A2, A3, A4, B1, B2, B3, B4, C1, C2  Needle Size:  20G, 21G, 22G, 23G, 24G, 25G, 26G | | | | | Infusion Set | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | -do- | **Legal Manufacture:**  M/s Jiangxi Fenglin Medical Appliances Co., Ltd., Fulin Road, Fuzhou City, Jiangxi 344100 Province China  (FSC Chnia Valid Till  01-01-2020)  **Fee Rs. 100,000/-** | | | Bio Soft Sterile Burette Type Infusion Sets for Single Use  Class B  Shelf Life: 5 Years  Model:  50ml, 100ml, 150ml | | | | | Sterile Burette Type Infusion Set | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | -do- | **Legal Manufacture:**  M/s Jiangxi Fenglin Medical Technology Co., Ltd., FengCheng Industrial Park, FengCheng City, Jiangxi Province, China  (FSC Chnia Valid Till  11-01-2020)  **Fee Rs. 100,000/-** | | | URO Cath Foley Catheter (Latex Silicon Coated)  Class B  Shelf Life: 5 Years  Model: Latex Urethral Catheters  6FR, 8FR, 10FR, 12FR, 14FR , 16FR, 18FR, 20FR, 22FR, 26FR, 28FR, 30FR | | | | | Foley’s Catheter / Urethral Catheter | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | -do- | **Legal Manufacture:**  M/s Jiangxi Fenglin Medical Technology Co., Ltd., FengCheng Industrial Park, FengCheng City, Jiangxi Province, China  (FSC Chnia Valid Till  11-01-2020)  **Fee Rs. 100,000/-** | | | URO Cath 100% Silicon Foley Catheter  Class B  Shelf Life: 5 Years  Model: Silicone Urethral Catheters  6FR, 8FR, 10FR, 12FR, 14FR , 16FR, 18FR, 20FR, 22FR, 26FR, 28FR, 30FR | | | | | Foley’s Catheter | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | -do- | **Manufacture:**  M/s Jiangxi Fenglin Medical Technology Co., Ltd., FengCheng Industrial Park, FengCheng City, Jiangxi Province, China  (FSC Chnia Valid Till  11-01-2020)  **Fee Rs. 100,000/-** | | | Bio Soft Safety Infusion Sets with Needles  Class B  Shelf Life: 5 Years | | | | | Infusion Set | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | -do- | **Manufacture:**  M/s Jiangxi Fenglin Medical Technology Co., Ltd., FengCheng Industrial Park, FengCheng City, Jiangxi Province, China  (FSC Chnia Valid Till  11-01-2020)  **Fee Rs. 100,000/-** | | | Flow Cath IV Cannula with Injection Port  Class B  Shelf Life: 5 Years  Model:  14G,16G,18G,20G,22G,24G,26G | | | | | IV Cannula with Catheter | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | -do- | **Manufacture:**  M/s Jiangxi Fenglin Medical Technology Co., Ltd., FengCheng Industrial Park, FengCheng City, Jiangxi Province, China  (FSC Chnia Valid Till  11-01-2020)  **Fee Rs. 100,000/-** | | | Flow Cath IV Cannula with small wings  Class B  Shelf Life: 5 Years  Model:  14G,16G,18G,20G,22G,24G,26G | | | | | IV Cannula with Catheter | | | **Approved.**  The Products are already approved by Registration Board in its 259th Meeting since inspection of manufacturer aborad was conducted by the panel and recommended for registration. | | | |
|  | M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi  (ELI-00030) | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | DuoDERM CGF Dressing  Class D  Shelf Life: 60 Months  Rs. 50000/- | | | | | Control Gel Formula Dressing | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag Dressing  Class D  Shelf Life: 36 Months  10x10cm (403708)  15x15cm (403710)  Rs. 50000/- | | | | | Hydrofiber Dressing with Silver | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag+ Extra Dressing  Class D  Shelf Life: 24 Months  5x5cm (413566)  10x10cm (413567)  15x15cm (413568)  20x30cm (413569)  Rs. 50000/- | | | | | Enhanced Hydrofiber Dressing with Silver & Strengthening Fiber | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag+ WSF  Class D  Shelf Life: 24 Months  2x45cm (1x5PK) Ster Eur  413571  Rs. 50000/- | | | | | Enhanced Hydrofiber Ribbon Dressing with Silver & Strengthening Fiber | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag Dressing with Strengthening Fibre  Class D  Shelf Life: 36 Months | | | | | Hydrofiber Dressing with Silver & Strengthening Fibre | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | DuoDERM Extra Thin Dressing  Class D  Shelf Life: 60 Months  7.5x7.5cm (1x5PK) GB  187951 | | | | | Hydrocolloid Dressing | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag SCD DRS  Class D  Shelf Life: 24 Months  9cmx10cm (412009)  9cmx15cm (412010)  9cmx25cm (412011)  9cmx30cm (420670)  9cmx35cm (412012) | | | | | Hydrofiber Surgical Cover Dressing with Silver | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag Foam Adh (Heel, Sacral)  Class D  Shelf Life: 24 Months  10cmx10cm(x10) (420681)  19.8cmx14cm (x5) (420647)  20cmx16.9cm(x5) (420648) | | | | | Adhesive Silicon Hydrofiber Foam Dressing with Silver | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag Foam Non Adh  Class D  Shelf Life: 24 Months  10cmx10cm(x10) (420642)  15cmx15cm (x5) (420645) | | | | | Non-Adhesive Hydrofiber Foam Dressing with Silver | | | **Approved** subject to provision of GMP report. | | | |
|  | -do- | **Manufacturer:** M/s ConvaTec Limited., First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK  (FSC UK Issuance Date  12-03-2018) | | | Aquacel Ag Burn DRS FLT  Class D  Shelf Life: 24 Months  13cmx10cm(x5) (403786)  17cmx15cm (x5) (403787)  23cmx30cm (x5) (403788)  23cmx100cm (x3) (403789)  54cmx45cm (x3) (403790) | | | | | Hydrofiber Dressing with Silver Reinforced with Nylon/ | | | **Approved** subject to provision of GMP report. | | | |
|  | M/s Bio Medics Medical System, F-597, F-Block, Satellite Town, Rawalpindi  (ELI-00022) | **Manufacturer:** M/s Ideal Healthcare SDN. BHD. No.70 & 71, Jalan Sungai Tukang 2/1, Kawasan Perusahaan Sungai Tukang, 08000 Sungai Petani, Kedah, Malaysia  (FSC Malaysia Valid Till  02-05-2019) | | | Idealcare Sterile Latex Foley Catheter  Class B  Shelf Life: 5 Years   1. **2 Way Paediatric**  * IC23120605, IC23120805, IC23121005  1. **2 Way Standard**  * IC21111210, IC21111410, IC21111610, IC21111810, IC21112010, IC21112210, IC21112410, IC21112610, IC21112810, IC21113010, IC21111230, IC21111430, IC21111630, IC21111830, IC21112030, IC21112230, IC21112430, IC21112630, IC21112830, IC21113030  1. **3 Way Standard**  * IC25121610, IC25121810, IC25122010, IC25122210, IC25122410, IC25122610, IC25121630, IC25121830, IC25122030, IC25122230, IC25122430, IC25122630  1. **2 Way Premium Paediatric Foley Catheter**  * GD23120605, GD23120805, GD23121005  1. **2 Way Premium Foley Catheter**  * GD21111210, GD21111410, GD21111610, GD21111810, GD21112010, GD21112210, GD21112410, GD21112610, GD21111230, GD21111430, GD21111630, GD21111830, GD21112030, GD21112230, GD21112430, GD21112630  1. **3 Way Premium Foley Catheter**  * GD25121610, GD25121810, GD25122010, GD25122210, GD25122410, GD25122610, GD25121630, GD25121830, GD25122030, GD25122230, GD25122430, GD25122630  1. **3 Way Premium Hematuria Reinforced Foley Catheter Gold (Couvelaire)**  * GD25421830, GD25422030, GD25422230, GD25422430, GD25422630, GD25422060, GD25422260, GD25422460, GD25422660 | | | | | Foley Catheter | | | **Approved**.  The firm has provided Free Sale Certificate for Belgium (Reference Country). | | | |
|  | -do- | **Manufacturer:** M/s Ideal Healthcare SDN. BHD. No.70 & 71, Jalan Sungai Tukang 2/1, Kawasan Perusahaan Sungai Tukang, 08000 Sungai Petani, Kedah, Malaysia  (FSC MalaysiaValid Till 02-05-2019) | | | I.V. Catheter with Injection Valve, Sterile  Class B  Shelf Life: 5 Years  IC2002-14, IC2002-16,  IC2002-18, IC2002-20,  IC2002-22, IC2002-24,  IC2002-26 | | | | | Intravenous Catheter | | | **Approved**  The firm has provided Free Sale Certificate for Belgium (Reference Country). | | | |
|  | M/s Nasir Brothers, 22B, 2nd Floor, Zeenat Medicine Market, North Napire Road, Karachi  (ELI-00036) | **Manufacturer:** M/s Shanxian Runte Medical Instruments Co. Ltd., Nuanduan Wenhua Road, Shan County, Heze City, Shandong Province, China  (FSC China Valid Till  20-10-2020) | | | Suicon Sutures  (Surgical Absorbable Suture Chromic Catgut with Needle)  Class D  Shelf Life: Not Mentioned  Model: PGA, PGLA, CATGUT, PDO, PGCL | | | | | Surgical Suture Silk Braided with Needle | | | **Approved** subject to provision of Embassy Attested Free Sale Certificate of MHRA, UK and stability study. | | | |
|  | M/s Nasir Brothers, 22B, 2nd Floor, Zeenat Medicine Market, North Napire Road, Karachi  (ELI-00036) | **Manufacturer:** M/s Shanxian Runte Medical Instruments Co. Ltd., Nuanduan Wenhua Road, Shan County, Heze City, Shandong Province, China  (FSC China Valid Till  20-10-2020) | | | Suicon Suture  (Surgical Suture Silk Braided with Needle)  Class D  Shelf Life: Not Mentioned  Model: PGA, PGLA, CATGUT, PDO, PGCL | | | | | Surgical Sutures Chromic Catgut with Needle | | | **Approved** subject to provision of Embassy Attested Free Sale Certificate of MHRA, UK and stability study. | | | |
|  | M/s Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi  (ELI-000046) | **Manufactured By:** M/sSP Medical A/S Mollevej 1, DK-4653, Karise, Denmark  (FSC Denmark Valid Till  31-10-2019) | | | Accoat Guidewire  Class D  Shelf Life: 5 Years  Codes and Sizes as per submitted Free Sale Certificate. | | | | | Guidewire | | | **Approved** subject to provision of valid ISO 13485 and  and GMP Audit report | | | |
|  | -do- | **Manufactured By:** M/sSP Medical A/S Mollevej 1, DK-4653, Karise, Denmark  (FSC Denmark Valid Till  31-10-2019) | | | Poseidon Hydrophilic Nitinol Guide Wire  Class D  Shelf Life: 3 Years  Hy-N-S-ST-018-D-L,  Hy-N-S-ST-025-D-L,  Hy-N-S-ST-032-D-L, ………………… | | | | | Hydrophilic Nitinol Guide Wire | | | **Approved** subject to provision of valid ISO 13485 and  and GMP Audit report | | | |
|  | M/s. Cor-Med, , 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi.  (ELI-00226) | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630  (FSC USFDA Valid Till  01-07-2020) | | | Performa® Diagnostic Cardiology Catheter   Class D  Shelf Life: 3 Years | | | | | Angiogaphic catheter with marker bands may also be used for anatomical measurements | | | **Approved.** | | | |
| Codes and sizes for following family headname with codes as per USFDA FSC No. 12407-6-2018  Performa Judkins Left Catheters.  Performa Judkins Left Short Tip Catheters  Performa Judkins Right Catheters  Performa Judkins Right Short Tip Catheters  Performa Judkins Right Modified Catheters  Performa MultiPack Plus Angiographic Cardiology Catheters  Performa Left Coronary Bypass Catheters  Performa Right Coronary Bypass Catheters  Performa Amplatz Left Diagnostic Cardiology Catheter  Performa Amplatz Right Diagnostic Catheters  Performa Progressive Right Cononary Catheter  Performa Internal Mammary Catheter  Peforma Straight Cardiac Pigtail Catheters  Performa 145 Degree Cardiac Pigtail Catheters  Performa 155 Degree Cardiac Pigtail Catheters  Performa Pedriatic Judkins Right & Left Catheters  Performa Multi Purpose Catheters  Performa Sones Catheters  Performa Cardiac Multipack Catheters  Performa Left brachial / Radial Catheters  Performa Right brachial / Radial Catheters  Performa Internal Mammary Left Brachial/ Radial Catheters  Performa Amplatz Left Brachial/ Radial Catheters  Performa Headhunter Diagnostic Radiology Catheters  Performa Newton Catheters  Performa Newton Catheters  Performa Benston Catheters  Performa Vertebral Catheters  Performa Mani Catheters  Performa Simmons Catheters  Performa Cobra Catheters  Performa Hook Catheters  Performa Catheters with Stopcock  Performa modified cerebral catheters  Performa berenstein catheters  Performa straight selective catheters  Performa MW2 catheters  Performa shepherd Hook Catheters  Performa Renal Double Curve Catheters  Performa Hockey Stick Catheters  Performa AMIR Motarjeme Catheters  Peforma Mikeelsson Curve Catheters  Performa KA Catheters  Performa KA2 Catheters  Performa DVS A1 Catheter (10cm TaperTip)  Performa UHF Shepherd Flush Catheters  Performa Ultra Blous Flush Cahteters  Performa Ultra High flow Pigtail Flush Catheters  Performa Straight Flush Catheters  Performa Modified Hook Flush Catheters  Performa Modified Hook Selective Catheters  Performa Judkins Right Flat Wire to Round Wire Diagnostic Cardiology Catheters  Performa Radial MultiPack Plus Catheters  Miscellaneous Performa Catheters  Performa Radial Catheters  Performa Ultimate Radial Catheters  Performa MIV TM Radial Pigtail Ventriculogram Catheters  Performa Ultimate Catheters  Performa Van Curves | | | | | | | | | | | |
|  | M/s. Cor-Med, , 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi. | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630  (FSC USFDA Valid Till  01-07-2020) | | | Impress Diagnostic (Angiography Catheters)  Class D  Shelf Life: 3 Years | | | | | It is used for delivering radio opaque media to selected sites in the vascular system | | | | | **Approved.** | |
| Codes and sizes for following family headname with codes as per USFDA FSC No. 12407-6-2018  Impress Catheter (30cm) Angiographic Catheter  Impress Sheperd Flush Catheter  Impress Ultra Bolus Catheter  Impress Modified Bolus Catheter  Impress Pigtail Flush Catheter  Impress Straight Flush Catheter  Impress Modified Hook Flush Catheter  Impress Osborn Catheter  Impress Multipurpose A1 Catheters  Impress Hydrophilic Multipurpose A1 Catheter  Impress 30cm Catheters  Impress Ultimate 1 Catheter  Impress Uterine Artery Catheter  Impress Carnevale Catheter  Impress Sorin Catheter | | | | | | | | | |
|  | M/s. Cor-Med, , 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi. | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630 | | | InqWire Diagnostic Wire  Class D  Shelf Life: 3 Years  IQR35F150B, IQR35F150J3, IQR35F150J3F,  IQR35F150BST, IQR35F260J3, IQR35F150J3S | | | | | Merit Medical guide wire are used to facilitate the placement of devices during diagnostic and interventional procedures. | | | | | **Approved** | |
|  | M/s. Cor-Med, , 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi. | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630 | | | CONCIERGETM Guiding Catheter  Class D  Shelf Life: 3 Years | | | | | It is used for delivering radio opaque media to selected sites in the vascular system | | | | | **Approved** | |
| Codes and sizes for following family headname with codes as per USFDA FSC No. 12407-6-2018  ConciergeJudkins Right Guiding Catheter  ConciergeJudkins Left Guiding Catheter  Concierge Implatz Right Guiding Catheter  Concierge Implatz Left Guiding Catheter  Concierge Multipurpose Catheters  Concierge Left Coronary Bypass Catheter  Concierge Right Coronary Bypass Catheter  Concierge Internal Mammary Catheter  Concierge EL gamal Catheter  Concierge Renal Double Curve  Concierge SBS Catheter  Concierge SBS Modified Guiding Catheter  Concierge Guiding Excellence Ultimate Catheter | | | | | | | | | |
|  | M/s. Cor-Med, , 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi. | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630 | | | Merit Maestro (R) Micro Catheter  Class D  Shelf Life: 3 Years  2.8F Taperto 2.4F  2.8F Taperto 2.1F  2.8F NoTaper 2.5F  2.9F NoTaper | | | | | The merit microcatheter is intended for general intravascular use. Including peripheral and coronary vasculure. Once the sub selective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic material into vessels. The catheter should not be used in to cerebral vessels. | | | | | **Approved** | |
| **Evaluator: Mrs. Unum Zia Shamsi** | | | | | | | | | | | | | | | | |
|  | M/s Ferozsons Laboratories Limited.  P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC US FDA  valid till 05-08-2020) | | | PT2TM Guidewire  Class D  Shelf Life: 25 Months  H74938931010 08714729471103  0.014", Light, 185cm, Straight  H74938931012  08714729471110  0.014", Light, 185cm, Straight, 5 pk  H7493893101J0  08714729471127  0.014", Light, 185cm, J Tip  H7493893101J2  08714729471134  0.014", Light, 185cm, J Tip, 5 pk  H74938931020  08714729471141  0.014", Light, 300cm, Straight  H74938931022  08714729471158  0.014", Light, 300cm, Straight, 5 pk  H7493893102J0  08714729471165  0.014", Light, 300cm, J Tip  H7493893102J2  08714729471172  0.014", Light, 300cm, J Tip, 5 pk  H74938931030  08714729471189  0.014", Moderate, 185cm, Straight  H74938931032  08714729471196  0.014", Moderate, 185cm, Straight, 5 pk  H7493893103J0  08714729471202  0.014", Moderate, 185cm, J Tip  H7493893103J2  08714729471219  0.014", Moderate, 185cm, J Tip, 5 pk  H74938931040  08714729471226  0.014", Moderate, 300cm, Straight  H74938931042  08714729471233  0.014", Moderate, 300cm, Straight, 5 pk  H7493893104J0  08714729471240  0.014", Moderate, 300cm, J Tip  H7493893104J2  08714729471257  0.014", Moderate, 300cm, J Tip, 5 pk  Fee submitted: Rs.50,000/- | | | | | The PT2 Guidewires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during percutaneous transluminal coronary angioplasty (PTCA) or percutaneous transluminal angioplasty (PTA), or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora,Heredia,Costa Rica  (FSC USFDA  valid till 05-08-2020) | | | V–18TM Control Wire TM Guidewire with ICETM Hydrophilic Coating  Class B  Shelf Life: 24 Months  M001468480  08714729715566  V-18 / .018 / 8cm / 110cm  M001468500  08714729070184  V-18 / .018 / 8cm / 150cm  M001468520  08714729070191  V-18 / .018 / 8cm / 200cm  M001468540  08714729070207  V-18 / .018 / 8cm / 300cm  M001468560  08714729070214  V-18 / .018 / 12cm / 150cm  M001468580  08714729070221  V-18 / .018 / 12cm / 200cm  M001468600  08714729070238  V-18 / .018 / 12cm / 300cm  Fee submitted: Rs.50,000/- | | | | | The V-18 Control Wire guidewire is available in 110, 150, 200 and 300 cm lengths. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. This device is intended for peripheral use only.The distal segment of the guidewire contains a core wire that is jacketed with a radiopaque polymer and is coated with ICE hydrophilic coating. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation Two Scimed Place, Maple Grove, MN 55311, USA  (FSC Ireland  valid till 20-08-2020) | | | NC Emerge TM MONORAIL TM PTCA Dilatation Catheter  Class D  Shelf Life: 24 Months  H7493927606200  846833  NC Emerge MR OUS 6mm x 2.00mm  H7493927606220  846840  NC Emerge MR OUS 6mm x 2.25mm  H7493927606250  646857  NC Emerge MR OUS 6mm x 2.50mm  H7493927606270  846864  NC Emerge MR OUS 6mm x 2.75mm  H7493927606300  846871  NC Emerge MR OUS 6mm x 3.00mm  H7493927606320  846888  NC Emerge MR OUS 6mm x 3.25mm  H7493927606350  846895  NC Emerge MR OUS 6mm x 3.50mm  H7493927606370  846901  NC Emerge MR OUS 6mm x 3.75mm  H7493927606400  846918  NC Emerge MR OUS 6mm x4.00mm  H7493927606450  846925  NC Emerge MR OUS 6mm x 4.50mm  H7493927606500  846932  NC Emerge MR OUS 6mm x 5.00mm  H7493927608200  846949  NC Emerge MR OUS 8mm x 2.00mm  H7493927608220  846956  NC Emerge MR OUS 8mm x 2.25mm  H7493927608250  846963  NC Emerge MR OUS 8mm x 2.50mm  H7493927608270  846970  NC Emerge MR OUS 8mm x 2.75mm  H7493927608300  846987  NC Emerge MR OUS 8mm x 3.00mm  H7493927608320  846994  NC Emerge MR OUS 8mm x 3.25mm  H7493927608350  847007  NC Emerge MR OUS 8mm x 3.50mm  H7493927608370  847014  NC Emerge MR OUS 8mm x 3.75mm  H7493927608400  847021  NC Emerge MR OUS 8mm x 4.00mm  H7493927608450  847038  NC Emerge MR OUS 8mm x 4.50mm  H7493927608500  847045  NC Emerge MR OUS 8mm x 5.00mm  H7493927608550  847052  NC Emerge MR OUS 8mm x 5.50mm  H7493927608600  847069  NC Emerge MR OUS 8mm x 6.00mm  H7493927612200  847076  NC Emerge MR OUS 12mm x 2.00mm  H7493927612220  847083  NC Emerge MR OUS 12mm x 2.25mm  H7493927612250  847090  NC Emerge MR OUS 12mm x 2.50mm  H7493927612270  847106  NC Emerge MR OUS 12mm x 2.75mm  H7493927612300  847113  NC Emerge MR OUS 12mm x 3.00mm  H7493927612320  847120  NC Emerge MR OUS 12mm x 3.25mm  H7493927612350  847137  NC Emerge MR OUS 12mm x 3.50mm  H7493927612370  847144  NC Emerge MR OUS 12mm x 3.75mm  H7493927612400  847151  NC Emerge MR OUS 12mm x 4.00mm  H7493927612450  847168  NC Emerge MR OUS 12mm x 4.50mm  H7493927612500  847175  NC Emerge MR OUS 12mm x 5.00mm  H7493927612550  847182  NC Emerge MR OUS 12mm x 5.50mm  H7493927612600  847199  NC Emerge MR OUS 12mm x 6.00mm  H7493927615200  847205  NC Emerge MR OUS 15mm x 2.00mm  H7493927615220  847212  NC Emerge MR OUS 15mm x 2.25mm  H7493927615250  847229  NC Emerge MR OUS 15mm x 2.50mm  H7493927615270  847236  NC Emerge MR OUS 15mm x 2.75mm  H7493927615300  847243  NC Emerge MR OUS 15mm x 3.00mm  H7493927615320  847250  NC Emerge MR OUS 15mm x 3.25mm  H7493927615350  847267  NC Emerge MR OUS 15mm x 3.50mm  H7493927615370  847274  NC Emerge MR OUS 15mm x 3.75mm  H7493927615400  847281  NC Emerge MR OUS 15mm x 4.00mm  H7493927615450  847298  NC Emerge MR OUS 15mm x 4.50mm  H7493927615500  847304  NC Emerge MR OUS 15mm x 5.00mm  H7493927615550  847311  NC Emerge MR OUS 15mm x 5.50mm  H7493927615600  847328  NC Emerge MR OUS 15mm x 6.00mm  H7493927620200  847335  NC Emerge MR OUS 20mm x 2.00mm  H7493927620220  847342  NC Emerge MR OUS 20mm x 2.25mm  H7493927620250  847359  NC Emerge MR OUS 20mm x 2.50mm  H7493927620270  847366  NC Emerge MR OUS 20mm x 2.75mm  H7493927620300 847373  NC Emerge MR OUS 20mm x 3.00mm  H7493927620320  847380  NC Emerge MR OUS 20mm x 3.25mm  H7493927620350  847397  NC Emerge MR OUS 20mm x 3.50mm  H7493927620370  847403  NC Emerge MR OUS 20mm x 3.75mm  H7493927620400  847410  NC Emerge MR OUS 20mm x 4.00mm  H7493927620450  847427  NC Emerge MR OUS 20mm x 4.50mm  H7493927620500  847434  NC Emerge MR OUS 20mm x 5.00mm  H7493927620550  847441  NC Emerge MR OUS 20mm x 5.50mm  H7493927620600  847458  NC Emerge MR OUS 20mm x 6.00mm  H7493927630200  847465  NC Emerge MR OUS 30mm x 2.00mm  H7493927630220  847472  NC Emerge MR OUS 30mm x 2.25mm  H7493927630250  847489  NC Emerge MR OUS 30mm x 2.50mm  H7493927630270  847496  NC Emerge MR OUS 30mm x 2.75mm  H7493927630300  847502  NC Emerge MR OUS 30mm x 3.00mm  H7493927630320  847519  NC Emerge MR OUS 30mm x 3.25mm  H7493927630350  847526  NC Emerge MR OUS 30mm x 3.50mm  H7493927630370  847533  NC Emerge MR OUS 30mm x 3.75mm  H7493927630400  847540  NC Emerge MR OUS 30mm x 4.00mm  Fee submitted: Rs.50,000/- | | | | | The NC Emerge Monorail (MR) PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion in patients with atherosclerosis.  The catheter is on a Monorail™ (MR) platform. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited.  P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC USFDA Valid Till  05-08-2020) | | | RotaWireTM and wireClip TorquerTM Guidewire and Guidewire Manipulation Device  Class D  Shelf Life: 24 Months  H802228240020  08714729185871  RotaWire, 330cm, Floppy GW/wireClip  H802228240022  08714729195566  RotaWire, 330cm, Floppy GW/wireClip,5pk  H802232390010  08714729144168  RotaWire, 330cm, Extra Sup Wire/wireClip  H802232390012  08714729195573  RotaWire. 330cm, Extra Sup  Wire/wireClip,5 pk  Fee submitted: Rs.50,000/- | | | | | The RotaWire Guidewire is a single-use device that acts as a guide rail for the Rotalink™ Exchangeable Catheter, which is placed over the wire once access to the lesion has been obtained. In this capacity, the wire acts to maintain the abrasive burr within the lumen being treated during all phases of a procedure, including catheter placement, treatment, and retraction. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Multi-Loop 18 Fibered Platinum Coil  Class C  Shelf Life: 36 Months  M0013120430  4mm/7mm Multi-Loop-18 (Bx/1)  M0013120431  4mm/7mm Multi-Loop-18 (Bx/5)  Fee submitted: Rs 50,000/- | | | | | Non-Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Interlock TM Fibered IDC TM Occlusion System  Class C  Shelf Life: 36 Months  M001361480 Interlock 2D 2mm x 4cm  M001361490 Interlock 2D 2mm x 6cm  M001361500 Interlock 2D 3mm x 6cm  M001361510 Interlock 2D 3mm x 12cm  M001361520 Interlock 2D 4mm x 8cm  M001361530 Interlock 2D 4mm x 15cm  M001361540 Interlock 2D 5mm x 8cm  M001361550 Interlock 2D 5mm x 15cm  M001361560 Interlock 2D 6mm x 10cm  M001361570 Interlock 2D 6mm x 20cm  M001361580 Interlock 2D 8mm x 20cm  M001361590 Interlock 2D 10mm x 20cm  M001361600 Interlock 2D 10mm x 30cm  M001361610 Interlock 2D 12mm x 20cm  M001361620 Interlock 2D 12mm x 30cm  M001361630 Interlock 2D 14mm x 20cm  M001361640 Interlock 2D 14mm x 30cm  M001361920 Interlock 2D 10mm x 50cm  M001361930 Interlock 2D 14mm x 50cm  M001361940 Interlock 2D 18mm x 50cm  M001361950 Interlock 2D 20mm x 50cm  M001361960 Interlock 2D 22mm x 60cm  M001361740 Interlock VortX Diamond Coil 2mm x 3mm x 2.3cm  M001361750 Interlock VortX Diamond Coil 2mm x 4mm x 4.1cm  M001361760 Interlock VortX Diamond Coil 2mm x 5mm x 5.8cm  M001361770 Interlock VortX Diamond Coil 2mm x 6mm x 8cm  Fee submitted: Rs 50,000/- | | | | | Non Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | IDC TMInterlocking Detachable Coil  Class C  Shelf Life: 36 Months  M0013602040 IDC Interlocking Detachable Coils 2mm x 4cm  M0013603060 IDC Interlocking Detachable Coils 3mm x 6cm  M0013603100 IDC Interlocking Detachable Coils 3mm x 10cm  M0013604040 IDC Interlocking Detachable Coils 4mm x 4cm  M0013604080 IDC Interlocking Detachable Coils 4mm x 8cm  M0013604120 IDC Interlocking Detachable Coils 4mm x 12cm  M0013605080 IDC Interlocking Detachable Coils 5mm x 8cm  M0013605150 IDC Interlocking Detachable Coils 5mm x 15cm  M0013606100 IDC Interlocking Detachable Coils 6mm x 10cm  M0013606200 IDC Interlocking Detachable Coils 6mm x 20cm  M0013607100 IDC Interlocking Detachable Coils 7mm x 10cm  M0013607200 IDC Interlocking Detachable Coils 7mm x 20cm  M0013608100 IDC Interlocking Detachable Coils 8mm x 10cm  M0013608200 IDC Interlocking Detachable Coils 8mm x 20cm  M0013609100 IDC Interlocking Detachable Coils 9mm x 10cm  M0013609200 IDC Interlocking Detachable Coils 9mm x 20cm  M0033601010 IDC Interlocking Detachable Coils 10mm x 10cm  M0013601020 IDC Interlocking Detachable Coils 10mm x 20cm  M0013601210 IDC Interlocking Detachable Coils 12mm x 10cm  M0013601220 IDC Interlocking Detachable Coils 12mm x 20cm  M0013601410 IDC Interlocking Detachable Coils 14mm x 10cm  M0013601420 IDC Interlocking Detachable Coils 14mm x 20cm  M0013612040 IDC Interlocking Detachable Coils Soft 2mm x 4cm  M0013613060 IDC Interlocking Detachable Coils Soft 3mm x 6cm  M0013613100 IDC Interlocking Detachable Coils Soft 3mm x 10cm  M0013614040 IDC Interlocking Detachable Coils Soft 4mm x 4cm  M0013614080 IDC Interlocking Detachable Coils Soft 4mm x 8cm  M0013614120 IDC Interlocking Detachable Coils Soft 4mm x 12cm  M0013615080 IDC Interlocking Detachable Coils Soft 5mm x 8cm  M0013615120 IDC Interlocking Detachable Coils Soft 5mm x 12cm  Fee submitted: Rs 50,000/- | | | | | Non Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Jetstream TM SC Over the wire Atherectomy Catheter  Class C  Shelf Life: 24 Months  112260-002  JETSTREAM SC OTW Atherectomy Catheter 1.6mm  112260-003  JETSTREAM SC OTW Atherectomy Catheter 1.6mm  112262-002  JETSTREAM SC OTW Atherectomy Catheter 1.85mm  112262-003  JETSTREAM SC OTW Atherectomy Catheter 1.85mm  Fee submitted: Rs 50,000/- | | | | | Intended for use in Atherectomy of the Peripheral Vasculature. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited.  P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | 2D Helical-35 Fibered Platinum Coil  Class C  Shelf Life: 36 Months  M0013723020  2D Helical-35 Fibered Platinum Coil, 3mm x 20mm  M0013723040  2D Helical-35 Fibered Platinum Coil, 3mm x 40mm  M0013724030  2D Helical-35 Fibered Platinum Coil, 4mm x 30mm  M0013725030  2D Helical-35 Fibered Platinum Coil, 5mm x 30mm  M0013725050  2D Helical-35 Fibered Platinum Coil, 5mm x 50mm  M0013726040  2D Helical-35 Fibered Platinum Coil, 6mm x 40mm  M0013727040  2D Helical-35 Fibered Platinum Coil, 7mm x 40mm  M0013729060  2D Helical-35 Fibered Platinum Coil, 9mm x 60mm  M0013723021  2D Helical-35 Fibered Platinum Coil, 3mm x 20mm (Bx5)  M0013723041  2D Helical-35 Fibered Platinum Coil, 3mm x 40mm (Bx5)  M0013724031  2D Helical-35 Fibered Platinum Coil, 4mm x 30mm (Bx5)  M0013725031  2D Helical-35 Fibered Platinum Coil, 5mm x 30mm (Bx5)  M0013725051  2D Helical-35 Fibered Platinum Coil, 5mm x 50mm (Bx5)  M0013726041  2D Helical-35 Fibered Platinum Coil, 6mm x 40mm (Bx5)  M0013727041  2D Helical-35 Fibered Platinum Coil, 7mm x 40mm (Bx5)  M0013729061  2D Helical-35 Fibered Platinum Coil, 9mm x 60mm (Bx5)  Fee submitted: Rs 50,000/- | | | | | Is intended for arterial and venous embolization in the peripheral vasculature. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | VortX TM Diamond-18 Fibered Platinum Coil  Class C  Shelf Life: 36 Months  M0013822030 VortX-18 Diamond 3mm/3.3mm  M0013822040 VortX-18 Diamond 4mm/3.7mm  M0013822050 VortX-18 Diamond 5mm/5.5mm  M0013822060 VortX-18 Diamond 6mm/6.7mm  M0013822031 VortX-18 Diamond 3mm/3.3mm (BX/5)  M0013822041 VortX-18 Diamond 4mm/3.7mm (BX/5)  M0013822051 VortX-18 Diamond 5mm/5.5mm (BX/5)  M0013822061 VortX-18 Diamond 6mm/6.7mm (BX/5)  Fee submitted: Rs 50,000/- | | | | | Non Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Jetstream TM XC Over the wire Atherectomy Catheter  Class C  Shelf Life: 24 Months  112264-002  JETSTREAM XC OTW Atherectomy Catheter 2.1mm/3.0mm  112264-003  JETSTREAM XC OTW Atherectomy Catheter 2.1mm/3.0mm  112266-002  JETSTREAM XC OTW Atherectomy Catheter 2.4mm/3.4mm  112266-003  JETSTREAM XC OTW Atherectomy Catheter 2.4mm/3.4mm  Fee submitted: Rs 50,000/- | | | | | Mechanical Atherectomy System, Peripheral | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited.  P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | VortX TM 35 Fibered Platinum Coil  Class C  Shelf Life: 36 Months  M0013732040 VortX- 35 Fibered Platinum Coil 4mm x 4.0mm  M0013733050 VortX- 35 Fibered Platinum Coil 5mm x 4.5mm  M0013733060 VortX- 35 Fibered Platinum Coil 6mm x 5.0mm  M0013733070 VortX- 35 Fibered Platinum Coil 7mm x 5.5mm  M0013732041 VortX- 35 Fibered Platinum Coil 4mm x 4.0mm (BX 5)  M0013733051 VortX- 35 Fibered Platinum Coil 5mm x 4.5mm (BX 5)  M0013733061 VortX- 35 Fibered Platinum Coil 6mm x 5.0mm (BX 5)  M0013733071 VortX- 35 Fibered Platinum Coil 7mm x 5.5mm (BX 5)  Fee submitted: Rs 50,000/- | | | | | Non Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/sBoston Scientific Corporation, 780 Brookside Drive Spencer, IN 47460 USA  (FSC US FDAValid Till  30-03-2019) | | | Soloist TM Single Needle Electrode  Class C  Shelf Life: 36 Months  M001262500 08714729122487  Fee submitted: Rs 50,000/- | | | | | Soloist single needle electrode is intended to be used in conjunction with the RF3000 generator for the thermal coagulation, necrosis of soft tissues, including partial or complete ablationof non-resectable liver lesions. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Ballybrit Business Park, Galway Ireland  (FSC Ireland Valid Till  05-03-2023) | | | Express TM Vascular SD Premounted Stent System  Class C  Shelf Life: 36 Months  H74937917415900 Express SD 4.0/15/90  H74937918419900  Express SD 4.0/19/90  H74937917515900  Express SD 5.0/15/90  H74937918519900  Express SD 5.0/19/90  H74937917614900  Express SD 6.0/14/90  H74937918618900  Express SD 6.0/18/90  H74937917715900  Express SD 7.0/15/90  H74937918719900  Express SD 7.0/19/90  H74937917415150  Express SD 4.0/15/150  H74937918419150  Express SD 4.0/19/150  H74937917515150  Express SD 5.0/15/150  H74937918519150  Express SD 5.0/19/150  H74937917614150  Express SD 6.0/14/150  H74937918618150  Express SD 6.0/18/150  H74937917715150  Express SD 7.0/15/150  H74937918719150  Express SD 7.0/19/150  Fee submitted: Rs 50,000/- | | | | | Multiple Peripheral Artery Stent | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston ScientificCorporation300, Boston Scientific Way, Marlborough, Massachusetts 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Limited, Ballybrit Business Park, Galway Ireland  (FSC IrelandValid Till  12-04-2023) | | | 2cm Peripheral Cutting Balloon TM Over The Wire Microsurgical Dilatation Device  Class B  Shelf Life: 24 Months  M001BP35520B0 2cm PCB 5.00mm x 20mm x 135cm OUS  M001BP35620B0 2cm PCB 6.00mm x 20mm x 135cm OUS  M001BP35720B0 2cm PCB 7.00mm x 20mm x 135cm OUS  M001BP35820B0 2cm PCB 8.00mm x 20mm x 135cm OUS  M001BP50520B0 2cm PCB 5.00mm x 20mm x 50cm OUS  M001BP50620B0 2cm PCB 6.00mm x 20mm x 50cm OUS  M001BP50720B0 2cm PCB 7.00mm x 20mm x 50cm OUS  M001BP50820B0 2cm PCB 8.00mm x 20mm x 50cm OUS  M001BP90520B0 2cm PCB 5.00mm x 20mm x 90cm OUS  M001BP90620B0 2cm PCB 6.00mm x 20mm x 90cm OUS  M001BP90720B0 2cm PCB 7.00mm x 20mm x 90cm OUS  M001BP90820B0 2cm PCB 8.00mm x 20mm x 90cm OUS  Fee submitted: Rs 25,000/- | | | | | 2cm Peripheral Cutting Balloon TM Over The Wire Microsurgical Dilatation Device is indicated for PTA of obstructive lesions in peripheral vasculature | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | TruePath TM CTO Device  Class B  Shelf Life: 2 Years  Fee submitted: Rs 25,000/- | | | | | TruePath CTO is indicated to facilitate the intraluminal placement of the conventional guidewire beyond peripheral artery chronic total occlusion | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Owner Operator/**  **Legal Manufacturer:**  M/s M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA  (FSC US FDA Valid Till  03-05-2020) | | | CrossBoss TM Catheter  Class D  Shelf Life: 17 Months  H749M2000A0 M-200008714729837510  CrossBoss 6F x 135cm  H749M2000B0 M-200008714729837466  CrossBoss 6F x 135cm  H749M2000C0 M-200008714729846062  CrossBoss 6F x 135cm  Fee submitted: Rs 50,000/- | | | | | Vascular Guide Catheter, Single Use | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Owner Operator/**  **Legal Manufacturer:**  M/s M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA  (FSC US FDA Valid Till  03-05-2020) | | | Threader TM MonorailTM Micro-Dilatation Catheter  Class D  Shelf Life: 2 Years  H7493926912120 08714729848127  Threader MR 1.2mm x 12mm  Fee submitted: Rs 50,000/- | | | | | Coronary Angioplasty Balloon Catheter, Basic | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | GatewayTM Plus Y Adaptor  Class B  Shelf Life: 2 Years  H74904483102 GateWay PLUS Y-Adapter (10 pk)  M001153223 GateWay PLUS Y-Adapter (10 pk)  Fee submitted: Rs 25,000/- | | | | | Stopcock | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited.  P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Figure 8-18 Fibered Platinum Coil  Class C  Shelf Life: 3 Years  M0013120210 2mm/5mm Figure 8 – 18 (Bx/1)  M0013120211 2mm/5mm Figure 8 – 18 (Bx/5)  Fee submitted: Rs 50,000/- | | | | | Non-neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | RenegadeTM Hi-FloTM Microcatheter Kit  Class C  Shelf Life: 3 Years  M001182980 Renegade (1) Hi-Flo Microcatheter Kit 105/10  M001182990 Renegade (1) Hi-Flo Microcatheter Kit 105/20  M001183000 Renegade (1) Hi-Flo Microcatheter Kit 115/10  M001183010 Renegade (1) Hi-Flo Microcatheter Kit 115/20  M001183020 Renegade (1) Hi-Flo Microcatheter Kit 135/10  M001183030 Renegade (1) Hi-Flo Microcatheter Kit 135/20  Fee submitted: Rs 50,000/- | | | | | Is intended for peripheral vascular use. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Interlock TM 35 Fibered IDCTM Occlusion System  Class C  Shelf Life: 36 Months  M001363500 Interlock-35 / 2D 3mm x 4cm  M001363510 Interlock-35 / 2D 4mm x 4cm  M001363520 Interlock-35 / 2D 4mm x 10cm  M001363540 Interlock-35 / 2D 6mm x 10cm  M001363550 Interlock-35 / 2D 6mm x 20cm  M001363570 Interlock-35 / 2D 8mm x 10cm  M001363580 Interlock-35 / 2D 8mm x 20cm  M001363590 Interlock-35 / 2D 8mm x 40cm  M001363600 Interlock-35 / 2D 10mm x 20cm  M001363610 Interlock-35 / 2D 10mm x 40cm  M001363620 Interlock-35 / 2D 12mm x 20cm  M001363630 Interlock-35 / 2D 12mm x 40cm  M001363640 Interlock-35 / 2D 15mm x 20cm  M001363650 Interlock-35 / 2D 15mm x 40cm  M001363660 Interlock-35 / 2D 18mm x 20cm  M001363670 Interlock-35 / 2D 18mm x 40cm  M001363700 Interlock-35 / Cube 4mm x 6cm  M001363720 Interlock-35 / Cube 6mm x 10cm  M001363730 Interlock-35 / Cube 6mm x 20cm  M001363750 Interlock-35 / Cube 8mm x 15cm  M001363760 Interlock-35 / Cube 8mm x 20cm  M001363780 Interlock-35 / Cube 10mm x 15cm  M001363790 Interlock-35 / Cube 10mm x 25cm  M001363800 Interlock-35 / Cube 10mm x 40cm  M001363810 Interlock-35 / Cube 15mm x 25cm  M001363820 Interlock-35 / Cube 15mm x 40cm  M001363830 Interlock-35 / Cube 20mm x 40cm  M001363910 Interlock-35 / Diamond 4mm x 4.5cm  M001363920 Interlock-35 / Diamond 6mm x 9.2cm  M001363930 Interlock-35 / Diamond 8mm x 14.0cm  M001363940 Interlock-35 / Diamond 10mm x 21.5cm  Fee submitted: Rs 50,000/- | | | | | Non-Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | RotalinkTM Burr Exchangeable Burr Catheter  Class D  Shelf Life: 24 Months  H802227680020  RotaLink / 1.25 mm burr, 135 cm long  H802227680030  RotaLink / 1.50 mm burr, 135 cm long  H802227680040  RotaLink / 1.75 mm burr, 135 cm long  H802227680050  RotaLink / 2.00 mm burr, 135 cm long  H802227680150  RotaLink / 2.15 mm burr, 135 cm long  H802227680060  RotaLink / 2.25 mm burr, 135 cm long  H802227680160  RotaLink / 2.38 mm burr, 135 cm long  H802227680070  RotaLink / 2.50 mm burr, 135 cm long  Fee submitted: Rs 50,000/- | | | | | Mechanical Atherectomy System, Coronary. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Stingray TM Catheter  Class D  Shelf Life: 24 Months  H749M1000B0  Stingray Catheter 135cm  Fee submitted: Rs 50,000/- | | | | | Vascular Guide Catheter, Single Use | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | RotalinkTM Advancer Catheter Advancing Device  Class D  Shelf Life: 24 Months  H80222782001A  Rotalink Advancer with Tubular Drive Shaft  Fee submitted: Rs 50,000/- | | | | | Mechanical Atherectomy System, Coronary. | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Complex Helical-18 Fibered Platinum Coil  Class C  Shelf Life: 36 Months  M0013120220  4mm/4mm Complex Helical -18 (Bx/1)  M0013120221  4mm/4mm Complex Helical -18 (Bx/5)  M0013120330  6mm/6mm Complex Helical -18 (Bx/1)  M0013120331  6mm/6mm Complex Helical -18 (Bx/5)  M0013120440  7mm/10mm Complex Helical -18 (Bx/1)  M0013120441  7mm/10mm Complex Helical -18 (Bx/5)  M0013120550  8mm/12mm Complex Helical -18 (Bx/1)  M0013120551  8mm/12mm Complex Helical -18 (Bx/5)  M0013120660  10mm/14mm Complex Helical -18 (Bx/1)  M0013120661  10mm/14mm Complex Helical -18 (Bx/5)  M0013120770  11mm/17mm Complex Helical -18 (Bx/1)  M0013120771  11mm/17mm Complex Helical -18 (Bx/5)  Fee submitted: Rs 50,000/- | | | | | Non-Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | VortX TM 18 Fibered Platinum Coil  Class C  Shelf Life: 36 Months  M0013812030 VortX-18 3mm/2.5mm  M0013812040 VortX-18 4mm/4.0mm  M0013812050 VortX-18 5mm/5.5mm  M0013812060 VortX-18 6mm/6.5mm  M0013812031 VortX-18 3mm/2.5mm (BX/5)  M0013812041 VortX-18 4mm/4.0mm (BX/5)  M0013812051 VortX-18 5mm/5.5mm (BX/5)  M0013812061 VortX-18 6mm/6.5mm (BX/5)  Fee submitted: Rs 50,000/- | | | | | Non-Neurovascular Embolization Coil | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Owner Operator:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Corporation 302 Parkway, Global Park, La Aurora, Heredia Costa Rica  (FSC US FDA Valid Till  05-08-2020) | | | Fathom TM 14 Steerable Guidewire  Class B  Shelf Life: 3 Years  M001508100 08714729801023 Fathom -14, 0.014”, 200cm x 10cm, 35cm tip  M001508110 08714729801030 Fathom -14, 0.014”, Pre-shaped 200cm x 10cm, 35cm  M001508140 08714729801047 Fathom -14, 0.014”, 300cm x 10cm, 35cm tip  M001508150 08714729801054 Fathom -14, 0.014”, Pre-shaped 300cm x 10cm, 35cm  Fee submitted: Rs 25,000/- | | | | | Peripheral Vascular Guidewire | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | DirexionTM Hi-FloTM FathomTM-16 System Pre-Loaded Torqueable Microcatheter  Class C  Shelf Life: 2 Years  M001195700 Large lumen, 105cm, Shapeable Tip, 140cm  M001195710 Large lumen, 130cm, Shapeable Tip, 180cm  M001195720 Large lumen, 155cm, Shapeable Tip, 180cm  M001195730 Large lumen, 105cm, Bern Tip, 140cm  M001195740 Large lumen, 130cm, Bern Tip, 180cm  M001195750 Large lumen, 155cm, Bern Tip, 180cm  Fee submitted: Rs 50,000/- | | | | | Intended for Peripheral Vascular Use | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | EncoreTM 26 Advantage Kit Inflation Device Kit  Class B  Shelf Life: 2 Years  H74904527011 Encore 26 Advantage Kit Single  H74904527052 Encore 26 Advantage Kit 5-Pack  Fee submitted: Rs 25,000/- | | | | | Catheter-Balloon Inflator, Single-Use (“Inflation Device) | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec) | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Direxion TM FathomTM -16 System Pre-Loaded Torqueable Microcatheter  Class C  Shelf Life: 2 Years  M001195600 Small lumen, 105cm, Shapeable Tip, 140cm  M001195610 Small lumen, 130cm, Shapeable Tip, 180cm  M001195620 Small lumen, 155cm, Shapeable Tip, 180cm  M001195630 Small lumen, 105cm, Bern Tip, 140cm  M001195640 Small lumen, 130cm, Bern Tip, 180cm  M001195650 Small lumen, 155cm, Bern Tip, 180cm  M001195660 SL, 130cm, Shapeable Tip, 2-RO marker bands, 180cm  M001195670 SL, 130cm, Bern Tip, 2-RO marker bands, 180cm  Fee submitted: Rs.50,000/- | | | | | Intended for Peripheral Vascular Use | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | DirexionTM Hi-FlowTM Torqueable Microcatheter  Class C  Shelf Life: 2 Years  M001195700 Large lumen, 105cm, Shapeable Tip, 140cm  M001195710 Large lumen, 130cm, Shapeable Tip, 180cm  M001195720 Large lumen, 155cm, Shapeable Tip, 180cm  M001195730 Large lumen, 105cm, Bern Tip, 140cm  M001195740 Large lumen, 130cm, Bern Tip, 180cm  M001195750 Large lumen, 155cm, Bern Tip, 180cm  Fee submitted: Rs.50,000/- | | | | | Intended for Peripheral Vascular Use | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec) | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC US FDA Valid Till  05-08-2020) | | | FathomTM – 16 Steerable Guidewire  Class B  Shelf Life: 3 Years  M001509000  08714729764410 Fathom -16, 0.016”, 140cm x 10cm, 25cm tip  M001509010  08714729764427 Fathom -16, 0.016”, 140cm x 20cm, 35cm tip  M001509100  08714729762553 Fathom -16, 0.016”, 180cm x 10cm, 25cm tip  M001509110  08714729762560 Fathom -16, 0.016”, 180cm x 20cm, 35cm tip  M001509120  08714729939658 Fathom -16, 180cm x 10cm, Angled, 25cm tip  M001509200  08714729961116 Fathom -16, 200cm x 10cm, Straight, 25cm tip  M001509210  08714729961123 Fathom -16, 200cm x 10cm, Angled, 25cm tip  M001509300  08714729961130 Fathom -16, 215cm x 10cm, Straight, 25cm tip  M001509310  08714729961147 Fathom -16, 215cm x 10cm, Angled, 25cm tip  Fee submitted: Rs.25,000/- | | | | | Peripheral Vascular Guidewire | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec) | | | |
|  | M/s Ferozsons Laboratories Limited. P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | **Legal Manufacturer:**  M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA  **Manufacturer:**  M/s Boston Scientific Limited, Business and Technology Park Model Farm Road Cork, Ireland  (FSC Ireland Valid Till  23-03-2022) | | | Equalizer Occlusion Balloon Catheter  Class D  Shelf Life: 18 Months  M001171050  EQL/20/7/2/65  M001171060  EQL/20/7/2/100  M001171070  EQL/27/7/2/65  M001171080  EQL/27/7/2/100  M001171090  EQL/33/7/2/65  M001171100  EQL/33/7/2/100  M001171110  EQL/40/7/2/65  M001171120  EQL/40/7/2/100  Fee submitted: Rs.50,000/- | | | | | Intravascular Occluding Catheter | | **Approved** subject to submission of valid Agency agreement (Existing expired on 31st Dec, 2018). | | | |
|  | 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 Diagnostic Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till 26-05-2022) | | | Alinity s HBsAgKit  Class D  (1) Alinity s HBsAg Reagent Kit 06P0255  Shelf Life: 12 Months  (2) Alinity s HBsAg Calibrator Kit 06P0202  Shelf Life: 12 Months  (3Alinity s HBsAg Assay Control Kit 06P0210  Shelf Life: 12 Months  (4) Alinity s HBsAg Release Control Kit 06P0212  Shelf Life: 12 Months  Fee submitted: Rs.50,000/- | | | | | In-Vitro Diagnostic Kit for HBsAg Testing | | **Approved.** | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd. Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany Issue 19-07-2018) | | | Alinity i Anti-HCVKit  Class D  (1) Alinity i Anti-HCV Calibrator 08P0601  Shelf Life: 12 Months  (2) Alinity i Anti-HCV Controls 08P0610  Shelf Life: 12 Months  (3)Alinity i Anti-HCV Reagent Kit (2 x 100 tests) 08P0622  Shelf Life: 09 Months  (4) Alinity i Anti-HCV Reagent Kit (2 x 500 tests) 08P0632  Shelf Life: 09 Months  Fee submitted: Rs.50,000/- | | | | | In-Vitro Diagnostic Kit For Anti-HCV Testing | | **Approved.** | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd. Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany Issue  19-07-2018 ) | | | Alinity i Chagas Kit  Class D  (1) Alinity i Chagas Calibrator 09P1901  Shelf Life: 09 Months  (2) Alinity i Chagas Controls 09P1910  Shelf Life: 10 Months  (3)Alinity i Chagas Reagent Kit 09P1922 (2 x 100 tests)  Shelf Life: 11 Months  (4) Alinity i Chagas Reagent Kit 09P1932 (2 x 500 tests)  Shelf Life: 11 Months  Fee submitted: Rs.50,000/- | | | | | In-Vitro Diagnostic Kit for ChagasTesting | | **Approved.** | | | |
|  | M/s Zenith International.  Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi  (ELI-00090) | | **Manufacturer:**  M/s Changzhou Chunguang Medical Equipment Co., Ltd., Shijiaqiao Dongqing Zhenlu Town, Changzhou City, Jiangsu Province, China  (FSC China Valid Till  01-04-2019) | | | Perfect + (Disposable Syringe, Sterile with Needle)  Class B  Shelf Life: 5 Years  Sizes: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml.  Fee submitted: Rs.25,000/- | | | | | Disposable Syringes, Sterile with Needle | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the MDB authorized Secretary, MDB to issue Registration Certificate if recommended by panel of inspectors. | | | |
|  | M/s Global Marketing Services.  111, Hali Road Westridge 1, Rawalpindi  (ELI-00109) | | **Manufaturer:** M/s KANEKA Corporation, 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka, 530-8288, Japan  **Manufacturing Site:** M/s KANEKA Coporation Osaka Plant 5-1-1, Torikai-Nishi, Settsu-City, OSAKA, 566-0072, Japan  (FSC Japan Issuance Date  24-04-2017) | | | Kaneka PTCA Catheter CO-R6, Raiden 3  Class D  Shelf Life: 3Years  RD3-15-450  RD3-8-150 RD3-18-200  RD3-8-175 RD3-18-225  RD3-8-200 RD3-18-250  RD3-8-225 RD3-18-275  RD3-8-250 RD3-18-300  RD3-8-275 RD3-18-325  RD3-8-300 RD3-18-350  RD3-8-325 RD3-18-375  RD3-8-350 RD3-18-400  RD3-8-375 RD3-18-425  RD3-8-400 RD3-18-450  RD3-8-425 RD3-20-200  RD3-8-450 RD3-20-225  RD3-10-200 RD3-20-250  RD3-10-225 RD3-20-275  RD3-10-250 RD3-20-300  RD3-10-275 RD3-20-325  RD3-10-300 RD3-20-350  RD3-10-325 RD3-20-375  RD3-10-350 RD3-20-400  RD3-10-375 RD3-20-425  RD3-10-400 RD3-20-450  RD3-10-425 RD3-30-200  RD3-10-450 RD3-30-225  RD3-13-200 RD3-30-250  RD3-13-225 RD3-30-275  RD3-13-250 RD3-30-300  RD3-13-275 RD3-30-325  RD3-13-300 RD3-30-350  RD3-13-325 RD3-30-375  RD3-13-350 RD3-30-400  RD3-13-375 RD3-30-425  RD3-13-400 RD3-30-450  RD3-13-425  RD3-13-450  RD3-15-200  RD3-15-225  RD3-15-250  RD3-15-275  RD3-15-300  RD3-15-325  RD3-15-350  RD3-15-375  RD3-15-400  RD3-15-425  Fee submitted: Rs.50,000/- | | | | | Angioplasty Balloon Catheter | | **Approved.** | | | |
|  | M/s A.S. Enterprises. 03 Mozang Road, Lahore  (ELI-00190) | | **Legal Manufacturer/ Manufacturing Site:** M/s Suzhou Laishi Transfusion Equipment Co., Ltd., Changsheng Road, Tongli Town, Wujiang District, Suzhou City, Jiangsu Province, PR China  FSC China Valid Till 10-09-2019) | | | Laishi Disposable Plastic Blood Bag  Class D  Shelf Life: 3 Years  Fee submitted: Rs.50,000/- | | | | | Disposable Plastic Blood Bag with CPDA-1 for Whole Blood (Human). Single, 500 ml with 17 G needle for Single Use | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the MDB authorized Secretary, MDB to issue Registration Certificate if recommended by panel of inspectors. | | | |
|  | M/s Med Art Pakistan. A-175, Block 13-C, KDA Scheme 24, Gulshan-e-Iqbal Karachi  (ELI-00024) | | **Legal Manufacturer:** M/s BioPolymer GmbH & Co. KG Walsmuhler Strabe 18, 19073 Dummer, Germany  (FSC Germany Issuance Date  29-03-2017) | | | Crespine Gel +®    Class D  Shelf Life: 3 Years  Fee submitted: Rs.50,000/- | | | | | Patented Stabilized cross-linked hyaluronic acid and prilocaine integrated complex | | **Approved.** | | | |
|  | M/s Med Art Pakistan. A 175, Block 13-C, KDA Scheme 24, Gulshan-e-Iqbal, Karachi.  (ELI-00024) | | **Legal Manufacturer/ Manufacturing Site:** M/s Regen Lab SA, En Burdon B2, 1052 Le Mont-sur-Lausanne, Switzerland  (FSC Switzerland Valid Till  13-05-2021) | | | RegenKit®-BCT  Class C  Shelf Life: 24 Months  RegenKit®-BCT-T  RegenKit®-BCT-3  Fee submitted: Rs 50,000/- | | | | | Used to prepare autologous Platelet Rich Plasma (PRP) and other plasma derived products. | | **Approved.** | | | |
|  | M/s Med Art Pakistan. A 175, Block 13-C, KDA Scheme 24, Gulshan-e-Iqbal, Karachi.  (ELI-00024) | | **Legal Manufacturer/ Manufacturing Site:** M/s Regen Lab SA, En Burdon B2, 1052 Le Mont-sur-Lausanne, Switzerland  (FSC Switzerland Valid Till  13-05-2021) | | | Cellular Matrix® A-CP-HA Kit  Class D  Shelf Life: 24 Months  Ref # A-CP-HA-3  Fee submitted: Rs 50,000/- | | | | | Device used to prepare intra-articular injection for symptomatic treatment of articular pain and mobility improvement. | | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd.  WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Manufacturing Site:**  M/s Siemens Healthcare Diagnostics Inc. 333 Coney Street, E.Walpole, MA, 02032-1597,USA  (FSC UK Valid Till 31-12-2020) | | | Siemens ADVIA Centaur HBc IgMAssay Kit  (i) Siemens ADVIA Centaur HBc IgM assay  Class D  Shelf Life: 18 Months  SMN:10308978  (ii) Siemens ADVIA Centaur HBc IgM Quality Control  Class D  Shelf Life: 18 Months  SMN:10308979  Fee submitted: Rs.50,000/- | | | | | The Assay is an In-Vitro Diagnostic immunoassay for the qualitative determination of IgM response to the core antigen of the Hepatitis B Virus in human serum or plasma. | | **Approved.** | | | |
|  | M/s Healthline Pharmaceuticals (Pvt), Ltd.  Office No.402, 4th Floor, Al Hafeez Heights, Gulberg III, Lahore  (ELI-00107) | | **Manufactured By:** M/s Medtrade Products Ltd., Electra House Crewe Business Park Crewe Cheshire CW1 6GL, UK  (FSC UK issuance date  24-04-2017) | | | Celox RAPID Gauze  Class D  Shelf Life: 5Years  FG08839021  Fee submitted: Rs.50,000/- | | | | | Hemostatic Gauze | | **Approved.** | | | |
|  | M/s Healthline Pharmaceuticals (Pvt), Ltd.  Office No.402, 4th Floor Al Hafeez Heights, Gulberg III, Lahore  (ELI-00107) | | **Manufactured By:** M/s Medtrade Products Ltd., Electra House Crewe Business Park Crewe Cheshire CW1 6GL, UK  (FSC UK Issuance Date  24-04-2017) | | | Celox Granules 15g  Class D  Shelf Life: 5 Years  FG08830181  Fee submitted: Rs.50,000/- | | | | | Hemostatic Granules | | **Approved.** | | | |
|  | M/s Tek Enterprises. Office No. MZ-9, Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore  (ELI-00189) | | **Manufacturer:** M/s Asahi Intecc Co., Ltd., 1703 Wakita-cho, Moriyama-ku, Nagoya, Aichi, 463-0024, Japan  **Manufacturing Site:**  (i) M/s Asahi Intecc Co., Ltd., 3-100 Akatsuki-Cho, 489-0071 Seto, Aichi, Japan  (ii) M/s Asahi Intecc (Thailand) Co., Ltd., 158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 1200 Thailand  (FSC Japan Issuance Date  07-03-2017) | | | ASAHI Hyperion Coronary Guide Catheter  Class D  Shelf Life: 3 Years  HW60JL350P10000  100cm, 6Fr, Judkins Left 3.5cm  HW60JL350P10001  100cm, 6Fr, Judkins Left 3.5cm, Short Tip  HW60JL352P10000  100cm, 6Fr, Judkins Left 3.5cm, Side Hole  HW60JL352P10001 100cm, 6Fr, Judkins Left 3.5cm, Short Tip, Side Hole  HW60JL400P10000  100cm, 6Fr, Judkins Left 4.0cm  HW60JL400P10001  100cm, 6Fr, Judkins Left 4.0cm, Short Tip  HW60JL402P10000  100cm, 6Fr, Judkins Left 4.0cm, Side Hole  HW60JL402P10001  100cm, 6Fr, Judkins Left 4.0cm, Short Tip, Side Hole  HW60JR350P10000  100cm, 6Fr, Judkins Right 3.5cm  HW60JR352P10000  100cm, 6Fr, Judkins Right 3.5cm, Side Hole  HW60JR400P10000  100cm, 6Fr, Judkins Right 4.0cm  HW60JR402P10000  100cm, 6Fr, Judkins Right 4.0cm, Side Hole  HW60AL070P10000  100cm, 6Fr, Amplatz Left 0. 75cm  HW60AL070P10001  100cm, 6Fr, Amplatz Left 0. 75cm, Short Tip  HW60AL072P10000  100cm, 6Fr, Amplatz Left 0. 75cm, Side Hole  HW60AL072P1000  100cm, 6Fr, Amplatz Left 0. 75cm, Short Tip, Side Hole  HW60AL100P10000  100cm, 6Fr, Amplatz Left 1.0cm  HW60AL100P10001  100cm, 6Fr, Amplatz Left 1.0cm, Short Tip  HW60AL102P10000  100cm, 6Fr, Amplatz Left 1.0cm, Side Hole  HW60AL102P10001  100cm, 6Fr, Amplatz Left 1.0cm, Short Tip, Side Hole  HW60AL150P10000 100cm, 6Fr, Amplatz Left 1.5cm  HW60AL150P10001  100cm, 6Fr, Amplatz Left 1.5cm, Short Tip  HW60AL152P10000  100cm, 6Fr, Amplatz Left 1.5cm, Side Hole  HW60AL152P10001  100cm, 6Fr, Amplatz Left 1.5cm, Short Tip, Side Hole  HW60AL070P10002  100cm, 6Fr, Short Amplatz Left 0.75cm  HW60AL072P10002  100cm, 6Fr, Short Amplatz Left 0.75cm, Side Hole  HW60AL100P10002  100cm, 6Fr, Short Amplatz Left 1.0cm  HW60AL102P10002  100cm, 6Fr, Short Amplatz Left 1.0cm, Side Hole  HW60AL150P10002  100cm, 6Fr, Short Amplatz Left 1.5cm  HW60AL152P10002  100cm, 6Fr, Short Amplatz Left 1.5cm, Side Hole  HW60PB300P10000  100cm, 6Fr, Power Backup 3.0cm  HW60PB302P10000  100cm, 6Fr, Power Backup 3.0cm, Side Hole  HW60PB350P10000  100cm, 6Fr, Power Backup 3.5cm  HW60PB352P10000  100cm, 6Fr, Power Backup 3.5cm, Side Hole  HW60PB370P10000  100cm, 6Fr, Power Backup 3.75cm  HW60PB372P10000  100cm, 6Fr, Power Backup 3.75cm, Side Hole  HW60PB400P10000  100cm, 6Fr, Power Backup 4.0cm  HW60PB402P10000  100cm, 6Fr, Power Backup 4.0cm, Side Hole  HW60RB070P10000  100cm, 6Fr, Right Backup 0.75cm  HW60RB072P10000  100cm, 6Fr, Right Backup 0.75cm, Side Hole  HW60RB100P10000  100cm, 6Fr, Right Backup 1.0cm  HW60RB102P10000  100cm, 6Fr, Right Backup 1.0cm, Side Hole  HW60SC350P10000  100cm, 6Fr, Special Curve 3.5cm  HW60SC352P10000  100cm, 6Fr, Special Curve 3.5cm, Side Hole  HW70JL350P10000  100cm, 7Fr, Judkins Left 3.5cm  HW70JL350P10001  100cm, 7Fr, Judkins Left 3.5cm, Short Tip  HW70JL352P10000  100cm, 7Fr, Judkins Left 3.5cm, Side Hole  HW70JL352P10001  100cm, 7Fr, Judkins Left 3.5cm, Short Tip, Side Hole  HW70JL400P10000  100cm, 7Fr, Judkins Left 4.0cm  HW70JL400P10001  100cm, 7Fr, Judkins Left 4.0cm, Short Tip  HW70JL402P10000  100cm, 7Fr, Judkins Left 4.0cm, Side Hole  HW70JL402P10001  100cm, 7Fr, Judkins Left 4.0cm, Short Tip, Side Hole  HW70AL070P10000  100cm, 7Fr, Amplatz Left 0. 75cm  HW70AL070P10001  100cm, 7Fr, Amplatz Left 0. 75cm, Short Tip  HW70AL072P10000  100cm, 7Fr, Amplatz Left 0. 75cm, Side Hole  HW70AL072P10001  100cm, 7Fr, Amplatz Left 0. 75cm, Short Tip, Side Hole  HW70AL100P10000  100cm, 7Fr, Amplatz Left 1.0cm  HW70AL100P10001  100cm, 7Fr, Amplatz Left 1.0cm, Short Tip  HW70AL102P10000  100cm, 7Fr, Amplatz Left 1.0cm, Side Hole  HW70AL102P10001  100cm, 7Fr, Amplatz Left 1.0cm, Short Tip, Side Hole  HW70AL150P10000 100cm, 7Fr, Amplatz Left 1.5cm  HW70AL150P10001  100cm, 7Fr, Amplatz Left 1.5cm, Short Tip  HW70AL152P10000  100cm, 7Fr, Amplatz Left 1.5cm, Side Hole  HW70AL152P10001  100cm, 7Fr, Amplatz Left 1.5cm, Short Tip, Side Hole  HW70AL070P10002  100cm, 7Fr, Short Amplatz Left 0.75cm  HW70AL072P10002  100cm, 7Fr, Short Amplatz Left 0.75cm, Side Hole  HW70AL100P10002  100cm, 7Fr, Short Amplatz Left 1.0cm  HW70AL102P10002  100cm, 7Fr, Short Amplatz Left 1.0cm, Side Hole  HW70AL150P10002  100cm, 7Fr, Short Amplatz Left 1.5cm  HW70AL152P10002  100cm, 7Fr, Short Amplatz Left 1.5cm, Side Hole  HW70PB300P10000 100cm, 7Fr, Power Backup 3.0cm  HW70PB302P10000 100cm, 7Fr, Power Backup 3.0cm, Side Hole  HW70PB350P10000 100cm, 7Fr, Power Backup 3.5cm  HW70PB352P10000  100cm, 7Fr, Power Backup 3.5cm, Side Hole  HW70PB400P10000  100cm, 7Fr, Power Backup 4.0cm  HW70PB402P10000 100cm, 7Fr, Power Backup 4.0cm, Side Hole  HW70SP300P10000 100cm, 7Fr, Super Power Backup 3.0cm  HW70SP302P10000 100cm, 7Fr, Super Power Backup 3.0cm, Side Hole  HW70SP350P10000 100cm, 7Fr, Super Power Backup 3.5cm  HW70SP352P10000 100cm, 7Fr, Super Power Backup 3.5cm, Side Hole  HW70SP370P10000 100cm, 7Fr, Super Power Backup 3.75cm  HW70SP372P10000 100cm, 7Fr, Super Power Backup 3.75cm, Side Hole  HW70SP400P10000 100cm, 7Fr, Super Power Backup 4.0cm  HW70SP402P10000 100cm, 7Fr, Super Power Backup 4.0cm, Side Hole  HW70RB070P10000 100cm, 7Fr, Right Backup 0.75cm  HW70RB072P10000 100cm, 7Fr, Right Backup 0.75cm, Side Hole  HW70RB100P10000 100cm, 7Fr, Right Backup 1.0cm  HW70RB102P10000 100cm, 7Fr, Right Backup 1.0cm, Side Hole  HW70SC350P10000 100cm, 7Fr, Special Curve 3.5cm  HW70SC352P10000 100cm, 7Fr, Special Curve 3.5cm, Side Hole  HW80JL352P10000  100cm, 8Fr, Judkins Left 3.5cm, Side Hole  HW80JL352P10001  100cm, 8Fr, Judkins Left 3.5cm, Short Tip, Side Hole  HW80JL402P10000  100cm, 8Fr, Judkins Left 4.0cm, Side Hole  HW80JL402P10001  100cm, 8Fr, Judkins Left 4.0cm, Short Tip, Side Hole  HW80JR352P10000  100cm, 8Fr, Judkins Right 3.5cm, Side Hole  HW80JR402P10000 100cm, 8Fr, Judkins Right 4.0cm, Side Hole  HW80AL072P10000  100cm, 8Fr, Amplatz Left 0. 75cm, Side Hole  HW80AL072P10001  100cm, 8Fr, Amplatz Left 0. 75cm, Short Tip, Side  Hole  HW80AL102P10000 100cm, 8Fr, Amplatz Left 1.0cm, Side Hole  HW80AL102P10001 100cm, 8Fr, Amplatz Left 1.0cm, Short Tip, Side Hole  HW80AL152P10000 100cm, 8Fr, Amplatz Left 1.5cm, Side Hole  HW80AL152P10001 100cm, 8Fr, Amplatz Left 1.5cm, Short Tip, Side Hole  HW80AL072P10002  100cm, 8Fr, Short Amplatz Left 0.75cm, Side Hole  HW80AL102P10002 100cm, 8Fr, Short Amplatz Left 1.0cm, Side Hole  HW80AL152P10002 100cm, 8Fr, Short Amplatz Left 1.5cm, Side Hole  HW80PB302P10000  100cm, 8Fr, Power Backup 3.0cm, Side Hole  HW80PB352P10000100cm, 8Fr, Power Backup 3.5cm, Side Hole  HW80PB402P10000 100cm, 8Fr, Power Backup 4.0cm, Side Hole  HW80SP302P10000 100cm, 8Fr, Super Power Backup 3.0cm, Side Hole  HW80SP352P10000 100cm, 8Fr, Super Power Backup 3.5cm, Side Hole  HW80SP372P10000 100cm, 8Fr, Super Power Backup 3.75cm, Side Hole  HW80SP402P10000  100cm, 8Fr, Super Power Backup 4.0cm, Side Hole  HW80SC352P10000  100cm, 8Fr, Special Curve 3.5cm, Side Hole  HW80RB072P10000 100cm, 8Fr, Right Backup 0.75cm, Side Hole  HW80RB102P10000  100cm, 8Fr, Right Backup 1.0cm, Side Hole  Fee submitted: Rs.50,000/- | | | | | Coronary Guide Catheter | | **Approved.** | | | |
|  | M/s Sakuf Trading.  2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | IVA Introducer Sheath  Class B  Shelf Life: 5 years  IVA3F, IVA3F50, IVA5F45, IVA5F41.45, IVA5F96.45, IVA6F80, IVA6F80ST, IVA6F80ST\_MP, IVA7F41.45, IVA7F96.45, IVA7F96.90.  Fee submitted: Rs 25,000/- | | | | | Introducer Sheath | | **Approved.** | | | |
|  | M/s Sakuf Trading.  2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Magic (Selective and Hyperselective Catheter)  Class D  Shelf Life: 5 Years  MAGIC1,2F, MAGIC1,2FM, MAGIC1,2FM180, MA1,2FOLIVE, MAGIC1,5F, MA1,5FMP, MA1,5FOLIVEMP, MAGICSTD, MAGICMP  Fee submitted: Rs 50,000/- | | | | | Selective and Hyperselective Catheter | | **Approved.** | | | |
|  | M/s Sakuf Trading.  2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Vasco+ (Selective and Hyperselective Catheter)  Class D  Shelf Life: 5 Years  VASCO+10D, VASCO+10MH\_D, VASCO+10MP, VASCO+10MH\_MP, VASCO+18D, VASCO+18MH\_D, VASCO+18MP, VASCO+18MH\_MP, VASCO+21D, VASCO+21MH\_D, VASCO+21MP, VASCO+21MH\_MP, VASCO+25D, VASCO+25MH\_D, VASCO+25MP, VASCO+25MH\_MP, VASCO+28D, VASCO+28MH\_D, VASCO+28MP, VASCO+28MH\_MP,  VASCO+35D, VASCO+35MH\_D, VASCO+35MP, VASCO+35MH\_MP, VASCO+35ASPI\_D, VASCO+35ASPI\_MP.  Fee submitted: Total Rs 50,000/- (25,000/- submitted earlier) | | | | | Selective and Hyperselective Catheter | | **Approved.** | | | |
|  | M/s Sakuf Trading.  2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | **Legal Manufacturer/ Manufacturing Site:** M/s BALT Extrusion, 10 rue de la Croix-Vigneron, 95160 Montmorency, France  (FSC France Issuance Date  26-06-2018) | | | Cirrus (FIB) Embolization Devices  Class D  Shelf Life: 5 Years  FIB ØXLP15, FIB ØXLP32,  FIB 6X60P32A, FIB 8X60P32A.  Fee submitted: Total Rs 50,000/- (25,000/- submitted earlier) | | | | | Embolization Coil. Spirals with synthetic fibres | | **Approved.** | | | |
|  | M/s Sakuf Trading.  2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | **Legal Manufacturer/ Manufacturer:** M/s BALT USA, LLC 29 Parker Irvine, CA 92618, USA  (FSC USFDA Valid Till  15-04-2020) | | | Optima Coil System  Class D  Shelf Life: 2 Years  **Complex – 10 Standard**  OPTI0517CST10 OPTI0724CST10 OPTI0930CST10  OPTI0611CST10 OPTI0816CST10 OPTI1027CST10  OPTI0620CST10 OPTI0827CST10  OPTI1034CST10  OPTI0713CST10 OPTI0923CST10  **Complex – 10 Soft**  OPTI0203CSF10 OPTI0308CSF10 OPTI0611CSF10  OPTI0204CSF10 OPTI0310CSF10 OPTI0620CSF10  OPTI0206CSF10  OPTI0407CSF10 OPTI0713CSF10  OPTI0208CSF10 OPTI0413CSF10 OPTI0724CSF10  OPTI0255CSF10 OPTI0509CSF10 OPTI0816CSF10  OPTI0306CSF10 OPTI0517CSF10 OPTI0827CSF10  **Complex – 10 Super Soft**  OPTI0101CSS10 OPTI0204CSS10 OPTI0310CSS10  OPTI0102CSS10 OPTI0206CSS10 OPTI0356CSS10  OPTI0103CSS10 OPTI0208CSS10 OPTI0358CSS10  OPTI0104CSS10 OPTI0253CSS10 OPTI0406CSS10  OPTI0152CSS10 OPTI0254CSS10 OPTI0408CSS10  OPTI0153CSS10 OPTI0256CSS10 OPTI0410CSS10  OPTI0154CSS10 OPTI0304CSS10 OPTI0508CSS10  OPTI0202CSS10 OPTI0306CSS10 OPTI0510CSS10  OPTI0203CSS10 OPTI0308CSS10 OPTI0513CSS10  **Helical – 10 Standard**  OPTI0615HST10 OPTI0730HST10 OPTI0930HST10  OPTI0620HST10 OPTI0820HST10  OPTI0720HST10 OPTI0830HST10 OPTI1030HST10  **Helical – 10 Soft**  OPTI0304HSF10 OPTI0408HSF10 OPTI0606HSF10  OPTI0306HSF10 OPTI0410HSF10 OPTI0608HSF10  OPTI0308HSF10 OPTI0506HSF10 OPTI0610HSF10  OPTI0310HSF10 OPTI0508HSF10 OPTI0406HSF10  OPTI0510HSF10  **Helical – 10 Super Soft**  OPTI0101HSS10 OPTI0202HSS10 OPTI0306HSS10  OPTI0102HSS10 OPTI0203HSS10 OPTI0308HSS10  OPTI0103HSS10 OPTI0204HSS10 OPTI0310HSS10  OPTI0104HSS10 OPTI0206HSS10 OPTI0406HSS10  OPTI0151HSS10 OPTI0208HSS10 OPTI0408HSS10  OPTI0152HSS10 OPTI0253HSS10 OPTI0410HSS10  OPTI0153HSS10 OPTI0254HSS10 OPTI0506HSS10  OPTI0154HSS10 OPTI0256HSS10 OPTI0508HSS10  OPTI0201HSS10 OPTI0304HSS10 OPTI0510HSS10  **Complex – 18**  OPTI0620COM18 OPTI1137COM18 OPTI1655COM18  OPTI0724COM18 OPTI1240COM18 OPTI1860COM18  OPTI0827COM18 OPTI1343COM18 OPTI2065COM18  OPTI0930COM18 OPTI1447COM18 OPTI2265COM18  OPTI1034COM18 OPTI1550COM18 OPTI2465COM18  Fee submitted: Rs 50,000/- | | | | | Implantable Embolization Coils | | **Approved.** | | | |
|  | M/s Sakuf Trading.  2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | **Legal Manufacturer/ Manufacturer:** M/s BALT USA, LLC 29 Parker Irvine, CA 92618, USA  (FSC US FDA Valid Till  15-04-2020) | | | Barricade Coil System  Class D  Shelf Life: 5 Years  **10 Complex Frame Coil**  9000000203FR10 9000010255FR10 9000020306FR10  9000030407FR10 9000680413FR10 9000050509FR10  9000690517FR10 9000070611FR10 9000700620FR10  9000090713FR10 9000710724FR10 9000110816FR10  9000720827FR10 9000140923FR10 9000730930FR10  9000161027FR10 9000741034FR10  **10 Complex Finish Coil**  9001300101CF10 9001010102CF10 9001310103CF10  9001020152CF10 9001030153CF10 9001040154CF10  9001050202CF10 9001060203CF10 9001070204CF10  9001080206CF10 9001100253CF10 9001110254CF10  9001130304CF10 9001140306CF10 9001150308CF10  9001160310CF10 9001330354CF10 9001340356CF10  9001350358CF10 9001180406CF10 9001190408CF10  9001200410CF10 9001230508CF10 9001240510CF10  9001250513CF10  **10 Helical Finish Coil**  9001260101FN10 9001270102FN10 9001280103FN10  9001290104FN10 9000460151FN10 9000470152FN10  9000480153FN10 9000930154FN10 9000490201FN10  9000500202FN10 9000510203FN10 9000520204FN10  9000950206FN10 9000960208FN10 9000530253FN10  9000540254FN10 9000550256FN10 9000560304FN10  9000570306FN10 9000980308FN10 9000990310FN10  9000580406FN10 9000590408FN10 9001000410FN10  9000600506FN10 9000610508FN10 9000620510FN10  9000630606FN10 9000640608FN10 9000650610FN10  **18 Complex Frame Coil**  9000170616FR18 9000180719FR18 9000770827FR18  9000780930FR18 9000791034FR18 9000801137FR18  9000811240FR18 9000821343FR18 9000831447FR18  9000841550FR18  **10 Helical Filling Coil**  9000270304FL10 9000280306FL10 9000290308FL10  9000300310FL10 9000320406FL10 9000330408FL10  9000340410FL10 9000850415FL10 9000860420FL10  9000350510FL10 9000360515FL10 9000870520FL10  9000370610FL10 9000380615FL10 9000390620FL10  9000400715FL10 9000410720FL10 9000910730FL10  9000420820FL10 9000430830FL10 9000440930FL10  9000451030FL10  Fee submitted: Total Rs 50,000/- (25,000/- submitted earlier) | | | | | Implantable Embolization Coil | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Caguas, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | SJM Masters HP Valved Graft with Gelweave ValsalvaTM Technology  Class D  Shelf Life: 5 Years  Model: 19VAVGJ-515, 21VAVGJ-515, 23VAVGJ-515, 25VAVGJ-515, 27VAVGJ-515, 29VAVGJ-515  Fee submitted: Rs 50,000/- | | | | | Aortic Valved Graft | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Cagus, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | St. Jude Medical® Mechanical Heart Valve-SJM® Master Series (Rotatable)  Aortic Hemodynamic Plus  Class D  Shelf Life: 5 Years  Model: 15AHPJ-505, 17AHPJ-505, 19AHPJ-505, 21AHPJ-505, 23AHPJ-505, 25AHPJ-505, 27AHPJ-505  Fee submitted: Rs 50,000/- | | | | | Mechanical Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Cagus, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | St. Jude Medical® Mechanical Heart Valve-SJM® Master Series (Rotatable)  Aortic Expanded Hemodynamic Plus  Class D  Shelf Life: 5 Years  Model: 17AEHPJ-505, 19AEHPJ-505, 21AEHPJ-505, 23AEHPJ-505, 25AEHPJ-505, 27AEHPJ-505  Fee submitted: Rs 50,000/- | | | | | Mechanical Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Caguas, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | St. Jude Medical® Regent TMMechanical Heart Valve (Rotatable) SJM Regent TM  Mechanical Heart Valve  Class D  Shelf Life: 5 Years  Model: 17AGN-751,19AGN-751, 21AGN-751, 23AGN-751, 25AGN-751, 27AGN-751, 29AGN-751  Fee submitted: Rs 50,000/- | | | | | Mechanical Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Cagus, PR 00725 USA  (FSC USFDA Valid Till  13-03-2020) | | | St. Jude Medical® Mechanical Heart Valve-SJM® Master Series (Rotatable)  Mitral Expanded  Class D  Shelf Life: 5 Years  Model: 19MECJ-502,  21MECJ-502, 23MECJ-502, 25MECJ-502, 27MECJ-502, 29MECJ-502, 31MECJ-502, 33MECJ-502  Fee submitted: Rs 50,000/- | | | | | Mechanical Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Caguas, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | St. Jude Medical® Mechanical Heart Valve-SJM® Master Series (Rotatable)  Mitral Hemodynamic Plus  Class D  Shelf Life: 5 Years  Model: 15MHPJ-505,  17MHPJ-505, 19MHPJ-505, 21MHPJ-505, 23MHPJ-505, 25MHPJ-505, 27MHPJ-505  Fee submitted: Rs 50,000/- | | | | | Mechanical Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Caguas, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | St. Jude Medical® Mechanical Heart Valve-SJM® Master Series (Rotatable)  Mitral Polyester Cuff  Class D  Shelf Life: 5 Years  Model: 19MJ-501, 21MJ-501, 23MJ-501, 25MJ-501, 27MJ-501, 29MJ-501, 31MJ-501, 33MJ-501, 35MJ-501, 37MJ-501  Fee submitted: Rs 50,000/- | | | | | Mechanical Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Site:**  (i) M/s St. Jude Medical, Costa Rica Ltda., Edificio # 44 Calle 0, Ave.2, Zona Franca Coyol El Coyol, Alajuela 1897-4500 Costa Rica  (ii) M/s St. Jude Medical Brasil Ltda., Rua Professor Jose Vieria de Mendonca, 1301 Bairro Engenho Nogueria Belo Horizonte, Minas Gerais 31.310-260 Brazil  (FSC US FDA Valid Till  23-05-2020) | | | St. Jude Medical® Tissue Valve Biocor TM Valve Aortic-Sizes 21mm-29mm  Class D  Shelf Life: 4 Years  Model: B100-21A, B100-23A, B100-25A, B100-27A,B100-29A  Fee submitted: Rs 50,000/- | | | | | Tissue Heart Valve | | **Approved.**  MDB deliberated the matter at length and decided that the firm shall mention in a box warning on the product label that the product is a Porcine Heart Valve and 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 Heart Valves. | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Site:**  (i) M/s St. Jude Medical, Costa Rica Ltda., Edificio # 44 Calle 0, Ave.2, Zona Franca Coyol El Coyol, Alajuela 1897-4500 Costa Rica  (ii) M/s St. Jude Medical Brasil Ltda., Rua Professor Jose Vieria de Mendonca, 1301 Bairro Engenho Nogueria Belo Horizonte, Minas Gerais 31.310-260 Brazil  (FSC US FDA Valid Till  23-05-2020) | | | St. Jude Medical® Tissue Valve Biocor TM Valve Mitral Sizes 25mm-33mm  Class D  Shelf Life: 4 Years  Model: B100-25M, B100-27M, B100-29M, B100-31M,  B100-33M  Fee submitted: Rs 50,000/- | | | | | Tissue Heart Valve | | **Approved.**  MDB deliberated the matter at length and decided that the firm shall mention in a box warning on the product label that the product is a Porcine Heart Valve and 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 Heart Valves. | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Site:**  (i) M/s St. Jude Medical, Costa Rica Ltda., Edificio # 44 Calle 0, Ave.2, Zona Franca Coyol El Coyol, Alajuela 1897-4500 Costa Rica  (ii) M/s St. Jude Medical Brasil Ltda., Rua Professor Jose Vieria de Mendonca, 1301 Bairro Engenho Nogueria Belo Horizonte, Minas Gerais 31.310-260 Brazil  (FSC US FDA Valid Till  23-05-2020) | | | St. Jude Medical® Tissue Valve Trifecta TMValve AorticSizes 19mm-29mm  Class D  Shelf Life: 4 Years  Model: TF-19A, TF-21A ,  TF-23A, TF-25A, TF-27A,  TF-29A  Fee submitted: Rs 50,000/- | | | | | Tissue Heart Valve | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Caguas, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | St. Jude Medical® Tailor TM Annuloplasty Ring  Class D  Shelf Life: 5 Years  Model: TARP-25, TARP-27, TARP-29, TARP-31, TARP-33, TARP-35  Fee submitted: Rs 50,000/- | | | | | Annuloplasty Ring | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Legal Manufacturer/ Manufacturing Site:** M/s St. Jude Medical 177 Country Road, BE Saint Paul, MN 55117 USA  **Manufacturing Facility:**  M/s St. Jude Medical, Puerto Rico, LLC, LOT 20-B ST, Cagus, PR 00725 USA  (FSC US FDA Valid Till  13-03-2020) | | | SJM ® Master Series Coated Aortic Valved Graft (alt Collagen Source)  Class D  Shelf Life: 5 Years  Model: 19CAVGJ-514 00, 21CAVGJ-514 00,  23CAVGJ-514 00,  25CAVGJ-514 00,  27CAVGJ-514 00,  29CAVGJ-514 00,  31CAVGJ-514 00,  33CAVGJ-514 00  Fee submitted: Rs 50,000/- | | | | | Aortic Valved Graft | | **Approved.** | | | |
|  | M/s Verizon.  60-D, F.C.C, Zahoor Elahi Road, Gulberg IV, Lahore  (ELI-00087) | | **Manufacturer:** M/s Toray Industries, Inc., 1-1 Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo, 103-8666, Japan  **Manufacturing Site:**  M/s Toray Industries, Inc., Seta Plant 1-1, Oe 1-chome, Otsu, Shiga, 520-2141 Japan  (FSC Japan Issuance Date  18-10-2018) | | | Inoue-Balloon  Class D  Shelf Life: 2 Years  Model: PTMC-20, PTMC-22, PTMC-24, PTMC-26, PTMC-28, PTMC-30, IMS-20, IMS-22, IMS-24, IMS-26, IMS-28,  IMS-30, KMS-1, DMS-1,  GMS-1, SMS-1, NMS-1  Fee submitted: Rs 50,000/- | | | | | PTMC (Percutaneous Transvenous Mitral Commissurotomy) Balloon | | **Approved.** | | | |
|  | M/s Gene-Tech Laboratories, 246/B, PECHS, Block 6, Karachi  (ELI-00089) | | **Legal Manufacturer:**  M/s Helsinn Healthcare SA, Via Pian Scairolo 9, 6912 Pazzallo, Switzerland  **Manufacturing Site:**  M/s Biokosmes s.r.l., Via dei Livelli No. 1, 23842 Bosisio Parini, Lecco, Italy  (FSC Switzerland Valid Till  12-01-2021) | | | Gelclair® Concentrated Oral Rinse Gel  Class B  Shelf Life: 36 Months  180ml Bottle  Fee submitted: Rs 25,000/- | | | | | Oral gel for mucositis relief | | **Approved** subject to provision of complete stability studies since the stability studies supporting 36 months shelf life not provided. | | | |
|  | M/s Gene-Tech Laboratories, 246/B, PECHS, Block 6, Karachi  (ELI-00089) | | **Legal Manufacturer:**  M/s Helsinn Healthcare SA, Via Pian Scairolo 9, 6912 Pazzallo, Switzerland  **Manufacturing Site:**  M/s Biokosmes s.r.l., Via dei Livelli No. 1, 23842 Bosisio Parini, Lecco, Italy  (FSC Switzerland Valid Till  12-01-2021) | | | Gelclair® Concentrated Oral Rinse Gel  Class B  Shelf Life: 36 Months  15ml x 15 Sachet Box  Fee submitted: Rs 25,000/- | | | | | Oral gel for mucositis relief | | **Approved** subject to provision of complete stability studies since the stability studies supporting 36 months shelf life not provided. | | | |
|  | M/s Optisurg  17/C-1, Valancia Town, Lahore  (ELI-00305) | | **Legal Manufacturer/ Manufacturer:** M/s Hoya Medical Singapore Pte. Ltd. 455A Jalan Ahmad Ibrahim 639939, Singapore  (FSC Singapore Valid Till 07-08-2020) | | | Hoya-PS AF-1 Hoya Preloaded System Intraocular Lens  Class C  Shelf Life: 3 Years  Model: PC-60R, PY-60R  Fee submitted: Rs 50,000/- | | | | | The Hoya-PS AF-1 is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens. | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secretary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | M/s Optisurg.  17/C-1, Valancia Town, Lahore  (ELI-00305) | | **Legal Manufacturer/ Manufacturer:** M/s Hoya Medical Singapore Pte. Ltd. 455A Jalan Ahmad Ibrahim 639939, Singapore  (FSC Singapore Valid Till  07-08-2020) | | | Hoya Vivinex iSert Preloaded Intraocular Lens  Class C  Shelf Life: 3 Years  Model:XY1 XC1  Fee submitted: Rs 50,000/- | | | | | The HOYA VivinexTM iSert® IOL is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | M/s Optisurg  17/C-1, Valancia Town, Lahore  (ELI-00305) | | **Legal Manufacturer/ Manufacturer:** M/s Hoya Medical Singapore Pte. Ltd. 455A Jalan Ahmad Ibrahim 639939, Singapore  (FSC Singapore Valid Till  07-08-2020) | | | Hoya iSert Preloaded Intraocular Lens  Class C  Shelf Life: 3 Years  Model: 150, 151, 250, 251  Fee submitted: Rs 50,000/- | | | | | The HOYA iSert® IOL is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | M/s Optisurg.  17/C-1, Valancia Town, Lahore  (ELI-00305) | | **Legal Manufacturer/ Manufacturer:** M/s Hoya Medical Singapore Pte. Ltd. 455A Jalan Ahmad Ibrahim 639939, Singapore  (FSC Singapore Valid Till  07-08-2020) | | | Hoya Vivinex Toric Preloaded Intraocular Lens  Class C  Shelf Life: 3 Years  Model: XY1AT2, XY1AT3, XY1AT4, XY1AT5, XY1AT6, XY1AT7, XY1AT8, XY1AT9  Fee submitted: Rs 50,000/- | | | | | The HOYA Vivinex Toric IOL is intended to be placed into the capsular bag of the eye after extracapsular cataract removal, functioning as a refractive medium to replace the natural crystalline lens | | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and the Secreatary is authorised to issue Registration Certificate on panel of inspectors recommendation. | | | |
|  | M/s Alliance Medical. 12-B, 1st Floor, Agro Flats, Shadman, Lahore  (ELI-00147) | | **Manufacturer:**  M/s Biosensors International Pte Ltd., 36 Jalan Tukang 619266, Singapore  (FSC Germany Issuance Date  22-07-2018) | | | Central Venous Catheter and Catheterization Kit  Class D  Shelf Life: 3 Years  Model:CV-401-16, CV-401-20, CVN-401-16, CVN-401-20, CV-  402-06, CV-402-10, CV-402-16, CVN-402-06, CVN-  402-10, CVN-402-16, CV-501-16, CV-501-20, CVN-  501-16, CVN-501-20, CV-502-10, CV-502-16, CV-502-  20, CVN-502-10, CVN-502-16, CVN-502-20, CV-503-  08, CV-503-13, CV-503-30, CVN-503-08, CVN-503-13,  CVN-503-30, CV-701-16, CV-701-20, CVN-701-16,  CVN-701-20, CV-702-16, CV-702-20, CV-702-30, CVN-  702-16, CVN-702-20, CVN-702-30, CV-703-10, CV-  703-16, CV-703-20, CV-703-30, CVN-703-10, CVN-  703-16, CVN-703-20, CVN-703-30, CV-713-10, CV-  713-16, CV-713-20, CV-713-30, CVN-713-10, CVN-  713-16, CVN-713-20, CVN-713-30, CV-802-16, CV-  802-20, CV-802-30, CVN-802-16, CVN-802-20, CVN-  802-30, CV-803-16, CV-803-20, CV-803-30, CVN-803-  16, CVN-803-20, CVN-803-30, CV-804-16, CV-804-20,  CV-804-30, CVN-804-16, CVN-804-20, CVN-804-30.  Fee submitted: Rs 50,000/- | | | | | Central Venous Catheters are designed for use in critical care patients to monitor central venous pressures; sample blood; and administer drugs and solutions intravenously | | **Approved** subject to the specifications / codes available on Free Sale Certificate of Germany**.** | | | |
|  | M/s Advance Cardiology System, 12, Al-Sehat Centre, Rafique H.J. Shaheed Road, Hotel Regent Plaza, Karachi  (ELI-00074) | | **Manufacturer:** M/s BrosMed Medical Co., Ltd., 3F, 15th Building, SMEs Venture Park, SongShan Lake Hi-Tech Industrial Development Zone, Dongguan City, Guangdong Province, China  (FSC The Netherlands Valid Till 20-10-2023) | | | Artimes Balloon Dilatation Catheter  Class D  Shelf Life: 2 Years  801-1005, 801-1010, 801-1015  801-1020, 801-1030, 801-1205  801-1210, 801-1215, 801-1220  801-1230, 801-1505, 801-1510  801-1515, 801-1520, 801-1530  801-1705, 801-1710, 801-1715  801-1720, 801-1730, 801-2005  801-2010, 801-2015, 801-2020  801-2030, 801-2205, 801-2210  801-2215, 801-2220, 801-2230  801-2505, 801-2510, 801-2515  801-2520, 801-2530, 801-2705  801-2710, 801-2715, 801-2720  801-2730, 801-3005, 801-3010  801-3015, 801-3020, 801-3030  801-3205, 801-3210, 801-3215  801-3220, 801-3230, 801-3505  801-3510, 801-3515, 801-3520  801-3530, 801-4005, 801-4010  801-4015, 801-4020, 801-4030  801-1008, 801-1012, 801-1025  801-1208, 801-1212, 801-1225  801-1508, 801-1512, 801-1525  801-1708, 801-1712, 801-1725  801-2008, 801-2012, 801-2025  801-2208, 801-2212, 801-2225  801-2508, 801-2512, 801-2525  801-2708, 801-2712, 801-2725  801-3008, 801-3012, 801-3025  801-3208, 801-3212, 801-3225  801-3508, 801-3512, 801-3525  801-3705, 801-3708, 801-3710  801-3712, 801-3715, 801-3720  801-3725, 801-3730, 801-4008  801-4012, 801-4025  Fee submitted: Rs 50,000/- | | | | | PTCA Coronary Dilatation Balloon Catheter | | **Approved** subject to the specifications / codes available on Free Sale Certificate of the Netherlands**.** | | | |
|  | M/s Iqbal & Company.  Alfalah Manzil Opp. National Police Foundation, Street No.26, Sector E-11/4, Islamabad  (ELI-00117) | | **Legal Manufacturer:**  M/s Medical Components Inc. DBA – Medcomp 1499 Delp Drive Harleysville, PA 19438, USA  **Contract Manufacturer:** M/s Martech Medical Products Calle Mercurio N 46 Parque Industrial Mexicali 1 Mexicali, Baja California 21210, Mexico  (FSC US FDA Valid Till  14-11-2019) | | | Duo-Flow® Double Lumen Catheter Set  Class B  Shelf Life: 5 Years  **XTP94MT=** 9F X 12CM DOUBLE LUMEN CATHETER SET  **XTP96MT=** 9F X 15CM DOUBLE LUMEN CATHETER SET  **XTP98MT=** 9F X 20CM DOUBLE LUMEN CATHETER SET  **XTP94IJS=** 9F X 12CM IJ CATHETER SET  **XTP96IJS=** 9F X 15CM IJ CATHETER SET  **XTP114MT=** 11F X 12CM DOUBLE LUMEN CATHETER SET  **XTP116MT=** 11F X 15CM DOUBLE LUMEN CATHETER SET  **XTP118MT=** 11F X 20CM DOUBLE LUMEN CATHETER SET  **XTP119MT=** 11F X 24CM DOUBLE LUMEN CATHETER SET  **XTP114IJS=** 11F X 12CM IJ DOUBLE LUMEN CATHETER SET  **XTP116IJS=** 11F X 15CM IJ DOUBLE LUMEN CATHETER SET  **XTP118IJS=**11F X 20CM IJ DOUBLE LUMEN CATHETER SET  **XTP126MT=** 12F X 15CM DOUBLE LUMEN CATHETER SET  **XTP128MT=** 12F X 20CM DOUBLE LUMEN CATHETER SET  **XTP129MT=** 12F X 24CM DOUBLE LUMEN CATHETER SET  **XTP125IJS=** 12F X 13CM IJ DOUBLE LUMEN CATHETER SET  **XTP126IJS=** 12F X 15CM IJ DOUBLE LUMEN CATHETER SET  **XTP128IJS=**12F X 20CM IJ DOUBLE LUMEN CATHETER SET  **XTP114CT=** 11F X 12CM DOUBLE LUMEN CATHETER  **XTP116CT=** 11F X 15CM DOUBLE LUMEN CATHETER  **XTP118CT=** 11F X 20CM DOUBLE LUMEN CATHETER  **XTP114IJC=** 11F X 12CM DOUBLE LUMEN CATHETER WITH CURVEED EXTENSIONS  **XTP116IJC=** 11F X 15CM DOUBLE LUMEN CATHETER WITH CURVEED EXTENSIONS  **XTP118IJC=** 11F X 15CM DOUBLE LUMEN CATHETER WITH CURVEED EXTENSIONS  Fee submitted: Rs.50,000/- | | | | | Double Lumen Hemodialysis Catheter (Non Implantable) | | **Approved.** | | | |
|  | M/s Med Lab Services.  Office No.1, First Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi  (ELI-00056) | | **Manufacturer:**  M/s GeneProof a.s. Videnska 101/119 Dolni Herspice 619 00 Brno Czech Republic  (FSC Czech Republic Valid Till 15-11-2020) | | | GeneProof Hepatitis C Virus (HCV) PCR Kit  Class D  Shelf Life: 18 Months  HCV/ISEX/025  HCV/ISEX/050  HCV/ISEX/100  HCV/PLUS/025  HCV/PLUS/050  HCV/PLUS/100  Fee submitted: Rs 50,000/- | | | | | Hepatitis C Virus Nucleic acid IVD, Kit, Nucleic acid Technique (NAT) | | **Approved** subject to notarized evidence of the export of this product to other European countries | | | |
|  | M/s Med Lab Services.  Office No.1, First Floor, ABC Plaza, Commercial Center, Satellite Town, Rawalpindi  (ELI-00056) | | **Manufacturer:**  M/s GeneProof a.s. Videnska 101/119 Dolni Herspice 619 00 Brno Czech Republic  (FSC Czech Republic Valid Till 15-11-2020) | | | GeneProof Hepatitis B Virus (HBV) PCR Kit  Class D  Shelf Life: 24 Months  HBV/ISEX/025  HBV/ISEX/050  HBV/ISEX/100  Fee submitted: Rs 50,000/- | | | | | Hepatitis B Virus Core Nucleic acid IVD, Kit, Nucleic acid Technique (NAT) | | **Approved** subject to notarized evidence of the export of this product to other European countries | | | |
|  | M/s UDL Distribution (Pvt) Limited.  1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  (i) M/s Arrow International Inc., 312 Commerce Place Asheboro, NC 27203, USA  (ii) M/s Arrow International de Chihuahua S.A. de C.V. Ave. Washington 3701, Edificios 4 and 36 Colonia Complejo Industrial Las Americas Chihuahua, Chihuahua CP 31114, Mexico  (FSC US FDA Valid Till  10-07-2020) | | | Cannon® II Plus Long-Term Access Hemodialysis Catheterization Set  Class D  Shelf Life: 3 Years  Codes: CS-15242-SP,CS-15282-SP,CS-15282-VSP,CS-15322-SP,  CS-15362-VSP,CS-15322-SP,CS-15322-VSP,CS-15362-SP  Fee submitted: Rs 50,000/- | | | | | The Cannon® II Plus is indicated for use in attaining long-term vascular access for hemodialysis and apheresis | | **Approved**. | | | |
|  | M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc., (subsidiary of Teleflex, Inc.), 2400 Bernville Road Reading, PA 19605 USA  **Manufacturing Facility:**  (i) M/s Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panamericana Chihuahua, Chihuahua CP 31200, Mexico  (ii) M/s Arrow International C.R. a.s. Jamska 2359/47 Zdar Nad Sazavou, Vysocina 591 01, Czech Republic  (FSC US FDA Valid Till  10-07-2020) | | | Central Venous Catheterization Set with ARROWg+ard Blue  Class D  Shelf Life: 2 Years  CV-24301-E,CS-24306-E  CS-24706-E, CV-24701-E  CV-24301-E, CV-24701-E  CA-24301, CA-24306  Fee submitted: Rs 50,000/- | | | | | The Arrow CVC catheter permits venous access to the central circulation of patients. | | **Approved**. | | | |
|  | M/s UDL Distribution (Pvt) Ltd.  1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc., (subsidiary of Teleflex, Inc.), 2400 Bernville Road Reading, PA 19605 USA  **Manufacturing Facility:**  (i) M/s Arrow International Inc. 16 Elizabeth Dr Chelmsford, MA 01824 USA  (ii) M/s Arrow International, Inc., 312 Commerce Place Asheboro, NC 27203 USA  (FSC US FDA Valid Till  15-04-2020) | | | Ultra 8® IAB Intra Aortic Balloon Catheters  Class D  Shelf Life: 2 Years  Model: IAB-05830-U,  IAB-05840-U  Fee submitted: Rs.50,000/- | | | | | Intra Aortic Balloon Catheters | | **Approved**. | | | |
|  | M/s UDL Distribution (Pvt) Ltd.  1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc., (subsidiary of Teleflex, Inc.), 2400 Bernville Road Reading, PA 19605 USA  **Manufacturing Facility:**  (i) M/s Arrow International Inc. 16 Elizabeth Dr Chelmsford, MA 01824 USA  (ii) M/s Arrow International, Inc., 312 Commerce Place Asheboro, NC 27203 USA  (FSC US FDA Valid Till  15-04-2020) | | | Rediguard® IAB Intra Aortic Balloon Catheters  Class D  Shelf Life: 2 Years  Model: IAB-R950-U, IAB-S730C  IAB-S840C  Fee submitted: Rs.50,000/- | | | | | Intra Aortic Balloon Catheters | | **Approved**. | | | |
|  | M/s UDL Distribution (Pvt) Limited.  1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  (i) M/s Arrow International De Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panacericana Chihuahua, Chihuahua, CP 31200, Mexico  (ii) M/s Arrow International Inc., 312 Commerce Place Asheboro, NC 27203, USA  (iii) M/s Arrow International CR.a.s.,JAMSKA 2359/47 ZDAR NAD SAZAVOU, Vysocina, Czech Republic, 59101.  (FSC USFDA Valid Till  10-07-2020) | | | Arrow Two-Lumen Hemodialysis Catheterization Set  Class D  Shelf Life: 5 Years  Codes: CS-12122-E,CS-12122-F,CS-15122-F ,CS-15142-F,CV-15122-F,MC-12122-F,MC-15122-F, CS-12142-F, CS-15122-E, CV12122F  Fee submitted: Rs 50,000/- | | | | | Indicated for temporary or short-term Hemodialysis and apheresis. | | **Approved**. | | | |
|  | M/s UDL Distribution (Pvt) Ltd., 1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc., (subsidiary of Teleflex, Inc.), 2400 Bernville Road Reading, PA 19605 USA  **Manufacturing Facility:**  (i) M/s Arrow Internacional de Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panamericana Chihuahua, Chihuahua CP 31200, Mexico  (ii) M/s Arrow International C.R. a.s. Jamska 2359/47 Zdar Nad Sazavou, Vysocina 591 01, Czech Republic  (FSC US FDA Valid Till  10-07-2020) | | | Arrow Multi-Lumen Central Venous Catheterization Set  Class D  Shelf Life: 5 Years  CS-12553-J,CS-12703-E,CS-12703,CS-12853-E,CS-14703,CS-14703-E,CS-15703,CS-15703-E,CS-15853-E,CS-15853,CS-16553-J,CV-12703,CV-12703-E,CV-14703,CV-14703-E,CV-15703,CV-15703-E  Fee submitted: Rs 50,000/- | | | | | CVCs are intended to permit venous access to the central circulation through a single puncture site by way of the  femoral, jugular, or subclavian veins. | | **Approved**. | | | |
|  | M/s UDL Distribution (Pvt) Limited.  1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  (i) M/s Arrow International De Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panacericana Chihuahua, Chihuahua, CP 31200, Mexico  (ii) M/s Arrow International C.R. a.s. Jamska 2359/47 Zdar NAD Sazavou, Vysocina 591 01, Czech Republic  (FSC US FDA Valid Till  10-07-2020) | | | Arrow Central Venous Catheterization Set  Class D  Shelf Life: 5 Years  Codes: CS-04300, CS-04400, CV-04301,CV-50016,CV-50016-BF,ES-04300,ES-04301,ES-04301-P,ES-04306,ES-04400,CS-04700,CS-04701,CV-04706,CV-04701,CV-50014,CV-50014-BF,ES-04700,ES-04701,ES-04701-P,ES-04706,ES-04730,ES-04522,ES-04706P,CV-04306,AK-04200,AK-04400,AK-04650-E, AK-04700  Fee submitted: Rs 50,000/- | | | | | CVCs are intended to permit venous access to the central circulation through a single puncture site by way of the  Femoral, jugular, or subclavian veins. | | **Approved**. | | | |
|  | M/s Sadqain Healthcare (Pvt) Ltd.  Safari Villas II, Commercial Complex, 3rdFloor, Bahria Town Phase 7, Rawalpindi  (ELI-00020) | | **Manufacturer:** M/s Intersurgical Limited, Crane House, Mlly Millars Lane, Wokingham, Berkshire, UK  (FSC UK Issuance Date  02-03-2016) | | | Inter-Guard Breathing Filter with Luer Port-Sterile  Class B  Shelf Life: 05 Years  Model:1344000S  Fee submitted: Rs 25,000/- | | | | | Breathing Filter to reduce microbial transmission in respiratory system and reduce bacterial and viral contamination of the patient, medical devices and equipements | | **Approved.** | | | |
|  | M/s Sadqain Healthcare (Pvt) Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi  (ELI-00020) | | **Manufacturer:** M/s Intersurgical Limited, Crane House, Mlly Millars Lane, Wokingham, Berkshire, UK  (FSC UK Issuance Date 02-03-2016) | | | Inter-Therm HMEF with Luer Port – Sterile  Class B  Shelf Life: 05 Years  Model:1341000S  Fee submitted: Rs 25,000/- | | | | | To reduce risk of bacterial and viral contamination of patient, medical devices and equipment whilst also reducing moisture loss from a patient’s airways. | | **Approved.** | | | |
|  | M/s Mira Khan and Co.,  Flat No.414, 4th Floor Park Tower, F-10/3, Islamabad  (ELI-Not Issued: Case of Establishment License presented in this meeting) | | **Manufacturer:** M/s RAYS S.p.A Via Francesco Crispi 26 – 60027 Osimo (AN) Italy  (FSC Italy Issuance Date  07-08-2018) | | | Hemoflon (IV Cannula)  Class B  Shelf Life: 5 Years  Fee submitted: Rs 25,000/- | | | | | IV Cannula | | **Approved** subject to provision of documented evidence that sizes / codes applied by the firm are manufactured and available in the country of origin. | | | |
|  | M/s Mira Khan and Co., Flat No.414, 4th Floor Park Tower, F-10/3, Islamabad  (ELI-Not Issued: Case of Establishment License presented in this meeting) | | **Manufacturer:** M/s RAYS S.p.A Via Francesco Crispi 26 – 60027 Osimo (AN) Italy  (FSC Italy Issuance Date  07-08-2018) | | | Veniflon Safe (IV Cannula with Safety System)  Class B  Shelf Life: 5 Years  Fee submitted: Rs 25,000/- | | | | | Disposable IV Cannula | | **Approved** subject to provision of documented evidence that sizes / codes applied by the firm are manufactured and available in the country of origin. | | | |
|  | M/s Mira Khan and Co.  Flat No.414, 4th Floor Park Tower, F-10/3, Islamabad  (ELI-Not Issued: Case of Establishment License presented in this meeting) | | **Manufacturer:** M/s RAYS S.p.A Via Francesco Crispi 26 – 60027 Osimo (AN) Italy  (FSC Italy Issuance Date  07-08-2018) | | | Feel Touch 300 PF (Surgical Glove, Powder Free-Sterile)  Class B  Shelf Life: 5 Years  Fee submitted: Rs.25,000/- | | | | | Powder free latex surgical gloves, sterile, polymer coated. | | **Approved.** | | | |
|  | M/s Mira Khan and Co.  Flat No.414, 4th Floor Park Tower, F-10/3, Islamabad  (ELI-Not Issued: Case of Establishment License presented in this meeting) | | **Manufacturer:** M/s RAYS S.p.A Via Francesco Crispi 26 – 60027 Osimo (AN) Italy  (FSC Italy Issuance Date  07-08-2018) | | | INSU-LIGHT  Class B  Shelf Life: 5 Years  Fee submitted: Rs.25,000/- | | | | | Disposable Insulin Syringe | | **Approved** subject to provision of documented evidence that sizes / codes applied by the firm are manufactured and available in the country of origin. | | | |
|  | M/s Mira Khan and Co.  Flat No.414, 4th Floor Park Tower, F-10/3, Islamabad  (ELI-Not Issued: Case of Establishment License presented in this meeting) | | **Manufacturer:** M/s RAYS S.p.A Via Francesco Crispi 26 – 60027 Osimo (AN) Italy  (FSC Italy Issuance Date  07-08-2018) | | | INJ-LIGHT  Class B  Shelf Life: 5 Years  Fee submitted: Rs.25,000/- | | | | | Disposable Syringe with Mounted Needle | | **Approved** subject to provision of documented evidence that sizes / codes applied by the firm are manufactured and available in the country of origin. | | | |
|  | M/s BSN Medical (Pvt) Ltd.  A/69, SITE Manghopir Road, Karachi  (ELI-00011) | | **Manufacturer:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  (FSC Germany Issuance Date  23-10-2018) | | | Cutimed® Siltec®  Class C  Shelf Life: 3 Years  5cm x 6cm  10cm x 10cm  10cm x 20cm  15cm x 15cm 20cm x 20cm  Fee submitted: Rs 50,000/- | | | | | Silicone Foam Dressing | | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | **Legal Manufacturer / Manufacturer:**  M/s MicroVention, Inc.  1311 Valencia Avenue  Tustin, California, 92780 USA  **Manufacturer/ Manufacturing Site:**  M/s MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA  **Contract Manufacturer/ Manufacturing Site:**  M/s MicroVention Costa Rica S.R.L, Edificio B33, Zona Franca Coyol Alajuela, Costa Rica  (FSC USFDA validity 14-12-2019) | | | SCEPTOR C Occlusion Balloon Catheter  Class D  Shelf Life: 3 Years  Codes Sizes  BC0410C 4 x 10  BC0415C 4 x 15  BC0420C 4 x 20  Fee submitted: Rs 50,000/- | | | | | SCEPTOR C Occlusion Balloon is used to temporarily occlude the blood vessels of the peripheral and neurovasculature. These catheters offer a vessel selective  technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms. | | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | **Legal Manufacturar**  M/s Microvention Europe:  30 bis rue du VieilAbreuvior, 78100 Saint Germain en Laye, France  **Design & Development/ Production Sites:**  M/s MicroVention, Inc.  1311 Valencia Avenue  Tustin, California, 92780 USA  **Production Sites:**  M/s MicroVention Costa Rica S.R.L  Edificio B33  Zona Franca Coyol  Alajuela, Costa Rica  (FSC France Issue 10-04-2020) | | | FREDTM (Flow Re-Direction  Endoluminal Device).  Class D  Shelf Life: 3 Year  Codes Sizes  FRED3507 3.5 x 7  FRED3509 3.5 x 9  FRED3511 3.5 x 11  FRED3513 3.5 x 13  FRED3516 3.5 x 17  FRED4007 4.0 x 7  FRED4009 4.0 x 9  FRED4012 4.0 x 12  FRED4014 4.0 x 14  FRED4017 4.0 x 17  FRED4508 4.5 x 8  FRED4511 4.5 x 11  FRED4513 4.5 x 13  FRED4518 4.5 x 18  FRED4525 4.5 x 25  FRED5009 5.0 x 9  FRED5011 5.0 x 11  FRED5014 5.0 x 14  FRED5019 5.0 x 19  FRED5026 5.0 x 26  FRED5514 5.5 x 14  FRED5519 5.5 x 19  FRED5524 5.5 x 24  FRED3524 3.5 x 24  FRED3536 3.5 x 36  FRED4026 4.0 x 26  FRED4038 4.0 x 38  FRED4528 4.5 x 28  FRED4539 4.5 x 39  FRED5029 5.0 x 29  Fee submitted: Rs 50,000/- | | | | | The FRED system is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED system may also be used with embolic coils for the treatment of intracranial neurovascular lesions. | | **Approved.** | | | |
|  | M/s Intek Corporation. Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | **Legal Manufacturer:** M/s Microvention Europe: 30 bis rue du Vieil Abreuvior, 78100 Saint Germain en Laye, France  **Design & Development/ Production Site:** M/s MicroVention, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA  (FSC France Issuance Date  18-01-2018) | | | PHILTM Liquid Embolic System  Class D  Shelf Life: 2 Years  Codes  LEN10250  LEN10300  LEN10350  Fee submitted: Rs.50,000/- | | | | | Liquid Embolic System | | **Approved.** | | | |
| **Evaluator: Hafiz Muhammad Asif, AD, MDMC** | | | | | | | | | | | | | | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs. 50,000/- | | | ADVIA Centaur HCV Kit  (i) ADVIA Centaur HCV  Class D  Shelf Life: 12 Months  SMN: 10309061  (ii) ADVIA Centaur HCV QC Material  Class D  Shelf Life: 12 Months  SMN: 10309062 | | | | | In-vitro Diagnositc kit for Antibodies to Hepatitis C Virus (aHCV) Assay | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs. 50,000/- | | | ADVIA Centaur HIV Combo Kit  (i) ADVIA Centaur HIV Ag/Ab Combo  Class D  Shelf Life: 10 Months  SMN:10283020  (ii) ADVIA Centaur HCV Ag/Ab Combo Quality Control Material  Class D  Shelf Life: 10 Months  SMN:10283022 | | | | | In- Vitro Diagnositc kit for Human Immunodeficiency Viruses Type 1 and Type 2 Detection of Antigen and Antibody (CHIV) Assay | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs. 50,000/- | | | Atellica IM anti Hepatis B e antigen (aHBe) Kit  (i)Atellica IM Anti Hepatitis B e Antigen (aHBe)  Class D  Shelf Life: 19 Months  SMN:10995451  (ii) Atellica IM Anti Hepatitis B e Antigen Quality Control (aHBe QC)  Class D  Shelf Life: 24 Months  SMN:10995452 | | | | | The assay is for in vitro diagnostic use in the qualitative determination of antibody response to the e antigen of the hepatitis B virus (HBV) in human serum and plasma | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till 31-12-2020)  Fee Rs. 50,000/- | | | ADVIA Centaur anti HB e Kit  (i)ADVIA Centaur Anti-Hbe  Class D  Shelf Life: 19 Months  SMN:10334094  (ii) ADVIA Centaur Anti-Hbe Quality Control Material  Class D  Shelf Life: 24 Months  SMN:10334181 | | | | | In-vitro diagnostic kit for antibodies To Hepatitis B e Antigen (aHBe) Assay | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020)  Fee Rs. 50,000/- | | | Atellica IM HIV Ag/Ab Combo Kit  (i)Atellica IM HIV Ag/Ab Combo  Class D  Shelf Life: 10 Months  SMN:10995527  (ii) Atellica IM HIV Ag/Ab Combo Quality Control  Class D  Shelf Life: 10 Months  SMN:11200769 | | | | | Human Immunodeficiency Viruses Type1 and Type 2 Detection of Antigen and Antibody (CHIV) Assay | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020)  Fee Rs. 50,000/- | | | Atellica IM HBeAg Kit  (i)Atellica IM Hepatitis B e Antigen (HBeAg)  Class D  Shelf Life: 24 Months  SMN:10995600  (ii) Atellica IM Hepatitis B e Antigen Quality Control (HBeAg QC)  Class D  Shelf Life: 19 Months  SMN:10995601 | | | | | Hepatitis B e Antigen (HBeAg) Assay | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020)  Fee Rs. 50,000/- | | | ADVIA Centaur HBc Total Kit  (i)ADVIA Centaur HBc Total  Class D  Shelf Life: 12 Months  SMN:10309508  (ii) ADVIA Centaur HBc Total Quality Control Material  Class D  Shelf Life: 18 Months  SMN:10309509 | | | | | The assay is an in vitro diagnostic test for the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human serum or EDTA plasma | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020)  Fee Rs. 50,000/- | | | ADVIA Centaur HBsII Kit  (i)ADVIA Centaur HBsII  Class D  Shelf Life: 12 Months  SMN:10492138  (ii) ADVIA Centaur HBsII  Class D  Shelf Life: 12 Months  SMN:10994742  (iii) ADVIA Centaur HBsAg Quality Control Material  Class D  Shelf Life: 24 Months  SMN:10309059 | | | | | Hepatitis B Surface Antigen (HBsII) Assay | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020)  Fee Rs. 50,000/- | | | Atellica IM EHIV Kit  (i)Atellica IM HIV 1/O/2 Enhanced (EHIV)  Class D  Shelf Life: 10 Months  SMN:10995610  (ii) Atellica IM HIV 1/O/2 Enhanced Quality Control (EHIV QC)  Class D  Shelf Life: 12 Months  SMN:10995612 | | | | | The assay is for in vitro diagnostic use in the qualitative determination of antibodies to human immunodeficiency virus type 1, including subtype O, and/or type 2 in human serum and plasma | **Approved.** | | | |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi  (ELI-00037) | | | **Legal Manufacturer:** M/s Siemens Healthcare Diagnostics Inc, 511 Benedict Avenue, Tarrytown, NY, 10591, USA  **Authorized Representative:**  M/s Siemens Healthcare Diagnostics Limited, Sir William Siemens Square, Frimley, Camberley, Surrey, GU16 8QD, UK  (FSC UK Valid Till31-12-2020)  Fee Rs. 50,000/- | | | Atellica IM Hepatitis B surface antigen II Kit  (i)Atellica IM Hepatitis B surface Antigen II (HBsII)  Class D  Shelf Life: 12 Months  SMN:10995604  (ii) Atellica IM Hepatitis B surface Antigen II Quality Control (HBsII QC)  Class D  Shelf Life: 12 Months  SMN:10995605 | | | | | Hepatitis B Surface Antigen (HBsII) Assay | **Approved.** | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee Rs. 50,000/- | | | ProtectaTM XT CRT-D  Class D  Shelf Life: 18 Months from the date of power source connection.  Model: D354TRM | | | | | Cardiac Resynchronization Therapy Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee Rs. 50,000/- | | | BravaTM CRT-D  Class D  Shelf Life: 18Months from the date of power source connection.  Model: DTBC2D4 | | | | | Cardiac Resynchronization Therapy Implantable Defibrillator | **Approved** subject to provision of fresh Agency Agreement and Design Examination Certificate. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee. 50,000/- | | | ProtectaTM XT VR  Class D  Shelf Life: 18Months from the date of power source connection.  Model: D354VRM | | | | | Single Chamber Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | BravaTM CRT-D  Class D  Shelf Life: 18Months from the date of power source connection.  Model: DTBC2D1 | | | | | Cardiac Resynchronization Therapy | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | ProtectaTM XT CRT-D  Class D  Shelf Life: 18Months from the date of power source connection.  Model: D354TRG | | | | | Cardiac Resynchronization Therapy Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee, 50,000/- | | | ProtectaTM XT DR  Class D  Shelf Life: 18Months from the date of power source connection.  Model: D354DRM | | | | | Dual Chamber Implantable | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee Rs. 50, 000/- | | | Evera MRITM XT DR SureScanTM  Class D  Shelf Life: 18Months from the date of power source connection.  Model: DDMB2D4 | | | | | Dual Chamber Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee Rs. 50,000/- | | | SensiaIPG  Class D  Shelf Life: 18Months from the date of power source connection.  Model: SESR01 | | | | | Single Chamber Pacemaker | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | AdaptaTM  Class D  Shelf Life: 18Months from the date of power source connection.  Model: ADDR01 | | | | | Dual Chamber Implantable Pacemaker, Rate-Responsive | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021) | | | Evera MRITM XT DR SureScanTM  Class D  Shelf Life: 18Months from the date of power source connection.  Model: DDMB2D1 | | | | | Dual Chamber Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee Rs. 50,000/- | | | ReliaTMIPG  Class D  Shelf Life: 18Months from the date of power source connection.  Model: RESR01 | | | | | Single Chamber Pacemaker | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee. Rs. 50,000/- | | | Evera MRITM XT DR SureScanTM  Class D  Shelf Life: 18Months from the date of power source connection.  Model: DVMB2D1 | | | | | Dual Chamber Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi  (ELI-00001) | | | **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 Totochenaz, Switzerland  (FSC Switzerland Valid Till  06-03-2021)  Fee. Rs. 50,000/- | | | Evera MRITM XT DR SureScanTM  Class D  Shelf Life: 18Months  Model: DDMB2D4 | | | | | Dual Chamber Implantable Defibrillator | **Approved** subject to provision of valid ISO 13485Certificate and fresh Agency Agreement. | | | |
|  | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore  (ELI-00094) | | | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA  **Manufacturing Sites:** (i) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA  (ii) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA  (FSC USFDA Valid Till  16-05-2020)  Fee Rs. 50,000/- | | | Hi-Torque® Balance Heavy Weight TM 0.014 Guide Wire with Hydrocoat Hydrophilic Coating  Class D  Shelf Life: 2Year  1000460H, 1000460HJ, 1000462H, 1000462HJ, 1000463H, 1000463HJ | | | | | PTCA Guide Wire | **Approved** subject to provision of Stability study. | | | |
|  | M/s S. Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078) | | | **Manufactured By:** M/s JMS Healthcare PHL, Inc., Lot 2-B-1, Phase 1B, First Philippine Industrial Park, Special Economic Zone, 4232 Tanauan City, Batangas, Philippines  (FSC Philippines Valid Till  14-08-2023)  Fee Rs. 50,000/- | | | JMS Blood Bag CPDA-1 (T) 500+300mlx2, 17G  Class D  Shelf Life: 3Years  Size: Triple Bag | | | | | Blood Bag | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017. | | | |
|  | M/s S. Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078) | | | **Manufactured By:** M/s JMS Healthcare PHL, Inc., Lot 2-B-1, Phase 1B, First Philippine Industrial Park, Special Economic Zone, 4232 Tanauan City, Batangas, Philippines  (FSC Philippines Valid Till  14-08-2023)  Fee Rs. 50,000/- | | | JMS Blood Bag CPDA-1 (D) 500+300mlx2, 17G  Class D  Shelf Life: 3Years  Size: Double Bag | | | | | Blood Bag | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR | | | |
|  | M/s S. Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078) | | | **Manufactured By:** M/s JMS Healthcare PHL, Inc., Lot 2-B-1, Phase 1B, First Philippine Industrial Park, Special Economic Zone, 4232 Tanauan City, Batangas, Philippines  (FSC Philippines Valid Till  14-08-2023)  Fee Rs. 50,000/- | | | JMS Blood Bag CPDA-1 (S) 250ml, 17G  Class D  Shelf Life: 3Years  Size: Single Bag | | | | | Blood Bag | **Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR | | | |
|  | M/s S. Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi  (ELI-00078) | | | **Manufactured By:** M/s JMS Healthcare PHL, Inc., Lot 2-B-1, Phase 1B, First Philippine Industrial Park, Special Economic Zone, 4232 Tanauan City, Batangas, Philippines  (FSC Philippines Valid Till  14-08-2023)  Fee Rs. 50,000/- | | | JMS Blood Bag CPDA-1 (S) 500ml, 17G  Class D  Shelf Life: 3Years  Size: Single Bag | | | | | Blood Bag | **Approved** subject to inspection of manufac-turer abroad under Rule 71 of MDR, 2017. | | | |
|  | M/s Tek Enterprises, Office No. MZ-9, Al-Hafeez Heights Sir Syed Road, Gulberg, Lahore  (ELI-00189) | | | **Legal Manufacturer:** M/s Emergo Europe B.V. Prinsessegracht 20 2514 AP s-Gravenhage, The Netherlands  **Manufacturer:**  M/s Asahi Intecc Co., Ltd., 3-100 Akatsuki-Cho, 489-0071 Seto, Aichi, Japan  **Manufacturing Site:**  M/s Asahi Intecc (Thailand) Co., Ltd., 158/1 Moo 5, Bangkadi Industrial Park Tiwanon Road, Tambol Bangkadi Amphur Muang, Pathumthani 1200 Thailand  (FSC The Netherlands Valid Till  01-05-2019) | | | ASAHI Caravel Microcatheter  Class D  Shelf Life: 3 Years  CRV135-19PASAHI Caravel Microcatheter, 2.6Fr, Straight-Tip, 135cm  CRV150-19PASAHI Caravel Microcatheter, 2.6Fr, Straight-Tip, 1.  +50cm | | | | | Microcathe-ter | **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) | | | **Manufacturer:** M/s Balton SP Z.O.O Nowy Swiat 7/1400496 Warszawa, Poland  (FSC Poland Issuance Date  26-01-2018) | | | Coronary Angioplasty Catheter Fryderyk  Class D  Shelf Life: 4 Years and 11 Months  Type : | | | | | Coronary Angioplasty Catheter | **Approved** subject to provision of EPSP. The firm has also provided Free Sale Certificate of a Reference Country, namely, Spain. | | | |
| |  |  | | --- | --- | | Reference | Szie | | CBA1.25x10140 | 1.25x10 | | CBA1.25x15140 | 1.25x15 | | CBA1.25x20140 | 1.25x20 | | CBA1.25x25140 | 1.25x25 | | CBA1.25x30140 | 1.25x30 | | CBA1.25x35140 | 1.25x35 | | CBA1.25x40140 | 1.25x40 | | CBA1.5x10140 | 1.5x10 | | CBA1.5x15140 | 1.5x15 | | CBA1.5x20140 | 1.5x20 | | CBA1.5x25140 | 1.5x25 | | CBA1.5x30140 | 1.5x30 | | CBA1.5x35140 | 1.5x35 | | CBA1.5x40140 | 1.5x40 | | CBA1.75x10140 | 1.75x10 | | CBA1.75x15140 | 1.75x15 | | CBA1.75x20140 | 1.75x20 | | CBA1.75x25140 | 1.75x25 | | CBA1.75x30140 | 1.75x30 | | CBA1.75x35140 | 1.75x35 | | CBA1.75x40140 | 1.75x40 | | CBA2.0x10140 | 2.0x10 | | CBA2.0x15140 | 2.0x15 | | CBA2.0x20140 | 2.0x20 | | CBA2.0x25140 | 2.0x25 | | CBA2.0x30140 | 2.0x30 | | CBA2.0x35140 | 2.0x35 | | CBA2.0x40140 | 2.0x40 | | CBA2.25x10140 | 2.25x10 | | CBA2.25x15140 | 2.25x15 | | CBA2.25x20140 | 2.25x20 | | CBA2.25x25140 | 2.25x25 | | CBA2.25x30140 | 2.25x30 | | CBA2.25x35140 | 2.25x35 | | CBA2.25x40140 | 2.25x40 | | CBA2.5x10140 | 2.5x10 | | CBA2.5x15140 | 2.5x15 | | CBA2.5x20140 | 2.5x20 | | CBA2.5x25140 | 2.5x25 | | CBA2.5x30140 | 2.5x30 | | CBA2.5x35140 | 2.5x35 | | CBA2.5x40140 | 2.5x40 | | CBA2.75x10140 | 2.75x10 | | CBA2.75x15140 | 2.75x15 | | CBA2.75x20140 | 2.75x20 | | CBA2.75x25140 | 2.75x25 | | CBA2.75x30140 | 2.75x30 | | CBA2.75x35140 | 2.75x35 | | CBA2.75x40140 | 2.75x40 | | CBA3.0x10140 | 3.0x10 | | CBA3.0x15140 | 3.0x15 | | CBA3.0x20140 | 3.0x20 | | CBA3.0x25140 | 3.0x25 | | CBA3.0x30140 | 3.0x30 | | CBA3.0x35140 | 3.0x35 | | CBA3.0x40140 | 3.0x40 | | CBA3.25x10140 | 3.25x10 | | CBA3.25x15140 | 3.25x15 | | CBA3.25x20140 | 3.25x20 | | CBA3.25x25140 | 3.25x25 | | CBA3.25x30140 | 3.25x30 | | CBA3.25x35140 | 3.25x35 | | CBA3.25x40140 | 3.25x40 | | CBA3.5x10140 | 3.5x10 | | CBA3.5x15140 | 3.5x15 | | CBA3.5x20140 | 3.5x20 | | CBA3.5x25140 | 3.5x25 | | CBA3.5x30140 | 3.5x30 | | CBA3.5x35140 | 3.5x35 | | CBA3.5x40140 | 3.5x40 | | CBA3.75x10140 | 3.75x10 | | CBA3.75x15140 | 3.75x15 | | CBA3.75x20140 | 3.75x20 | | CBA3.75x25140 | 3.75x25 | | CBA3.75x30140 | 3.75x30 | | CBA3.75x35140 | 3.75x35 | | CBA3.75x40140 | 3.75x40 | | CBA4.0x10140 | 4.0x10 | | CBA4.0x15140 | 4.0x15 | | CBA4.0x20140 | 4.0x20 | | CBA4.0x25140 | 4.0x25 | | CBA4.0x30140 | 4.0x30 | | CBA4.0x35140 | 4.0x35 | | CBA4.0x40140 | 4.0x40 | | CBA4.5x10140 | 4.5x10 | | CBA4.5x15140 | 4.5x15 | | CBA4.5x20140 | 4.5x20 | | CBA4.5x25140 | 4.5x25 | | CBA4.5x30140 | 4.5x30 | | CBA4.5x35140 | 4.5x35 | | CBA4.5x40140 | 4.5x40 | | CBA5.0x10140 | 5.0x10 | | CBA5.0x15140 | 5.0x15 | | CBA5.0x20140 | 5.0x20 | | CBA5.0x25140 | 5.0x25 | | CBA5.0x30140 | 5.0x30 | | CBA5.0x35140 | 5.0x35 | | CBA5.0x40140 | 5.0x40 | | | | | | | | | | |
|  | 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) | | | **Manufacturer:** M/s Balton SP Z.O.O Nowy Swiat 7/1400496 Warszawa, Poland  (FSC Poland Issuance Date  26-01-2018) | | | Sirolimus Eluting Cobalt Chromium Coronary Stents “ALEX” with Delivery System RX  Class D  Shelf Life: 23 Months | | | | | Cobalt Chromium Sirolimus Eluting Coronary Stent with Delivery System | | | | **Approved** subject to provision of EPSP. The firm has also provided Free Sale Certificate of a Reference Country, namely, Spain. |
| |  |  | | --- | --- | | Reference | Szie | | ZSTC2.0 x 0814CFS | 2.0x08 | | ZSTC2.0 x 1014CFS | 2.0x10 | | ZSTC2.0 x 1214CFS | 2.0x12 | | ZSTC2.0 x 1514CFS | 2.0x15 | | ZSTC2.0 x 1814CFS | 2.0x18 | | ZSTC2.0 x 2214CFS | 2.0x22 | | ZSTC2.0 x 2514CFS | 2.0x25 | | ZSTC2.0 x 2914CFS | 2.0x29 | | ZSTC2.0 x 3414CFS | 2.0x34 | | ZSTC2.0 x 3614CFS | 2.0x36 | | ZSTC2.0 x 4014CFS | 2.0x38 | | ZSTC2.0 x 2514CFS | 2.0x40 | | ZSTC2.25 x 0814CFS | 2.25x08 | | ZSTC2.25 x 1014CFS | 2.25x10 | | ZSTC2.25 x 1214CFS | 2.25x12 | | ZSTC2.25 x 1514CFS | 2.25x15 | | ZSTC2.25 x 1814CFS | 2.25x18 | | ZSTC2.25 x 2214CFS | 2.25x22 | | ZSTC2.25 x 2514CFS | 2.25x25 | | ZSTC2.25 x 2914CFS | 2.25x29 | | ZSTC2.25 x 3414CFS | 2.25x34 | | ZSTC2.25 x 3614CFS | 2.25x36 | | ZSTC2.25 x 3814CFS | 2.25x38 | | ZSTC2.25 x 4014CFS | 2.25x40 | | ZSTC2.50 x 0814CFS | 2.50x08 | | ZSTC2.50 x 1014CFS | 2.50x10 | | ZSTC2.50 x 1214CFS | 2.50x12 | | ZSTC2.50 x 1514CFS | 2.50x15 | | ZSTC2.50 x 1814CFS | 2.50x18 | | ZSTC2.50 x 2214CFS | 2.50x22 | | ZSTC2.50 x 2514CFS | 2.50x25 | | ZSTC2.50 x 2914CFS | 2.50x29 | | ZSTC2.50 x 3414CFS | 2.50x34 | | ZSTC2.50 x 3614CFS | 2.50x36 | | ZSTC2.50 x 3814CFS | 2.50x38 | | ZSTC2.50 x 4014CFS | 2.50x40 | | ZSTC2.75 x 0814CFS | 2.75x08 | | ZSTC2.75 x 1014CFS | 2.75x10 | | ZSTC2.75 x 1214CFS | 2.75x12 | | ZSTC2.75 x 1514CFS | 2.75x15 | | ZSTC2.75 x 1814CFS | 2.75x18 | | ZSTC2.75 x 2214CFS | 2.75x22 | | ZSTC2.75 x 2514CFS | 2.75x25 | | ZSTC2.75 x 2914CFS | 2.75x29 | | ZSTC2.75 x 3414CFS | 2.75x34 | | ZSTC2.75 x 3614CFS | 2.75x36 | | ZSTC2.75 x 3814CFS | 2.75x38 | | ZSTC2.75 x 4014CFS | 2.75x40 | | ZSTC3.0 x 0814CFS | 3.0x08 | | ZSTC3.0 x 1014CFS | 3.0x10 | | ZSTC3.0 x 1214CFS | 3.0x12 | | ZSTC3.0 x 1514CFS | 3.0x15 | | ZSTC3.0 x 1814CFS | 3.0x18 | | ZSTC3.0 x 2214CFS | 3.0x22 | | ZSTC3.0 x 2514CFS | 3.0x25 | | ZSTC3.0 x 2914CFS | 3.0x29 | | ZSTC3.0 x 3414CFS | 3.0x34 | | ZSTC3.0 x 3614CFS | 3.0x36 | | ZSTC3.0 x 3814CFS | 3.0x38 | | ZSTC3.0 x 4014CFS | 3.0x40 | | ZTS3.25x814CFS | 3.25x8 | | ZTS3.25x1014CFS | 3.25x10 | | ZTS3.25x1214CFS | 3.25x12 | | ZTS3.25x1514CFS | 3.25x15 | | ZTS3.25x1814CFS | 3.25x18 | | ZTS3.25x2214CFS | 3.25x22 | | ZTS3.25x2514CFS | 3.25x25 | | ZTS3.25x2914CFS | 3.25x29 | | ZTS3.25x3414CFS | 3.25x34 | | ZTS3.25x3614CFS | 3.25x36 | | ZTS3.25x3814CFS | 3.25x38 | | ZTS3.25x4014CFS | 3.25x40 | | ZSTC3.50 x 0814CFS | 3.50x08 | | ZSTC3.50 x 1014CFS | 3.50x10 | | ZSTC3.50 x 1214CFS | 3.50x12 | | ZSTC3.50 x 1514CFS | 3.50x15 | | ZSTC3.50 x 1814CFS | 3.50x18 | | ZSTC3.50 x 2214CFS | 3.50x22 | | ZSTC3.50 x 2514CFS | 3.50x25 | | ZSTC3.50 x 2914CFS | 3.50x29 | | ZSTC3.50 x 3414CFS | 3.50x34 | | ZSTC3.50 x 3614CFS | 3.50x36 | | ZSTC3.50 x 3814CFS | 3.50x38 | | ZSTC3.50 x 4014CFS | 3.50x40 | | ZSTC3.75 x 0814CFS | 3.75x08 | | ZSTC3.75 x 1014CFS | 3.75x10 | | ZSTC3.75 x 1214CFS | 3.75x12 | | ZSTC3.75 x 1514CFS | 3.75x15 | | ZSTC3.75 x 1814CFS | 3.75x18 | | ZSTC3.75 x 2214CFS | 3.75x22 | | ZSTC3.75 x 2514CFS | 3.75x25 | | ZSTC3.75 x 2914CFS | 3.75x29 | | ZSTC3.75 x 3414CFS | 3.75x34 | | ZSTC3.75 x 3614CFS | 3.75x36 | | ZSTC3.75 x 3814CFS | 3.75x38 | | ZSTC3.75 x 4014CFS | 3.75x40 | | ZTS4.0x814CFS | 4.0x8 | | ZTS4.0x1014CFS | 4.0x10 | | ZTS4.0x1214CFS | 4.0x12 | | ZTS4.0x1514CFS | 4.0x15 | | ZTS4.0x1814CFS | 4.0x18 | | ZTS4.0x2214CFS | 4.0x22 | | ZTS4.0x2514CFS | 4.0x25 | | ZTS4.0x2914CFS | 4.0x29 | | ZTS4.0x3414CFS | 4.0x34 | | ZTS4.0x3614CFS | 4.0x36 | | ZTS4.0x3814CFS | 4.0x38 | | ZTS4.0x4014CFS | 4.0x40 | | ZTS4.5x814CFS | 4.5x8 | | ZTS4.5x1014CFS | 4.5x10 | | ZTS4.5x1214CFS | 4.5x12 | | ZTS4.5x1514CFS | 4.5x15 | | ZTS4.5x1814CFS | 4.5x18 | | ZTS4.5x2214CFS | 4.5x22 | | ZTS4.5x2514CFS | 4.5x25 | | ZTS4.5x2914CFS | 4.5x29 | | ZTS4.5x3414CFS | 4.5x34 | | ZTS4.5x3614CFS | 4.5x36 | | ZTS4.5x3814CFS | 4.5x38 | | ZTS4.5x4014CFS | 4.5x40 | | ZTS5.0x814CFS | 5.0x8 | | ZTS5.0x1014CFS | 5.0x10 | | ZTS5.0x1214CFS | 5.0x12 | | ZTS5.0x1514CFS | 5.0x15 | | ZTS5.0x1814CFS | 5.0x18 | | ZTS5.0x2214CFS | 5.0x22 | | ZTS5.0x2514CFS | 5.0x25 | | ZTS5.0x2914CFS | 5.0x29 | | ZTS5.0x3414CFS | 5.0x34 | | ZTS5.0x3614CFS | 5.0x36 | | ZTS5.0x3814CFS | 5.0x38 | | ZTS5.0x4014CFS | 5.0x40 | | | | | | | | | | |
|  | 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) | | | **Manufacturer:** M/s Balton SP Z.O.O Nowy Swiat 7/1400496 Warszawa, Poland  (FSC PolandIssuance Date  26-01-2018) | | | Introducer Version Braided or Non-Braided Kits to Introduce and Exchange Catheters and Endocavitary Electrodes, with Hemostasis Valve  Class D  Shelf Life: 4 Years and 11 months.  Model: | | | | | Introducer | | **Approved** subject to provision of EPSP. The firm has also provided Free Sale Certificate of a Reference Country, namely, Spain. | | |
| |  |  |  | | --- | --- | --- | | INT8.5A, | ZWERK6F | INT12F | | INT5FK50 | ZWERK7F | INT14F | | INT5FK55 | ZWERK8F | INT16F | | INT5FK60 | ZWERK9F | INT3F | | INT5FK65 | ZWERK10F | INT4F | | INT5FK70 | INT5FKR | INT5F | | INT5FK80 | INT5FKRP | INT6F | | INT5FK90 | INT5F21KRP | INT16F | | INT6FK50 | INT5FKR23 | INT16F23 | | INT6FK55 | INT5FKR23P | INT18F | | INT6FK60 | INT5F21KR23P | INT18F23 | | INT6FK65 | INT6FKR | INT7F | | INT6FK70 | INT6FKRP | INT8F | | INT6FK80 | INT6F21KRP | INT9F | | INT6FK90 | INT6FKR23 | INT10F | | INT7FK50 | INT6FKR23P | INT11F | | INT7FK55 | INT6F21KR23P | INT11F23 | | INT7FK60 | INT7FKR | INT12F | | INT7FK65 | INT7FKRP | INT12F23 | | INT7FK70 | INT7F21KRP | INT14F | | INT7FK80 | INT7FKR23 | INT14F23 | | INT7FK90 | INT7FKR23P |  | | INT8FK50 | INT7F21KR23P |  | | INT8FK55 | INT8FK70 |  | | INT8FK60 | INT8FK80 |  | | INT8FK65 | INT8FK90 |  | | | | | | | | | | |
|  | 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) | | | **Manufacturer:** M/s Balton SP Z.O.O Nowy Swiat 7/1400496 Warszawa, Poland  (FSC PolandIssuance Date  26-01-2018) | | | Cobalt Chromium Coronary Stents “CoFlexus” with Delivery System Rapid Exchange  Class D  Shelf Life: 23 Months | | | | | Cobalt Chromium Sirolimus Eluting Coronary Stent with Delivery System | | **Approved** subject to provision of EPSP. The firm has also provided Free Sale Certificate of a Reference Country, namely, Spain. | | |
| |  |  | | --- | --- | | Reference | Szie | | ZSTC2.0 x 0814CFS | 2.0x08 | | ZSTC2.0 x 1014CFS | 2.0x10 | | ZSTC2.0 x 1214CFS | 2.0x12 | | ZSTC2.0 x 1514CFS | 2.0x15 | | ZSTC2.0 x 1814CFS | 2.0x18 | | ZSTC2.0 x 2214CFS | 2.0x22 | | ZSTC2.0 x 2514CFS | 2.0x25 | | ZSTC2.0 x 2914CFS | 2.0x29 | | ZSTC2.0 x 3414CFS | 2.0x34 | | ZSTC2.0 x 3614CFS | 2.0x36 | | ZSTC2.0 x 4014CFS | 2.0x38 | | ZSTC2.0 x 2514CFS | 2.0x40 | | ZSTC2.25 x 0814CFS | 2.25x08 | | ZSTC2.25 x 1014CFS | 2.25x10 | | ZSTC2.25 x 1214CFS | 2.25x12 | | ZSTC2.25 x 1514CFS | 2.25x15 | | ZSTC2.25 x 1814CFS | 2.25x18 | | ZSTC2.25 x 2214CFS | 2.25x22 | | ZSTC2.25 x 2514CFS | 2.25x25 | | ZSTC2.25 x 2914CFS | 2.25x29 | | ZSTC2.25 x 3414CFS | 2.25x34 | | ZSTC2.25 x 3614CFS | 2.25x36 | | ZSTC2.25 x 3814CFS | 2.25x38 | | ZSTC2.25 x 4014CFS | 2.25x40 | | ZSTC2.50 x 0814CFS | 2.50x08 | | ZSTC2.50 x 1014CFS | 2.50x10 | | ZSTC2.50 x 1214CFS | 2.50x12 | | ZSTC2.50 x 1514CFS | 2.50x15 | | ZSTC2.50 x 1814CFS | 2.50x18 | | ZSTC2.50 x 2214CFS | 2.50x22 | | ZSTC2.50 x 2514CFS | 2.50x25 | | ZSTC2.50 x 2914CFS | 2.50x29 | | ZSTC2.50 x 3414CFS | 2.50x34 | | ZSTC2.50 x 3614CFS | 2.50x36 | | ZSTC2.50 x 3814CFS | 2.50x38 | | ZSTC2.50 x 4014CFS | 2.50x40 | | ZSTC2.75 x 0814CFS | 2.75x08 | | ZSTC2.75 x 1014CFS | 2.75x10 | | ZSTC2.75 x 1214CFS | 2.75x12 | | ZSTC2.75 x 1514CFS | 2.75x15 | | ZSTC2.75 x 1814CFS | 2.75x18 | | ZSTC2.75 x 2214CFS | 2.75x22 | | ZSTC2.75 x 2514CFS | 2.75x25 | | ZSTC2.75 x 2914CFS | 2.75x29 | | ZSTC2.75 x 3414CFS | 2.75x34 | | ZSTC2.75 x 3614CFS | 2.75x36 | | ZSTC2.75 x 3814CFS | 2.75x38 | | ZSTC2.75 x 4014CFS | 2.75x40 | | ZSTC3.0 x 0814CFS | 3.0x08 | | ZSTC3.0 x 1014CFS | 3.0x10 | | ZSTC3.0 x 1214CFS | 3.0x12 | | ZSTC3.0 x 1514CFS | 3.0x15 | | ZSTC3.0 x 1814CFS | 3.0x18 | | ZSTC3.0 x 2214CFS | 3.0x22 | | ZSTC3.0 x 2514CFS | 3.0x25 | | ZSTC3.0 x 2914CFS | 3.0x29 | | ZSTC3.0 x 3414CFS | 3.0x34 | | ZSTC3.0 x 3614CFS | 3.0x36 | | ZSTC3.0 x 3814CFS | 3.0x38 | | ZSTC3.0 x 4014CFS | 3.0x40 | | ZTS3.25x814CFS | 3.25x8 | | ZTS3.25x1014CFS | 3.25x10 | | ZTS3.25x1214CFS | 3.25x12 | | ZTS3.25x1514CFS | 3.25x15 | | ZTS3.25x1814CFS | 3.25x18 | | ZTS3.25x2214CFS | 3.25x22 | | ZTS3.25x2514CFS | 3.25x25 | | ZTS3.25x2914CFS | 3.25x29 | | ZTS3.25x3414CFS | 3.25x34 | | ZTS3.25x3614CFS | 3.25x36 | | ZTS3.25x3814CFS | 3.25x38 | | ZTS3.25x4014CFS | 3.25x40 | | ZSTC3.50 x 0814CFS | 3.50x08 | | ZSTC3.50 x 1014CFS | 3.50x10 | | ZSTC3.50 x 1214CFS | 3.50x12 | | ZSTC3.50 x 1514CFS | 3.50x15 | | ZSTC3.50 x 1814CFS | 3.50x18 | | ZSTC3.50 x 2214CFS | 3.50x22 | | ZSTC3.50 x 2514CFS | 3.50x25 | | ZSTC3.50 x 2914CFS | 3.50x29 | | ZSTC3.50 x 3414CFS | 3.50x34 | | ZSTC3.50 x 3614CFS | 3.50x36 | | ZSTC3.50 x 3814CFS | 3.50x38 | | ZSTC3.50 x 4014CFS | 3.50x40 | | ZSTC3.75 x 0814CFS | 3.75x08 | | ZSTC3.75 x 1014CFS | 3.75x10 | | ZSTC3.75 x 1214CFS | 3.75x12 | | ZSTC3.75 x 1514CFS | 3.75x15 | | ZSTC3.75 x 1814CFS | 3.75x18 | | ZSTC3.75 x 2214CFS | 3.75x22 | | ZSTC3.75 x 2514CFS | 3.75x25 | | ZSTC3.75 x 2914CFS | 3.75x29 | | ZSTC3.75 x 3414CFS | 3.75x34 | | ZSTC3.75 x 3614CFS | 3.75x36 | | ZSTC3.75 x 3814CFS | 3.75x38 | | ZSTC3.75 x 4014CFS | 3.75x40 | | ZTS4.0x814CFS | 4.0x8 | | ZTS4.0x1014CFS | 4.0x10 | | ZTS4.0x1214CFS | 4.0x12 | | ZTS4.0x1514CFS | 4.0x15 | | ZTS4.0x1814CFS | 4.0x18 | | ZTS4.0x2214CFS | 4.0x22 | | ZTS4.0x2514CFS | 4.0x25 | | ZTS4.0x2914CFS | 4.0x29 | | ZTS4.0x3414CFS | 4.0x34 | | ZTS4.0x3614CFS | 4.0x36 | | ZTS4.0x3814CFS | 4.0x38 | | ZTS4.0x4014CFS | 4.0x40 | | ZTS4.5x814CFS | 4.5x8 | | ZTS4.5x1014CFS | 4.5x10 | | ZTS4.5x1214CFS | 4.5x12 | | ZTS4.5x1514CFS | 4.5x15 | | ZTS4.5x1814CFS | 4.5x18 | | ZTS4.5x2214CFS | 4.5x22 | | ZTS4.5x2514CFS | 4.5x25 | | ZTS4.5x2914CFS | 4.5x29 | | ZTS4.5x3414CFS | 4.5x34 | | ZTS4.5x3614CFS | 4.5x36 | | ZTS4.5x3814CFS | 4.5x38 | | ZTS4.5x4014CFS | 4.5x40 | | ZTS5.0x814CFS | 5.0x8 | | ZTS5.0x1014CFS | 5.0x10 | | ZTS5.0x1214CFS | 5.0x12 | | ZTS5.0x1514CFS | 5.0x15 | | ZTS5.0x1814CFS | 5.0x18 | | ZTS5.0x2214CFS | 5.0x22 | | ZTS5.0x2514CFS | 5.0x25 | | ZTS5.0x2914CFS | 5.0x29 | | ZTS5.0x3414CFS | 5.0x34 | | ZTS5.0x3614CFS | 5.0x36 | | ZTS5.0x3814CFS | 5.0x38 | | ZTS5.0x4014CFS | 5.0x40 | | ZSTC5.0x4014CF | 5.0x40 | | | | | | | | | | |
|  | M/s Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi  (ELI-000046) | | | **Manufactured By:** M/s Pendracare International B.V. Van der Waalspark 22 9351 VC Leek, The Netherlands  (FSC The Netherlands Valid Till 01-01-2021) | | | Pointer Angiographic Catheter  Class D  Shelf Life: 3Years  Codes and sizes | | | | | Angiographic Catheter | | **Approved** | | |
| |  |  |  |  | | --- | --- | --- | --- | | **Shape** | **4F** | **5F** | **6F** | | JL3 | 14102001 | 15102001 | 16102001 | | JL3.5 | 14102101 | 15102101 | 16102101 | | JL4 | 14102201 | 15102201 | 16102201 | | JL4.5 | 14102301 | 15102301 | 16102301 | | JL5 | 14102401 | 15102401 | 16102401 | | JL6 | 14102501 | 15102501 | 16102501 | | JR3 | 14102601 | 15102601 | 16102601 | | JR3.5 | 14102701 | 15102701 | 16102701 | | JR4 | 14102801 | 15102801 | 16102801 | | JR4.5 | 14102901 | 15102901 | 16102901 | | JR5 | 14103001 | 15103001 | 16103001 | | JR6 | 14103101 | 15103101 | 16103101 | | 3DS | 14100001 | 15100001 | 16100001 | | SONES 1 | 14105801 | 15105801 | 16105801 | | SONES 1/2 | 14105901 | 15105901 | 16105901 | | SONES 2 | 14106001 | 15106001 | 16106001 | | SONES 2/2 | 14106101 | 15106101 | 16106101 | | GAMAL | 14101201 | 15101201 | 16101201 | | AL1 | 14100201 | 15100201 | 16100201 | | AL2 | 14100301 | 15100301 | 16100301 | | AL3 | 14100401 | 15100401 | 16100401 | | AR1MOD | 14100601 | 15100601 | 16100601 | | AR2MOD | 14100801 | 15100801 | 16100801 | | ARMOD | 14100901 | 15100901 | 16100901 | | MPA | 14103601 | 15103601 | 16103601 | | MPA/2 | 14103701 | 15103701 | 16103701 | | MPB | 14103801 | 15103801 | 16103801 | | MPB/2 | 14103901 | 15103901 | 16103901 | | RAD | 14105001 | 15105001 | 16105001 | | TIG2 | 14107001 | 15107001 | 16107001 | | IM | 14101701 | 15101701 | 16101701 | | LCB | 14103401 | 15103401 | 16103401 | | RCB | 14105501 | 15105501 | 16105501 | | PIG 110/8 | 14114001 | 15114001 | 16114001 | | PIG 145/110/8 | 14114101 | 15114101 | 16114101 | | PIG 155/110/8 | 14114201 | 15114201 | 16114201 | | PIG 130/8 | 14134001 | 15134001 | 16134001 | | PIG 145/130/8 | 14134101 | 15134101 | 16134101 | | PIG 155/130/8 | 14134201 | 15134201 | 16134201 | | JR4/JL4 | 14200701 | 15200701 | 16200701 | | JR4/JL3.5/PIG145/8 | 14315101 | 15315101 | 16315101 | | JR3.5/JL4/PIG/8 | 14316001 | 15316001 | 16316001 | | 3DS/JL4/PIG 145/8 | 14315501 | 15315501 | 16315501 | | JR4/JL4 | 14200701 | 15200701 | 16200701 | | JR4/JL4/PIG 145/8 | 14316301 | 15316301 | 16316301 | | JR4/JL4/PIG/8 | 14316201 | 15316201 | 16316201 | | ARMOD/JL4/PIG 145/8 | - | 15315801 | - | | 3DS/JL4/PIG/8 | - | - | 16315401 | | | | | | | | | | |
|  | M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi  (ELI-00006) | | | **Manufacturer:** M/s B.Braun Surgical S.A. Carretera. De Terrassa, 121 08191 Rubi (Barcelona), Spain  (FSC Spain Issuance Date  12-12-2017) | | | Novosyn Aborbable Surgical Suture  Class D  Shelf Life: 5 Years  C0068048 NOVOSYN VIOLET 0 (3,5) 70CM HR30 (M) DDP  C0068056 NOVOSYN VIOLET 0 (3,5) 70CM HR40S (M)DDP  C0068065 NOVOSYN VIOLET 0 (3,5) 70CM HR60 (M) DDP  C0068252 NOVOSYN VIOLET 0 (3,5) 70CM HS30 (M) DDP  C0068408 NOVOSYN VIOLET 0 (3,5)70CM JR36SS (M)DDP  C0068556 NOVOSYN VIOLET 0 (3,5) 90CM HR40S (M)DDP  C0068561 NOVOSYN VIOLET 0 (3,5) 90CM HR48 (M) DDP  C0068052 NOVOSYN VIOLET 0 (3.5) 70CM HR37 (M)  G0058208 NOVOSYN VIOLET 0 (3.5) 140CM  G0058447 NOVOSYN VIOLET 0 (3.5) 5X70CM  G0058627 NOVOSYN VIOLET 0 (3.5) 3X45CM    C0068049 NOVOSYN VIOLET 1 (4) 70CM HR30 (M) DDP  C0068057 NOVOSYN VIOLET 1 (4) 70CM HR40S (M) DDP  C0068066 NOVOSYN VIOLET 1 (4) 70CM HR60 (M) DDP  C0068253 NOVOSYN VIOLET 1 (4) 70CM HS30 (M) DDP  C0068478 NOVOSYN VIOLET 1 (4) 70CM JR40S (M) DDP  C0068557 NOVOSYN VIOLET 1 (4) 90CM HR40S (M) DDP  C0068806 NOVOSYN VIOLET 1 (4) 70CM HS40 (M) DDP  B0058649 NOVOSYN VIOLET 1 (4) 6X45CM  B0058669 NOVOSYN VIOLET 1 (4) 12X45CM  C0068097 NOVOSYN VIOLET 1 (4) 70CM HR37S (M)  C0068481 NOVOSYN VIOLET 1 (4) 70CM JR30S (M)  C0068597 NOVOSYN VIOLET 1 (4) 90CM HR37S (M)    C0068058 NOVOSYN VIOLET 2 (5) 70CM HR40S (M) DDP  C0068063 NOVOSYN VIOLET 2 (5) 70CM HR48 (M) DDP  C0068558 NOVOSYN VIOLET 2 (5) 90CM HR40S (M) DDP  C0068588 NOVOSYN VIOLET 2 (5) 90CM HS40S (M) DDP  C0068770 NOVOSYN VIOLET 2 (5) 70CM HS40S (M) DDP    C0068629 NOVOSYN VIOLET 2/0 (3) 30CM SKR26 (M)  C0068754 NOVOSYN VIOLET 2/0 (3) 20CM SKR19 (M)  C0068757 NOVOSYN VIOLET 2/0 (3)120CM SKR19 (M)  C0068475 NOVOSYN VIOLET 2/0 (3) 70CM JR30 (M)  C0068193 NOVOSYN VIOLET 2/0(3)120CM JRC30S (M)  C0068410 NOVOSYN VIOLET 2/0 (3)70CM JR36SS (M)  C0068031 NOVOSYN VIOLET 2/0 (3) 70CM HR22 (M) DDP  C0068042 NOVOSYN VIOLET 2/0 (3) 70CM HR26 (M) DDP  C0068047 NOVOSYN VIOLET 2/0 (3) 70CM HR30 (M) DDP  C0068236 NOVOSYN VIOLET 2/0 (3) 70CM DS24 (M) DDP  C0068242 NOVOSYN VIOLET 2/0 (3) 70CM HS26 (M) DDP  C0068251 NOVOSYN VIOLET 2/0 (3) 70CM HS30 (M) DDP  C0068266 NOVOSYN VIOLET 2/0 (3) 70CM GS60 (M) DDP  C0068274 NOVOSYN VIOLET 2/0 (3) 70CM GS51 (M) DDP  C0068381 NOVOSYN VIOLET 2/0 (3) 70CM HR40 (M) DDP  C0069236 NOVOSYN UNDYED 2/0 (3) 70CM DS24 (M) DDP  C0069247 NOVOSYN UNDYED 2/0 (3) 70CM DS30 (M) DDP  C0069560 NOVOSYN UNDYED 2/0 (3)70CM DSMP30 (M)DDP    C0068014 NOVOSYN VIOLET 3/0 (2) 70CM HR17 (M) DDP  C0068030 NOVOSYN VIOLET 3/0 (2) 70CM HR22 (M) DDP  C0068041 NOVOSYN VIOLET 3/0 (2) 70CM HR26 (M) DDP  C0068046 NOVOSYN VIOLET 3/0 (2) 70CM HR30 (M) DDP  C0068050 NOVOSYN VIOLET 3/0 (2) 70CM HR37 (M) DDP  C0068235 NOVOSYN VIOLET 3/0 (2) 70CM DS24 (M) DDP  C0068265 NOVOSYN VIOLET 3/0 (2) 70CM GS60 (M) DDP  C0068421 NOVOSYN VIOLET 3/0 (2) 70CM DS19 (M) DDP  C0068514 NOVOSYN VIOLET 3/0 (2) 70CM DS16 (M) DDP  C0069046 NOVOSYN UNDYED 3/0 (2) 70CM HR30 (M) DDP  C0069235 NOVOSYN UNDYED 3/0 (2) 70CM DS24 (M) DDP  C0069302 NOVOSYN UNDYED 3/0 (2) 70CM DS16 (M) DDP  C0069421 NOVOSYN UNDYED 3/0 (2) 70CM DS19 (M) DDP    C0068013 NOVOSYN VIOLET 4/0 (1,5)70CM HR17 (M)DDP  C0068029 NOVOSYN VIOLET 4/0 (1,5)70CM HR22 (M)DDP  C0068040 NOVOSYN VIOLET 4/0 (1,5)70CM HR26 (M)DDP  C0068234 NOVOSYN VIOLET 4/0 (1,5)70CM DS24 (M)DDP  C0068420 NOVOSYN VIOLET 4/0 (1,5)70CM DS19 (M)DDP  C0068513 NOVOSYN VIOLET 4/0 (1,5)70CM DS16 (M)DDP  C0069234 NOVOSYN UNDYED 4/0 (1,5)70CM DS24 (M)DDP  C0069420 NOVOSYN UNDYED 4/0 (1,5)70CM DS19 (M)DDP  C0069555 NOVOSYN UNDYED 4/0(1,5)70CM DSMP24 (MDDP    C0068003 NOVOSYN VIOLET 5/0 (1) 70CM HR10 (M) DDP  C0068007 NOVOSYN VIOLET 5/0 (1) 70CM HR13 (M) DDP  C0068012 NOVOSYN VIOLET 5/0 (1) 70CM HR17 (M) DDP  C0068028 NOVOSYN VIOLET 5/0 (1) 70CM HR22 (M) DDP  C0068419 NOVOSYN VIOLET 5/0 (1) 70CM DS19 (M) DDP  C0068507 NOVOSYN VIOLET 5/0 (1) 70CM DS12 (M) DDP  C0068512 NOVOSYN VIOLET 5/0 (1) 70CM DS16 (M) DDP  C0069331 NOVOSYN UNDYED 5/0 (1) 70CM DS12 (M) DDP  C0069419 NOVOSYN UNDYED 5/0 (1) 70CM DS19 (M) DDP    C0068002 NOVOSYN VIOLET 6/0 (0,7)70CM HR10 (M)DDP  C0068006 NOVOSYN VIOLET 6/0 (0,7)70CM HR13 (M)DDP  C0068011 NOVOSYN VIOLET 6/0 (0,7)70CM HR17 (M)DDP  C0068506 NOVOSYN VIOLET 6/0 (0,7)70CM DS12 (M)DDP  C0068688 NOVOSYN VIOLET 6/0(0,7)70CM DSMP11 (MDDP  C0069330 NOVOSYN UNDYED 6/0 (0,7)70CM DS12 (M)DDP  G0068299 NOVOSYN VIOLET 6/0 (0,7)70CM VLM8 (M)DDP  G0068616 NOVOSYN VIOLET 6/0(0.7)30CM 2XVLM6 (M  G0069734 NOVOSYN UNDYED 6/0(0.7)45CM 2XVLM8 (M    C0068101 NOVOSYN VIOLET 7/0 (0.5)45CM DR10 (M)  C0068407 NOVOSYN VIOLET 7/0(0.5)70CM DSMP7 (M)  C0068732 NOVOSYN VIOLET 7/0(0.5)45CM 2XVLM6 (M  C0068684 NOVOSYN VIOLET 7/0(0.5)45CM DSMP11 (M    C0068133 NOVOSYN VIOLET 8/0 (0.4) 30CM DR8 (M)  G0068699 NOVOSYN VIOLET8/0(0.4)30CM2XDLM5 150M  G0068701 NOVOSYN VIOLET8/0(0.4)45CM2XDLM6 150M  G0068724 NOVOSYN VIOLET 8/0(0.4)30CM DLM6 150M | | | | | Aborbable Surgical Suture Material Product from a Copolymer Composed of 90% glucolate and 10% L-lactate | **Approved** | | | |
|  | M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block No.9, Clifton, Karachi  (ELI-00006) | | | **Manufacturer:** M/s B.Braun Surgical S.A. Carretera. De Terrassa, 121 08191 Rubi (Barcelona), Spain  (FSC Spain Issuance Date  12-12-2017) | | | Optilene Non-Absorbable Monofilament Suture  Class D  Shelf Life: 5 Years  C3090048  OPTILENE 0 (3,5) 75CM HR30 (M) RCP  C3090052 OPTILENE 0 (3,5) 75CM HR37 (M) RCP  C3090152 OPTILENE 0 (3,5) 75CM HR37S (M) RCP  C3095789 OPTILENE 0 (3,5) 90CM HR37 (M) RCP  C3095796 OPTILENE 0 (3,5) 75CM HRC26 CV RCP  C3090256 OPTILENE 0 (3,5) 75CM DS39 (M) RCP  C3090276 OPTILENE 0 (3,5) 75CM HS30 (M) RCP  C3090280 OPTILENE 0 (3,5) 75CM HS37 (M) RCP  C3090281 OPTILENE 0 (3,5) 75CM HS40 (M) RCP  C3090106 OPTILENE 0 (3,5) 100CM HR40SS (M) RCP  C3090199 OPTILENE 0 (3,5) 75CM HR40S (M) RCP    C3090100 OPTILENE 1 (4) 100CM HR40 (M) RCP  C3090053 OPTILENE 1 (4) 75CM HR37 (M) RCP  C3090153 OPTILENE 1 (4) 75CM HR37S (M) RCP  C3090200 OPTILENE 1 (4) 75CM HR40S (M) RCP  C3090300 OPTILENE 1 (4) 100CM HR40S (M) RCP  C3090170 OPTILENE 1 (4) 75CM HR48 (M) RCP  C3090257 OPTILENE 1 (4) 75CM DS39 (M) RCP  C3095200 OPTILENE 1 (4) 75CM DS30 (M) RCP  C3090093 OPTILENE 1 (4) 75CM HR30S (M) RCP  C3090304 OPTILENE 1 (4) 100CM HS48 (M) RCP  C3090049 OPTILENE 1 (4) 75CM HR30 (M) RCP  C3090262 OPTILENE 1 (4) 75CM DS90 (M) .RCP  C3090287 OPTILENE 1 (4) 75CM HS40 (M) RCP  B3095584 OPTILENE 1 (4) 150CM HR65 (M) .RCP  C3090272 OPTILENE 1 (4) 100CM HS40 (M) RCP  C3095190 OPTILENE 1 (4) 100CM DS45 (M) RCP    C3090244 OPTILENE 2 (5) 75CM DS39 (M) .RCP  C3095340 OPTILENE 2 (5) 75CM HR37S (M) .RCP  C3090478 OPTILENE 2 (5) 90CM HR40S (M) .RCP  B3095585 OPTILENE 2 (5) 150CM HR65 (M) .RCP    C3090236 OPTILENE 2/0 (3) 75CM DS24 (M) RCP  C3090002 OPTILENE 2/0 (3) 90CM 2XHR30 (M).RCP  C3090042 OPTILENE 2/0 (3) 75CM HR26 CV RCP  C3090047 OPTILENE 2/0 (3) 75CM HR30 (M) RCP  C3090266 OPTILENE 2/0 (3) 75CM GS60 (M) .RCP  C3090051 OPTILENE 2/0 (3) 75CM HR37 (M) RCP  C3090033 OPTILENE 2/0 (3) 75CM HR40S (M) RCP  C3090087 OPTILENE 2/0 (3) 75CM 2XHR26 CV RCP  C3090474 OPTILENE 2/0 (3) 75CM HRC26 CV RCP  C3090725 OPTILENE 2/0 (3) 75CM 2XDR26 CV RCP  C3095052 OPTILENE 2/0 (3) 90CM 2XHRC17 CV RCP  C3095572 OPTILENE 2/0 (3) 75CM HRC22 CV RCP  C3095636 OPTILENE 2/0 (3) 90CM 2XDRC26 CV RCP  C3095825 OPTILENE 2/0 (3) 90CM 2XHRC26 CV RCP    C3090514 OPTILENE 3/0 (2) 75CM DS16 (M) RCP  C3090521 OPTILENE 3/0 (2) 75CM DS19 (M) RCP  C3090235 OPTILENE 3/0 (2) 75CM DS24 (M) RCP  C3090246 OPTILENE 3/0 (2) 75CM DS30 (M) RCP  C3090014 OPTILENE 3/0 (2) 75CM HR17 CV RCP  C3090030 OPTILENE 3/0 (2) 75CM HR22 CV RCP  C3090041 OPTILENE 3/0 (2) 75CM HR26 CV RCP  C3090284 OPTILENE 3/0 (2) 75CM GS51 (M) .RCP  C3090426 OPTILENE 3/0 (2) 90CM 2XHR20 CV RCP  C3090495 OPTILENE 3/0(2) 20CM HR26 CV PF3 .RCP  C3090536 OPTILENE 3/0 (2) 90CM 2XDRC22 CV RCP  C3090566 OPTILENE 3/0 (2) 75CM HRC22 CV RCP  C3090579 OPTILENE 3/0 (2) 75CM HRC17 CV RCP  C3090581 OPTILENE 3/0 (2) 90CM 2XHRC22 CV RCP  C3090711 OPTILENE 3/0 (2) 75CM 2XHRC17 CV RCP  C3090903 OPTILENE 3/0 (2) 90CM 2XHR17 CV RCP  C3090908 OPTILENE 3/0 (2) 90CM 2XHR26 CV RCP  C3090977 OPTILENE 3/0 (2) 90CM 2XHR22 CV RCP  C3095633 OPTILENE 3/0 (2) 90CM 2XDRC26 CV RCP  C3095983 OPTILENE 3/0 (2) 75CM DGMP19 RCP  C3095999 OPTILENE 3/0 (2) 75CM DGMP16 RCP    C3090013 OPTILENE 4/0 (1,5) 75CM HR17 CV RCP  C3090029 OPTILENE 4/0 (1,5) 75CM HR22 CV RCP  C3090040 OPTILENE 4/0 (1,5) 75CM HR26 CV RCP  C3090234 OPTILENE 4/0 (1,5) 75CM DS24 (M) RCP  C3090245 OPTILENE 4/0 (1,5) 75CM DS30 (M) RCP  C3090513 OPTILENE 4/0 (1,5) 75CM DS16 (M) RCP  C3090520 OPTILENE 4/0 (1,5) 75CM DS19 (M) RCP  C3090571 OPTILENE 4/0 (1,5) 90CM 2XHRC17 CV RCP  C3090863 OPTILENE 4/0 (1,5) 75CM 2XHR22 CV RCP  C3090902 OPTILENE 4/0 (1,5) 90CM 2XHR17 CV RCP  C3090907 OPTILENE 4/0 (1,5) 90CM 2XHR26 CV RCP  C3090976 OPTILENE 4/0 (1,5) 90CM 2XHR22 CV RCP  C3095165 OPTILENE 4/0 (1,5) 75CM DRC18 CV RCP  C3095195 OPTILENE 4/0 (1,5) 75CM 2XDRC18 CV RCP  C3095910 OPTILENE 4/0 (1,5) 45CM DGMP13 RCP    C3090012 OPTILENE 5/0 (1) 75CM HR17 CV RCP  C3090403 OPTILENE 5/0 (1) 75CM HR10 CV RCP  C3090500 OPTILENE 5/0 (1) 75CM HR13 CV RCP  C3090207 OPTILENE 5/0 (1) 45CM DS12 (M) RCP  C3090512 OPTILENE 5/0 (1) 75CM DS16 (M) RCP  C3090869 OPTILENE 5/0 (1) 75CM 2XHR10 CV RCP  C3090901 OPTILENE 5/0 (1) 90CM 2XHR17 CV RCP  C3090930 OPTILENE 5/0 (1) 90CM 2XDRC10 CV RCP  C3090954 OPTILENE 5/0 (1) 75CM 2XHR13 CV RCP  C3091098 OPTILENE 5/0 (1) 90CM 2XHRC13 CV RCP  C3095129 OPTILENE 5/0 (1) 30CM 2XSLM6 (M) RCP  C3095164 OPTILENE 5/0 (1) 75CM DRC18 CV RCP  C3095171 OPTILENE 5/0 (1) 90CM 2XDRC13 CV RCP  C3095194 OPTILENE 5/0 (1) 75CM 2XDRC18 CV RCP  C3095205 OPTILENE 5/0 (1) 75CM 2XHRC10 CV RCP  C3095518 OPTILENE 5/0 (1) 45CM DGMP13 RCP  C3095549 OPTILENE 5/0 (1) 45CM DGMP16 RCP  C3095550 OPTILENE 5/0 (1) 45CM DGMP19 RCP  C3095756 OPTILENE 5/0 (1) 75CM 2XDRC15 CV RCP    C3090402 OPTILENE 6/0 (0,7) 75CM HR10 CV RCP  C3090499 OPTILENE 6/0 (0,7) 75CM HR13 CV RCP  C3090206 OPTILENE 6/0 (0,7) 45CM DS12 (M) RCP  C3090211 OPTILENE 6/0 (0,7) 45CM DS16 (M) RCP  C3095400 OPTILENE 6/0 (0,7) 45CM DS19 (M) RCP  C3090407 OPTILENE 6/0 (0,7) 75CM DSMP11 (M) RCP  C3090428 OPTILENE 6/0 (0,7) 75CM DSMP16 (M) RCP  C3090868 OPTILENE 6/0 (0,7) 75CM 2XHR10 CV RCP  C3090886 OPTILENE 6/0 (0,7) 75CM 2XDR8 CV RCP  C3090898 OPTILENE 6/0 (0,7) 90CM 2XHR17 CV RCP  C3090953 OPTILENE 6/0 (0,7) 75CM 2XHR13 CV RCP  C3095020 OPTILENE 6/0 (0,7) 90CM 2XHRC13 CV RCP  C3095144 OPTILENE 6/0 (0,7) 75CM DRC13 CV RCP  C3095175 OPTILENE 6/0 (0,7) 75CM 2XDRC13 CV RCP  C3095305 OPTILENE 6/0 (0,7) 90CM 2XDRC13 CV RCP  C3095498 OPTILENE 6/0 (0,7) 60CM HR10 CV RCP  C3095588 OPTILENE 6/0 (0,7) 45CM DGMP11 RCP  C3095589 OPTILENE 6/0 (0,7) 45CM DGMP13 RCP    C3090401 OPTILENE 7/0 (0,5) 75CM HR10 CV RCP  C3090541 OPTILENE 7/0 (0,5) 75CM DR10 CV RCP  C3090603 OPTILENE 7/0 (0,5) 30CM HR6 CV RCP  C3090488 OPTILENE 7/0 (0,5) 60CM 2XHR10 CV RCP  C3095905 OPTILENE 7/0 (0,5) 75CM 2XDR13 CV RCP  C3090176 OPTILENE 7/0 (0,5) 75CM 2XDRC8 CV RCP  C3090538 OPTILENE 7/0 (0,5) 75CM DRC10 CV RCP  C3090545 OPTILENE 7/0 (0,5) 75CM 2XDRC10 CV RCP  C3090885 OPTILENE 7/0 (0,5) 75CM 2XDR8 CV RCP  C3095286 OPTILENE 7/0 (0,5) 75CM 2XDR6 CV RCP    C3090004 OPTILENE 8/0 (0,4) 75CM 2XDR8 CV RCP  C3090169 OPTILENE 8/0 (0,4) 75CM 2XDRC8 CV RCP  C3090880 OPTILENE 8/0 (0,4) 45CM 2XDR6 CV RCP  C3090980 OPTILENE 8/0 (0,4) 75CM 2XDR6 CV RCP  C3095272 OPTILENE 8/0 (0,4) 75CM 2XDRC6 CV RCP    G3090482 OPTILENE 9/0(0,3)45CM 2XDRM5 100MIC BLT  G3090594 OPTILENE 9/0(0,3) 15CM DLM6S 200MIC BLT  G3090597 OPTILENE 9/0(0,3)30CM2XDLM6S 200MIC BLT  G3090783 OPTILENE 9/0 (0,3) 15CM DRM6 140MIC BLT | | | | | Non-Absorbable Monofilament Suture Made of Polypropylene and Polyethylene | **Approved** | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC USFDA  valid till 05-08-2020) | | | Amplatz Super Stiff™ Guidewires  Class D  Shelf Life: 36Months  M001465001  08714729115847  Amplatz SS JTip 035/145/3mm, 5 pk  M001465011  08714729115854  Amplatz SS JTip 035/180/3mm, 5 pk  M001465021  08714729115861  Amplatz SS JTip 035/260/3mm, 5 pk  M001465031  08714729115915  Amplatz SS JTip 038/145/3mm, 5 pk  M001465041  08714729115922  Amplatz SS JTip 038/180/3mm, 5 pk  M001465091  08714729115953  Amplatz SS 035/260/1, 5 pk    M001465101  08714729115960  Amplatz SS 038/260/1, 5 pk    M001465171  08714729115885  Amplatz SS GW/038/145, 5 pk  M001465181  08714729115939  Amplatz SS ST/038/145, 5 pk  M001465191  08714729115892  HI Perf SS XCH/038/180, 5 pk  M001465201  08714729115908  Amplatz SS XCH/038/260, 5 pk  M001465231  08714729115809  Amplatz SS GW/035/145, 5 pk  M001465241  08714729115946  AmplatzSS ST/035/145, 5 pk  M001465251  08714729115823  HI-Perf SS XCH/035/180, 5 pk  M001465261  08714729115830  Amplatz SS XCH/035/260, 5 pk  M001465631  08714729114604  Amplatz SS 75 CM .035, 5 pk  M001465641  08714729115878  Amplatz SS 75CM .038, 5 pk | | | | | The Amplatz Super Stiff Guidewires facilitate catheter placement and exchange during diagnostic or interventional procedures.  They are not intended for use in the coronary arteries. | **Approved** subject to submission of valid Agency Agreement (Existing expired on 31st Dec., 2018) | | | |
|  | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan  (ELI-00120) | | | **Legal Manufacturer:** M/s Boston Scientific Corporation  300, Boston Scientific Way, Marlborough, MA 01752 USA  **Manufacturing Site:**  M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica  (FSC USFDA  valid till 05-08-2020) | | | ChoICETM PT Guidewire with ICETM Hydrophilic Coating  Class D  Shelf Life: 24Month  H74912154011  08714729252467  0.014", 300cm, Straight  H74912154012  08714729150633  0.014", 300cm, Straight, 5 pk  H7491215401J1  08714729252474  0.014", 300cm, J Tip  H7491215401J2  08714729193708  0.014", 300cm, J Tip, 5 pk  H74912155011  08714729303039  0.014", 300cm, Straight  H74912155012  08714729177012  0.014", 300cm. Straight, 5 pk  H7491215501J1  08714729252498  0.014", 300cm, J Tip  H7491215501J2  08714729176947  0.014", 300cm, J Tip, 5 pk  H74912160011  08714729252504  0.014", 182cm, Straight  H74912160012  08714729150626  0.014", 182cm, Straight, 5 pk  H7491216001J1  08714729252511  0.014", 182cm, J Tip  H7491216001J2  08714729193715  0.014", 182cm, J Tip, 5 pk  H74912161011  08714729252528  0.014", 182cm, Straight  H74912161012  08714729176992  0,014", 182cm, Straight, 5 pk  H7491216101JI  08714729252535  0.014", 182cm, J Tip  H7491216101J2  08714729177005  0.014", 182cm, J Tip, 5 pk | | | | | Intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interven-tional procedures. They are not intended for use in the cerebral vasculature. | **Approved** subject to submission of valid Agency Agreement (Existing expired on 31st Dec., 2018) | | | |
|  | M/s Iqbal and Company, Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector E-11/4, Islamabad  (ELI-00117) | | | **Manufacturer By:** M/s Medical Components Inc. DBA – Medcomp 1499, Delp Drive Harleysville, PA 19438, USA  **Contract Manufacturer:**  M/s Martech Medical Products Calle Mercurio N 46, Parque Industrial Mexicali 1 Mexicali, Baja California, 21210 Mexico  (FSC USFDA Valid Till  14-11-2019)  **Fee. Rs. 50,000** | | | Quad Lumen Multi-Cath Catheter Sets  Class D  Shelf Life: 5 Years  MC4L-6S (8.5F X 15CM) Quad Lumen Infusion Catheter Set  MC4L-8S (8.5F X 20CM) Quad Lumen Infusion Catheter Set  MC4L-8SR (8.5F X 20CM) Quad Lumen Infusion Catheter Set with Raulerson Syringe | | | | | Central Venous Catheter | **Approved** in Class D without Design Examination Certificate since the product is in Class B in the country of origin. | | | |
|  | M/s Iqbal and Company, Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector E-11/4, Islamabad  (ELI-00117) | | | **Manufacturer By:** M/s Medical Components Inc. DBA – Medcomp 1499, Delp Drive Harleysville, PA 19438, USA  **Contract Manufacturer:**  M/s Martech Medical Products Calle Mercurio N 46, Parque Industrial Mexicali 1 Mexicali, Baja California, 21210 Mexico  (FSC USFDA Valid Till  14-11-2019)  **Fee. Rs. 50,000/-** | | | Triple Lumen Multi-Cath Catheters Sets  Class D  Shelf Life: 5 Years  MC3L-12S (7F X 30CM) Triple Lumen Infusion Catheter Set  MC3L-6S (7F X 15CM) Triple Lumen Infusion Catheter Set  MC3L-712S (7.5F X 12CM) Triple Lumen Infusion Catheter Set  MC3L-715S (7.5F X 15CM) Triple Lumen Infusion Catheter Set  MC3L-720S (7.5F X 20CM) Triple Lumen Infusion Catheter Set  MC3L-730S (7.5F X 30CM) Triple Lumen Infusion Catheter Set  MC3L-8S (7F X 20CM) Triple Lumen Infusion Catheter Set  MC3L-530S (5.5F X 30CM) Triple Lumen Infusion Catheter Set  MC3LP-58S (5.5F X 8CM) Triple Lumen Infusion Catheter Set  MC3L-5S (5.5F X 13CM) Triple Lumen Infusion Catheter Set  MC3L-6SR (7.5F X 12CM) Triple Lumen Infusion Catheter Set With Raulerson Syringe  MC3L-8SR (7F X 20CM) Triple Lumen Infusion Catheter Set With Raulerson Syringe  MC3L-12SR (7F X 30CM) Triple Lumen Infusion Catheter Set With Raulerson Syringe | | | | | Central Venous Catheter | **Approved** in Class D without Design Examination Certificate since the product is in Class B in the country of origin. | | | |
|  | M/s Iqbal and Company, Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector E-11/4, Islamabad  (ELI-00117) | | | **Manufacturer By:** M/s Medical Components Inc. DBA – Medcomp 1499, Delp Drive Harleysville, PA 19438, USA  **Contract Manufacturer:**  M/s Martech Medical Products Calle Mercurio N 46, Parque Industrial Mexicali 1 Mexicali, Baja California, 21210 Mexico  (FSC USFDA Valid Till  14-11-2019)  Fee. Rs. 50,000/- | | | Single Lumen Multi-Cath Catheters Sets  Class D  Shelf Life: 5 Years  MC-1406 (14GA X 15 CM) Single Lumen Infusion Catheter Set  MC-1408 (14GA X 20 CM) Single Lumen Infusion Catheter Set  MC-1412 (14GA X 30 CM) Single Lumen Infusion Catheter Set  MC-1606 (16GA X 15 CM) Single Lumen Infusion Catheter Set  MC-1608 (16GA X 20 CM) Single Lumen Infusion Catheter Set  CSP-1608R (16GA X 20 CM) Single Lumen Infusion Catheter Set With Raulerson Syringe  MC-1612 (16GA X 30 CM) Single Lumen Infusion Catheter Set  CSP-1612R (16GA X 30 CM) Single Lumen Infusion Catheter Set With Raulerson Syringe  MC-1806 (18GA X 15 CM) Single Lumen Infusion Catheter Set  CSP-1806R (18GA X 15 CM) Single Lumen Infusion Catheter Set With Raulerson Syringe  MC-1808 (18GA X 20 CM) Single Lumen Infusion Catheter Set  CSP-1808R (18GA X 20 CM) Single Lumen Infusion Catheter Set With Raulerson Syringe  MC-1812 (18GA X 30 CM) Single Lumen Infusion Catheter Set  CSP-1812R (18GA X 30 CM) Single Lumen Infusion Catheter Set With Raulerson Syringe  MC-2005(20 GA X 13 CM) Single Lumen Infusion Catheter Set  MC-2405 (24 GA X 14 CM) Single Lumen Infusion Catheter Set | | | | | Central Venous Catheter | **Approved** in Class D without Design Examination Certificate since the product is in Class B in the country of origin. | | | |
|  | M/s Iqbal and Company, Alfalah Manzil Opp. National Police Foundation, Street No. 26, Sector E-11/4, Islamabad  (ELI-00117) | | | **Manufacturer By:** M/s Medical Components Inc. DBA – Medcomp 1499, Delp Drive Harleysville, PA 19438, USA  **Contract Manufacturer:**  M/s Martech Medical Products Calle Mercurio N 46, Parque Industrial Mexicali 1 Mexicali, Baja California, 21210 Mexico  (FSC USFDA Valid Till  14-11-2019)  **Fee. Rs. 50,000/-** | | | Double Lumen Multi-Cath Catheters Sets  Class D  Shelf Life: 5 Years  MC2L-12S (7F X 30CM) Double Lumen Infusion Catheter Set  MC2L-6S (7F X 15CM) Double Lumen Infusion Catheter Set  MC2L-6SR (7F X 15CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2L-715S (7.5F X 15CM) Double Lumen Infusion Catheter Set  MC2L-720S (7.5F X 20CM) Double Lumen Infusion Catheter Set  MC2L-730S (7.5F X 30CM) Double Lumen Infusion Catheter Set  MC2L-8S (7F X 20CM) Double Lumen Infusion Catheter Set  MC2L-8S-ID (7F X 20CM) Double Lumen Infusion Catheter Set with mini Scalpel  MC2L-8SR (7F X 20CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-313S (4F X 13CM) Double Lumen Infusion Catheter Set  MC2LP-313S-ID (4F X 13CM) Double Lumen Infusion Catheter Set With Mini Scalpel  MC2LP-313SR (4F X 13CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-330S (4F X 30CM) Double Lumen Infusion Catheter Set  MC2LP-330SR (4F X 30CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-35S (4F X 5CM) Double Lumen Infusion Catheter Set  MC2LP-35SR (4F X 5CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-38S (4F X 8CM) Double Lumen Infusion Catheter Set  MC2LP-38SR (4F X 8CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-418S (4F X 18CM) Double Lumen Infusion Catheter Set  MC2LP-515S (5F X 15CM) Double Lumen Infusion Catheter Set  MC2LP-530S (5F X 30CM) Double Lumen Infusion Catheter Set  MC2LP-530SR (5F X 30CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-58S (5F X 8CM) Double Lumen Infusion Catheter Set  MC2LP-58SR (5F X 8CM) Double Lumen Infusion Catheter Set with Raulerson Syringe  MC2LP-5S (5F X 13CM) Double Lumen Infusion Catheter Set  MC2LP-5S-ID (5F X 13CM) Double Lumen Infusion Catheter Set WITH Mini Scalpel  MC2LP-5SR (5F X 13CM) Double Lumen Infusion Catheter Set with Raulerson Syringe | | | | | Central Venous Catheter | **Approved** in Class D without Design Examination Certificate since the product is in Class B in the country of origin. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer/ Manufacturing Site:** M/s Abbott GmbH & Co. KG  Max-Planck-Ring 2 65205 Wiesbaden Germany  (FSC Germany Issue 19-07-2018 )  Fee. Rs. 50,000/- | | | Alinity i Anti-HBc IgMKit  Class D  (1) Alinity i Anti-HBc IgM Calibrators  07P8601  Shelf Life: 14 Months  (2) Alinity i Anti-HBc IgM Controls 07P8610  Shelf Life: 15 Months  (3)Alinity i Anti-HBc IgM Reagent Kit 07P8622  Shelf Life: 15 Months | | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i Anti-HBc IgMTesting | **Approved** suject to provision of valid ISO 13485 Certificate. | | | |
|  | 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 Diagnostic Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022 )  Fee. Rs. 50,000/- | | | Alinity i HBsAg Qualitative II Kit  Class D  (1) Alinity i HBsAg Qualitative II Calibrators 08P1001  Shelf Life: 12 Months  (2) Alinity i HBsAg Qualitative II Controls 08P1010  Shelf Life: 12 Months  (3)Alinity i HBsAg Qualitative II Confirmatory Reagent Kit 08P1122  Shelf Life: 15 Months  (4) Alinity i HBsAg Qualitative II Confirmatory Manual Diluent 08P1140  Shelf Life: 12 Months | | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i HBsAg Qualitative IIConfirmatory Testing | **Approved**. | | | |
|  | 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 Diagnostic Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till  26-05-2022 )  Fee. Rs. 50,000/- | | | Alinity i HBsAg Qualitative II Kit  Class D  (1) Alinity i HBsAg Qualitative II Calibrators 08P1001  Shelf Life: 12 Months  (2) Alinity i HBsAg Qualitative II Controls 08P1010  Shelf Life: 12 Months  (3)Alinity i HBsAg Qualitative II Reagent Kit 08P1022  Shelf Life: 15 Months  (4) Alinity i HBsAg Qualitative II Reagent Kit 08P1032  Shelf Life: 12 Months | | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i HBsAg Qualitative II Testing | **Approved**. | | | |
|  | 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 Diagnostic Division, Finisklin Business Park, Sligo, Ireland  (FSC Ireland Valid Till 26-05-2022 )  Fee. Rs. 50,000/- | | | Alinity i Anti-HBs Kit  Class D  (1) Alinity i Anti-HBs Calibrators  07P8901  Shelf Life: 12 Months  (2) Alinity i Anti-HBs Controls 07P8910  Shelf Life: 10 Months  (3 Alinity i Anti-HBs Reagent Kit 07P8922  Shelf Life: 15 Months  (4) Alinity i Anti-HBs Reagent Kit 07P8932  Shelf Life: 15 Months  (5) Alinity i Anti-HBs Reagent Kit 07P8952  Shelf Life: 15 Months  (6) Alinity i Anti-HBs Reagent Kit 07P8957  Shelf Life: 15 Months  (7) Alinity i Anti-HBs Specimen Diluent 07P8942  Shelf Life: 12 Months | | | | | IN-VITRO DIAGNOSTIC Kit for Alinity i Anti-HBsTesting | **Approved**. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer:**  M/s Alere Medical Co., Ltd., 7F Shinjuku NS Building, 2-4-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0807, Japan  **Manufacturing Site:**  M/s Alere Medical Co., Ltd., Chiba Plant 357 Matsuhidai, Matsudo-shi, Chiba 270-2214, Japan  (FSC JAPAN Issuance Date  29-07-2016)  Fee Rs. 50,000/- | | | Alere Determine HIV-1/2 Rapid Detection Kit.  Class D  Shelf Life: 18 Months  7D2343 | | | | | In-vitro diagnostic for qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as rapid test to detect antibodies to HIV-1/HIV-2 from infected indviduals. The test is professional use only. | **Approved**. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc., 65, Borahagal-co, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea  (FSC Korea Issuance Date  11-08-2017)  Fee. Rs. 50,000/- | | | SD BIOILINE HCV  Class D  (i) SD BIOILINE HCV  02FK10  Shelf Life: 24Months  (ii) SD BIOILINE HCV Multi 02FK11  Shelf Life: 24 Months | | | | | IVD Reagents for Diagnosis of HCV Immunological Method | **Approved** subject to verification of WHO prequalified product. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc., 65, Borahagal-co, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea  (FSC Korea Issuance Date  11-08-2017)  Fee. Rs. 50,000/- | | | SD BIOILINE HIV 1/2 3.0  Class D  (i) SD BIOLINE HIV 1/2 3.0  03FK10  Shelf Life: 24Months  (ii) SD BIOLINE HIV 1/2 3.0 03FK16  Shelf Life: 24Months  (iii) SD BIOLINE HIV 1/2 3.0 Multi 03FK11  Shelf Life: 24 Months | | | | | IVD Reagents for Diagnosis of HIV Immunological Method | **Approved** subject to verification of WHO prequalified product. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc., 65, Borahagal-co, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea  (FSC Korea Issuance Date  11-08-2017)  Fee. Rs. 50,000/- | | | SD BIOILINE HIV/Syphilis Duo  Class D  (i) SD BIOILINE HIV/Syphilis Duo  06FK30  Shelf Life: 24Months  (ii) SD BIOILINE HIV/Syphilis Duo 06FK35  Shelf Life: 24 Months | | | | | IVD Reagents for Diagnosis of Immunological HIV/Syphilis Duo Method | **Approved** subject to verification of WHO prequalified product. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer/ Manufacturing Site:**  M/s Standard Diagnostics Inc., 65, Borahagal-co, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea  (FSC Korea Issuance Date  11-08-2017)  Fee. Rs. 50,000/- | | | SD BIOILINE HBsAg WB  Class D  (i) SD BIOILINE HBsAg WB  01FK10W  Shelf Life: 24Months  (ii) SD BIOILINE HBsAg WB Multi 01FK11W  Shelf Life: 24 Months | | | | | IVD Reagents for Diagnosis of Immunological HBsAg WB Method | **Approved** subject to verification of WHO prequalified product. | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer:**  M/s Alere Medical Co., Ltd., 7F Shinjuku NS Building, 2-4-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0807, Japan  **Manufacturing Site:**  M/s Alere Medical Co., Ltd., Chiba Plant 357 Matsuhidai, Matsudo-shi, Chiba 270-2214, Japan  (FSC JAPAN Issuance Date  09-02-2017) | | | Alere HIV Combo  Class D  Shelf Life: 18 Months  Alere HIV Combo 7D2842 (20 tests/Kit)  Alere HIV Combo 7D2843 (100 tests/Kit) | | | | | Qualitative detection of HIV-I and HIV-II antibodies and non immunocomplex (free) HIV-I P24 antigen in humen capillary venous whole blood plasma and serum | **Approved.** | | | |
|  | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi  (ELI-00019) | | | **Legal Manufacturer:**  M/s Alere Medical Co., Ltd., 7F Shinjuku NS Building, 2-4-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-0807, Japan  **Manufacturing Site:**  M/s Alere Medical Co., Ltd., Chiba Plant 357 Matsuhidai, Matsudo-shi, Chiba 270-2214, Japan  (FSC JAPAN Issuance Date  26-03-2017) | | | Determine HBsAg2  Class D  Shelf Life: 18 Months  Determine HBsAg27D2942  (20 tests/Kit)  Determine HBsAg2 7D2943  (100 Tests/Kit) | | | | | Qualitative immunoassay for the detection of Hepatitis B surface Antigen in humen serum, plasma or whole blood | **Approved.** | | | |
|  | M/s Allmed Solutions, A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi  (ELI-00029) | | | **Manufactured By:** M/s Bactiguard AB, Alfred Nobels Alle 150, 146 48 Tullinge, Sweden  (FSC Sweden validity date  01-10-2023 Copy)  Fee. Rs. 50,000/- | | | BIP Central Venous Catheter  Class D  Shelf Life: 3 Years | | | | | Central Venous Catheter | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | | **Marketed By:** M/s KANEKA Corporation, 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka, 530-8288, Japan  **Manufacturing Site:** M/s KANEKA Medix Corporation Kanagawa Plant 225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun, KANAGAWA, 258-0113 Japan  (FSC Japan Issuance Date  07-12-2015)  Fee. Rs. 50,000/- | | | Thrombuster II  Class D  Shelf Life: 3 Years  Codes Sizes  T2R6SA4W 6-Fr | | | | | Aspiration Cahteter | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | | **Marketed By:** M/s KANEKA Corporation, 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka, 530-8288, Japan  **Manufacturing Site:** M/s KANEKA Medix Corporation Kanagawa Plant 225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun, KANAGAWA, 258-0113 Japan  (FSC Japan Issuance Date  01-04-2018)  Fee. Rs. 50,000/- | | | Crusade Bilumen Catheter  Class D  Shelf Life: 3 Years  Codes Sizes  KMF0114A 140cm  0.014 Guidewire supported | | | | | Bilumen Coronary Catheter | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | | **Manufacturer/ Manufacturing Site:** M/s Occlutech GmbH Eildenbruchstrasse 15, 07745 Jena, Germany  (FSC Germany Issuance Date  30-01-2018)  Fee. Rs. 50,000/- | | | Figulla® Flex II ASD Occluder  Class D  Shelf Life: 5 Years  Codes Sizes  29ASD04 4mm  29ASD05 5mm  29ASD06 6mm  29ASD07 7mm  29ASD09 9mm  29ASD10 10mm  29ASD12 12mm  29ASD13 13mm  29ASD15 15mm  29ASD16 16mm  29ASD18 18mm  29ASD1919.5mm  29ASD21 21mm  29ASD24 24mm  29ASD27 27mm  29ASD30 30mm  29ASD33 33mm  29ASD36 36mm  29ASD39 39mm  29ASD40 40mm | | | | | Atrial Septal Defect Closure Device | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | | **Manufacturer/ Manufacturing Site:** M/s Occlutech GmbH Eildenbruchstrasse 15, 07745 Jena, Germany  (FSC Germany Issuance Date  30-01-2018)  Fee. Rs. 50,000/- | | | Occlutech® Delivery System  Class D  Shelf Life: 2 Years  **Codes Sizes Length**  45 Degree Angle  51DS007 7Fr 800mm  51DS008 8Fr 800mm  51DS009 9Fr 800mm  51DS010 10Fr 800mm  51DS011 11Fr 800mm  51DS012 12Fr 800mm  51DS014 14Fr 800mm  45x45 Degree  51CH012  51CH014  180 Degree Angle  51US006 6Fr 800mm  51US007 7Fr 800mm  51US008 8Fr 800mm  51US009 9Fr 800mm | | | | | Occluder Delivery System | **Approved.** | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | | **Manufacture:**  M/s Shanghai Shape Memory Alloy Co., Ltd 1F and 5F, Tower 41, No. 258 Xinzhuan Development District Shanghai 201612, China.  (FSC Netherlands Valid Till 23-11-2021) | | | MemoPartTMVentricular Septal Defect (VSD)Occluder  Class D  Shelf Life: 3 Years  Sizes | | | | | Occluder System | **Approved.** | | | |
| SQFDQ-I a04 WTSQFDQ-I a04 SQFDQ-II b04  SQFDQ-I a05 WTSQFDQ-I a05 SQFDQ-II b05  SQFDQ-I a06 WTSQFDQ-I a06 SQFDQ-II b06  SQFDQ-I a07 WTSQFDQ-I a07 SQFDQ-II b07  SQFDQ-I a08 WTSQFDQ-I a08 SQFDQ-II b08  SQFDQ-I a09 WTSQFDQ-I a09 SQFDQ-II b09  SQFDQ-I a10 WTSQFDQ-I a10 SQFDQ-II b10  SQFDQ-I a12 WTSQFDQ-I a12 SQFDQ-II b12  SQFDQ-I a14 WTSQFDQ-I a14 SQFDQ-II b14  SQFDQ-I a16 WTSQFDQ-I a16 SQFDQ-II b16  SQFDQ-I a18 WTSQFDQ-I a18 SQFDQ-II b18  SQFDQ-II b20SQFDQ-I b04 WTSQFDQ-I b04 WTSQFDQ-II b04SQFDQ-I b05 WTSQFDQ-I b05 WTSQFDQ-II b05SQFDQ-I b06 WTSQFDQ-I b06 WTSQFDQ-II b06SQFDQ-I b07 WTSQFDQ-I b07 WTSQFDQ-II b07SQFDQ-I b08 WTSQFDQ-I b08 WTSQFDQ-II b08SQFDQ-I b09 WTSQFDQ-I b09 WTSQFDQ-II b09SQFDQ-I b10 WTSQFDQ-I b10 WTSQFDQ-II b10SQFDQ-I b12 WTSQFDQ-I b12 WTSQFDQ-II b12SQFDQ-I b14 WTSQFDQ-I b14 WTSQFDQ-II b14SQFDQ-I b16 WTSQFDQ-I b16 WTSQFDQ-II b16SQFDQ-I b18 WTSQFDQ-I b18 WTSQFDQ-II b18WTSQFDQ-II b20  SQFDQ-I c04 WTSQFDQ-I c04 SQFDQ-III 04  SQFDQ-I c05 WTSQFDQ-I c05 SQFDQ-III 05  SQFDQ-I c06 WTSQFDQ-I c06 SQFDQ-III 06  SQFDQ-I c07 WTSQFDQ-I c07 SQFDQ-III 07  SQFDQ-I c08 WTSQFDQ-I c08 SQFDQ-III 08  SQFDQ-I c09 WTSQFDQ-I c09 SQFDQ-III 09  SQFDQ-I c10 WTSQFDQ-I c10 SQFDQ-III 10  SQFDQ-I c12 WTSQFDQ-I c12 SQFDQ-III 12  SQFDQ-I c14 WTSQFDQ-I c14 SQFDQ-III 14  SQFDQ-I c16 WTSQFDQ-I c16 SQFDQ-III 16  SQFDQ-I c18 WTSQFDQ-I c18 SQFDQ-III 18  WTSQFDQ-III 04 SQFDQ-IV 04 WTSQFDQ-III 05 SQFDQ-IV 05 WTSQFDQ-III 06 SQFDQ-IV 06  WTSQFDQ-III 07 SQFDQ-IV 07  WTSQFDQ-III 08 SQFDQ-IV 08  WTSQFDQ-III 09 SQFDQ-IV 09  WTSQFDQ-III 10 SQFDQ-IV 10  WTSQFDQ-III 12 SQFDQ-IV 12  WTSQFDQ-III 14 SQFDQ-IV 14  WTSQFDQ-III 16 SQFDQ-IV 16  WTSQFDQ-III 18 | | | | | |
|  | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi  (ELI-00034) | | | **Manufacturer:** M/s Shanghai Shape Memory Alloy Co., Ltd 1F and 5F, Tower 41, No. 258 Xinzhuan Development District Shanghai 201612, China  (FSC Netherlands Valid Till 23-11-2021) | | | MemoPartTMAtrial Septal Defect (ASD) Occluder  Class D  Shelf Life: 3 Years  Sizes: | | | | | Occluder System | **Approved.** | | | |
| FQFDQ I 06 WTFQFDQ I 06FQFDQ I 07 WTFQFDQ I 07FQFDQ I 08 WTFQFDQ I 08  FQFDQ I 09 WTFQFDQ I 09FQFDQ I 10 WTFQFDQ I 10FQFDQ I 11 WTFQFDQ I 11  FQFDQ I 12 WTFQFDQ I 12FQFDQ I 13 WTFQFDQ I 13FQFDQ I 14 WTFQFDQ I 14  FQFDQ I 15 WTFQFDQ I 15 WTFQFDQ II 06  FQFDQ I 16 WTFQFDQ I 16 WTFQFDQ II 08  FQFDQ I 17 WTFQFDQ I 17WTFQFDQ II 10  FQFDQ I 18 WTFQFDQ I 18WTFQFDQ II 12  FQFDQ I 19 WTFQFDQ I 19WTFQFDQ II 14  FQFDQ I 20 WTFQFDQ I 20FQFDQ I 22 WTFQFDQ I 22FQFDQ I 24 WTFQFDQ I 24  FQFDQ I 26 FQFDQ I 28FQFDQ I 30 FQFDQ II 06  FQFDQ I 32 FQFDQ II 08FQFDQ I 34 FQFDQ II 10  FQFDQ I 36 FQFDQ II 12FQFDQ I 38 FQFDQ II 14  FQFDQ I 40 FQFDQ II 16FQFDQ I 42 FQFDQ II 18  FQFDQ I 44 FQFDQ II 20FQFDQ I 46 FQFDQ II 22  FQFDQ I 48 FQFDQ II 24 FQFDQ I 50 | | | | | |
|  | M/s UDL Distribution (Pvt) Limited, 1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  M/s Arrow International De Chihuahua S.A. de C.V. Ave. Washington 3701, Interior Circuito Industrial Alta Tecnologia Edificios 40 and 2, Colonia Panacericana Chihuahua, Chihuahua, CP 31200, Mexico  (FSC USFDA Valid Till  10-07-2020)  Fee Rs. 50,000/- | | | Arrow Spring-Wire Guide  Class D  Shelf Life: 5 Years  AW-01700,  AW-04018,  AW-04021-C,  AW-04025,  AW-04025J,  AW-04032,  AW-04225,  AW-04235,  AW-04235-C,  AW-04432,  AW-04435,  AW-14725,  AW-14732,  AW-14735,  AW-16402,  AW-17752,  PW-18045,P  W-18180,  PW-18130 | | | | | Permit central venous catheter introduction or exchange. | **Approved**  subject to submission of stablity data as per claim of shelf life. | | | |
|  | M/s UDL Distribution (Pvt) Limited, 1-D-13, Sector 30, Korangi Industrial Area, Karachi  (ELI-00073) | | | **Legal Manufacturer:** M/s Arrow International, Inc. (Subsidiary of Teleflex, Inc.) 2400 Bernville Road Reading, PA 19605, USA  **Manufacturing Facilities:**  (i) M/s Arrow International, Inc. 16 Elizabeth Drive, Chelmsford, MA 01824  (ii) M/s Arrow International Inc., 312 Commerce Place Asheboro, NC 27203, USA  (FSC USFDA Valid Till  10-07-2020)  Fee. Rs. 50,000/- | | | Ultraflex Arrow Intra-Aortic Balloon Catheter    Class D  Shelf Life: 2 Years  IAB-06830-U, IAB-06835-U, IAB-06840-U | | | | | Balloon Catheter | **Approved**  subject to submission of stablity data as per claim of shelf life. | | | |
|  | M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi  (ELI-00273) | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Manufacturing Facility:**  (i) M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico  (ii) M/s Medtronic Perfusion Systems 18501 E Plaza Dr  Parker, CO 80134, USA  (FSC USFDA Valid Till  13-09-2019)  Fee Rs. 50,000/- | | | Affinity PixieTM Hollow Fiber Oxygenator with BalanceTM Biosurface  Class D  Shelf Life: 2 Years  BBP211- | | | | | Reservoir, Blood, Cardiopulmonary bypass | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Manufacturing Facility:**  (i) M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico  (ii) M/s Medtronic Perfusion Systems 18501 E Plaza Dr Parker, CO 80134, USA  (FSC USFDA Valid Till  13-09-2019) | | | Affinity Fusion® Oxy w/ Integrated Arterial Filter and Balance® Biosurface  Class D  Shelf Life: 2 Years  BB841 | | | | | Reservoir, Blood, Cardiopulmonary bypass | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Manufacturing Facility:**  (i) M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico  (ii) M/s Medtronic Perfusion Systems 18501 E Plaza Dr  Parker, CO 80134, USA  (FSC USFDA Valid Till  13-09-2019) | | | MyOtherm XP® 4:1T  Class D  Shelf Life: 2 Years  4:1T | | | | | Cardioplegia Solution Administration Kit | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | DLP® Curved Tip Arterial Cannulae With One Piece Wirewound Body  Class D  Shelf Life: 3 Years  Codes:  87020  87022  87920  87922  87924  87324  87424 | | | | | Cardipulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/ Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | DLP® High Flow Coronary Artery Ostial Cannula  Class D  Shelf Life: 3 Years  Codes:  30110, 30112, 30114, 30212,  30155, 30255 | | | | | Coronary Sinus Cannula | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | DLP® Metal Tip Arterial Cannulae  Class D  Shelf Life: 3 Years  Codes:  80020  80022  80024  80120  80122  80124  80220  80222  80224  80320  80322  80324 | | | | | Cardiopulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | Select Series® Straight Tip Arterial Cannulae  Class D  Shelf Life: 3 Years  Codes:  72120  72122  72124  72220  72222  72224 | | | | | Cardiopulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | DLP® Curved Tip Arterial Cannulae  Class D  Shelf Life: 3 Years  Codes:  83020  83022  83024  84020  84022  84024  88020  88022  88024  88120  88122  88124  89020  89022  89024  89120  89122  89124  85122  85124  86024  81020  81022  81024  81118  81120  81122  81124  82020  82022  82024  82120  82122  82124 | | | | | Cardiopulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | EOPA® One Piece Arterial Cannulae  Class D  Shelf Life: 3 Years  Codes:   |  |  | | --- | --- | | 77418 77420 77422 77424 77518 77520 77522 77524 | 77618 77620 77622 77624 77718 77720 77722 77724 | | | | | | Cardiopulmonary bypass Cannula, | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  (i) M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (ii) M/s Medtronic Mexico S.de R.L. de CV Av, Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210, MEXICO  (FSC USFDA Valid Till  12-02-2020) | | | CG FutureTM Annuloplasty Ring, 638R  Class D  Shelf Life: 5 Years | | | | | For reconstruction and remodeling of pathological mitral valves | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  (i) M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (ii) M/s Medtronic Mexico S.de R.L. de CV Av, Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210, MEXICO  (FSC USFDA Valid Till  12-02-2020) | | | CG FutureTM Annuloplasty Band, 638B  Class D  Shelf Life: 5 Years  Codes and Sizes as per submitted Free Sale Certificate. | | | | | For reconstruction and remodeling of pathological miteral valves | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturing Facility:**  (i) M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  (ii) M/s Medtronic Perfusion Systems, 18501 E Plaza Dr Parker, CO 80134, USA  (FSC USFDA Valid Till  15-02-2020) | | | HR-ACT Cartride, 2 Channel  Class B  Shelf Life: 32 Weeks | | | | | Use in dwetermining the activated clotting time of whole blood. For in vitro use | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Contract Manufacturer:**  M/s MedPlast Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  08-03-2020) | | | DLP® Pediatric One Piece Arterial Cannulae  Class B  Shelf Life: 3 Years  Codes:  77006  77106  77206  77208  77210  77212  77306  77308  77310  77312  77008  77010  77012  77014  77016  77108  77110  77112  77114  77116 | | | | | Cardiopulmonary bypass Cannula, | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Contract Manufacturer:**  M/s MedPlast Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  08-03-2020) | | | DLP® Straight Tip Arterial Cannulae  Class B  Shelf Life: 3 Years  Codes:  76118  76320  76322  76324  73016  70016  75008  75010  75012  75014  75318  75320  75322  75324  76020  76022  76024  76120  76122  76124 | | | | | Cardiopulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Contract Manufacturer:**  M/s MedPlast Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  08-03-2020) | | | Select Series® Angled Tip Arterial Cannulae  Class B  Shelf Life: 3 Years  Codes:  72420  72422  72424  72520  72522  72524  72622  72720  72722  72724  72820  72822  72824  73420  73422  73424  73520  73522  73524  72720  72724  72820  72822  72824 | | | | | Cardiopulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Manufacturer:** M/s Medtronic Vascular 37A Cherry Hill Dr Danvers, MA 01923, USA  **Manufacturing Facility:**  M/s C.R. BARD, Inc., 289 Bay Rd Queensbury, NY 12804, USA  (FSC USFDA Valid Till  06-02-2020) | | | Angiographic Guide Wire  Class D  Shelf Life: 4 Years and 07 months | | | | | Disposable Cardiovascular Guide Wire | **Approved.** | | | |
|  | -do- | | | **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  **Contract Manufacturer:**  M/s AvailMed S.A. De C.V. C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A. Col. Cd. Industrial Tijuana, Baja California 22444, Mexico  (FSC USFDA Valid Till  31-07-2019) | | | DxTerity Angioplasty Catheters  (TRA EZ-Pak)  Class D  Shelf Life: 3 Years  ------- | | | | | Angioplasty Catheters | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (FSC USFDA Valid Till  04-12-2018) | | | ContegraTM Pulmonary Valved Conduit, Model 200 (Unsupported)  Class D  Shelf Life: 4 Years  Codes:  PVC212, PVC214, PVC216 | | | | | Pulmonary Heart Valve Bio Prosthesis | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, 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  **Contract Manufacturer:**  (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA  (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  11-06-2019) | | | DLP® Pericardial Sumps  Class B  Shelf Life: 3 Years  120, 12011 | | | | | Cardiopulmonary bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  (i) M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (ii) M/s Medtronic Mexico S.de R.L. de CV Av, Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210, MEXICO  (FSC USFDA Valid Till  12-02-2020) | | | Duran AnCoreTM Annuloplasty Ring (Model: 620R)  Class D  Shelf Life: 5 Years  Codes:  700FF23 700FF25  700FF27 700FF29  700FF31 700FF33  700FF35 700FF37  700FF39 | | | | | Mitral/Tricuspad Annuloplasty Ring | **Approved.** | | | |
|  | -do- | | | **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  **Contract Manufacturer:**  M/s CEA Global Dominicana S.R.L. Zona Franca Industrial San Pedro de Macoris, San Pedro de Macoris 80916 Dominican Republic  (FSC USFDA Valid Till  20-09-2019) | | | IntuitionTM Steerable Guidewires  Class D  Shelf Life: 3 Years  Codes:  NTU180HS INTU180SS  INTU300HS INTU300HS | | | | | PTCA Guide Wires | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic AFT 8200 Coral Sea Street Moundsview, MN 55112  **Contract Manufacturer:**  M/s MedPlast Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  07-11-2019) | | | Cardioblate® Surgical Ablation Pen  Class D  Shelf Life: 2 Years  Model:60813 | | | | | Ablation Monopolar | **Approved.** | | | |
|  | -do- | | | **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  **Contract Manufacturer:**  M/s CEA Global Dominicana S.R.L. Zona Franca Industrial San Pedro de Macoris, San Pedro de Macoris 80916 Dominican Republic  (FSC USFDA Valid Till  20-09-2019) | | | Pro ViaTMSteerable Guidewires  Class D  Shelf Life: 3 Years  Codes:  3PROV180HS 3PROV180SS  3PROV300HS 3PROV300SS  6PROV180HS 6PROV180SS  6PROV300HS 6PROV300SS  9PROV180HS 9PROV180SS  9PROV300HS 9PROV300SS | | | | | PTCA Guide Wires | **Approved.** | | | |
|  | -do- | | | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Contract Manufacturer:**  M/s Vention Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  02-03-2019) | | | TSMICS1\_Octopus® Nuvo Tissue Stabilizer, Heart Positioners  Class D  Shelf Life: 3 Years  TSMICS1 | | | | | Heart Positioner and stabalizer | **Approved.** | | | |
|  | -do- | | | **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  **Contract Manufacturer:**  M/s CEA Global Dominicana S.R.L. Zona Franca Industrial San Pedro de Macoris, San Pedro de Macoris 80916 Dominican Republic  (FSC USFDA Valid Till  20-09-2019) | | | Zinger TM Steerable Guidewires  Class D  Shelf Life: 3 Years  Codes:  LVZRLS180J  LVZRLS180S  LVZRMS180J  LVZRMS180S  LVZRXT180J  LVZRXT180S  ZNGRLS180HJ  ZNGRLS180HS  ZNGRLS180J  ZNGRLS180S  ZNGRLS300HJ  ZNGRLS300HS  ZNGRLS300J  ZNGRLS300S  ZNGRMK180HJ  ZNGRMK180HS  ZNGRMK180J  ZNGRMK180S  ZNGRMK300HJ  ZNGRMK300HS  ZNGRMK300J  ZNGRMK300S  ZNGRMS180HJ  ZNGRMS180HS  ZNGRMS180J  ZNGRMS180S  ZNGRMS300HJ  ZNGRMS300HS  ZNGRMS300J  ZNGRMS300S  ZNGRS180HJ  ZNGRS180HS  ZNGRS180J  ZNGRS180S  ZNGRS300HJ  ZNGRS300HS  ZNGRS300J  ZNGRS300S | | | | | PTCA Guide Wires | **Approved.** | | | |
|  | -do- | | | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Contract Manufacturer:**  M/s Vention Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  02-03-2019) | | | TS2000\_Octopus® Evolution Tissue Stabilizer, Heart Positioners  Class B  Shelf Life: 3 Years  TS2000 | | | | | Patient Positioner and stabalizer | **Approved.** | | | |
|  | -do- | | | **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  **Contract Manufacturer:**  M/s CEA Global Dominicana S.R.L. Zona Franca Industrial San Pedro de Macoris, San Pedro de Macoris 80916 Dominican Republic  (FSC USFDA Valid Till  20-09-2019) | | | ThunderTM Steerable Guidewires  Class D  Shelf Life: 3 Years  Codes:  THNDR190J THNDR190S  THNDR300J THNDR300S | | | | | PTCA Guide Wires | **Approved.** | | | |
|  | -do- | | | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (FSC USFDA Valid Till  10-08-2019) | | | HancockTM II Bioprosthesis, Model T510 (mitral)  Class D  Shelf Life: 5 Years  -------- | | | | | Mitral Heart Valve Bioprosthesis | **Approved.** | | | |
|  | -do- | | | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Contract Manufacturer:**  M/s MedPlast Medical Inc 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  08-03-2020) | | | DLP® Intracardiac Sumps  Class B  Shelf Life: 3 Years  12012, 12013 | | | | | Cardiopulmonary Bypass Cannula, Arterial | **Approved** as Class D Medical Device without Design Examination Certificate since the product is Class B in the country of origin. | | | |
|  | -do- | | | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer/Distributor:**  M/s Medtronic Inc., 710 Medtronic Pkwy Minneapolis, MN 55432, USA  **Manufacturer:**  (i) M/s Medtronic Vascular 37A Cherry Hill Dr Danvers, MA 01923, USA  (ii) M/s Availmed S.A. DE C.V. (MEXICO) Ave. Paseo Reforma No. 8950 Interior C1, E2 La Mesa Tijuana, Baja California 22116 Mexico  (FSC USFDA Valid Till  30-01-2020) | | | Transseptal Introducer Catheters  Class D  Shelf Life: 5 Years  ------- | | | | | Transseptal Catheter Introducer Sets | **Approved** subject to provision of codes. | | | |
|  | -do- | | | **Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (FSC USFDA Valid Till  10-08-2019) | | | HancockTM II Bioprosthesis, Model T505 (aortic)  Class D  Shelf Life: 5 Years  -------- | | | | | Aortic Heart Valve Bioprosthesis | **Approved** subject to provision of codes. | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  (i) M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (ii) M/s Medtronic Mexico S.de R.L. de CV Av, Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210, MEXICO  (FSC USFDA Valid Till  12-02-2020) | | | Duran AnCoreTM Annuloplasty Handle, 7620H  Class D  Shelf Life: 5 Years  Model:7620H 216mm Length  7620HXL 373mm Length | | | | | Heart Valve Prosthesis Sinzer Handle | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Vascular 37A Cherry Hill Dr Danvers, MA 01923, USA  **Contract Manufacturer:**  M/s Medplast Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Heredia Costa Rica  (FSC USFDA Valid Till  17-08-2019) | | | TRAcelet Compression Device  Class B  Shelf Life: 1 Year  TRACR, TRACL | | | | | Compression Device | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic AFT 8200 Coral Sea Street Moundsview, MN 55112  **Contract Manufacturer:**  M/s MedPlast Medical Inc., 620 Watson SW GR, MI 49504, USA  (FSC USFDA Valid Till  07-11-2019) | | | Cardioblate® XL Pen  Class D  Shelf Life: 2 Years  Model:60814 | | | | | Surgical Ablation Pen (Ablation Biopolar) | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  (i) M/s Medtronic Heart Valve Division 1851 East Deere Ave., Santa Ana, CA 92705, USA  (ii) M/s Medtronic Mexico S.de R.L. de CV Av, Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210, MEXICO  (FSC USFDA Valid Till  12-02-2020) | | | Duran AnCoreTM Sizer Set  Class D  Shelf Life: 5 Years  Model:7620S | | | | | Mitral/Tricuspad Annuloplasty Ringband | **Approved.** | | | |
|  | -do- | | | **Owner Operator/**  **Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA  **Manufacturer:**  M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA  **Manufacturing Facility:**  (i) M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico  (ii) M/s Medtronic Perfusion Systems 18501 E Plaza Dr Parker, CO 80134, USA  (FSC USFDA Valid Till  13-09-2019) | | | 540T – Affinity® Cardiotomy/Venous Reservoir with Filter (CVR) with Trillium® Biosurface  Class D  Shelf Life: 2years | | | | | Oxygenator | **Approved.** | | | |
|  | M/s Dora Enterprises, 54-B, Model Town Lahore(HO)  Suite No. 2, First Floor 35-C, Civic Centre M Block Ext Model Town, Lahore  (ELI-00108) | | | **Legal Manufacturer:** M/s MT Promedt Consulting GmbH Altenhofstr. 80, 66386 St. Ingbert, Germany  **Manufacturer:**  M/s Bain Medical Equipment (Guangzhou) Co., Ltd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou 510760, China  (FSC Germany Issuance Date  04-06-2018) | | | Dora  Disposable A.V. Fistula Needle Sets (DORA®)    Class B  Shelf Life: 3 Years  Fee: 25000/-  Sizes:  15G, 16G, 17G, 18G | | | | | Needles, Dialysis | **Approved** subject to provision of Free Sale Certificate of Country of Origin with sizes. | | | |
|  | -do- | | | **Legal Manufacturer:** M/s MT Promedt Consulting GmbH Altenhofstr. 80, 66386 St. Ingbert, Germany  **Manufacturer:**  M/s Bain Medical Equipment (Guangzhou) Co., Ktd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou 510760, China  (FSC Germany Issuance Date  04-06-2018) | | | Dora  Tubing Sets for Hemodialysis    Class B  Shelf Life: 3 Years  Sizes:  Blood tubing sets, 6.3x9.8mm tubing line adult  Blood tubing sets, 8.0x12mm tubing line adult  Blood tubing sets, | | | | | Hemodialysis Tubing Set | **Approved** subject to provision of Free Sale Certificate of Country of Origin with sizes. | | | |
|  | -do- | | | **Legal Manufacturer:** M/s MT Promedt Consulting GmbH Altenhofstr. 80, 66386 St. Ingbert, Germany  **Manufacturer:**  M/s Bain Medical Equipment (Guangzhou) Co., Ktd. No. 10, Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou 510760, China  (FSC Germany Issuance Date  04-06-2018) | | | Dora  Hemodialyzers (Hollow Fiber Dialyzer DORA® )    Class C  Shelf Life: 3 Years  Codes:  B-14P, B-16P, B-18P,  B-20P | | | | | Dialyzers, Hemodialysis, Hollow-Fiber | **Approved.** | | | |
|  | M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi  (ELI-00061) | | | **Manufacturer:** M/s UNISIS Corp., 4-11-4 Taito, Taito-ku, Tokyo 110-0016, Japan  (FSC Japan Issuance Date  18-07-2018) | | | Uniever  Disposable Combined Spinal Epidural Anesthesia Minitray  Class D  Shelf Life: 5 Years | | | | | Disposable Combined Spinal Epidural Anesthesia Minitray | **Approved.** | | | |
|  | -do- | | | **Manufacturer:** M/s UNISIS Corp., 4-11-4 Taito, Taito-ku, Tokyo 110-0016, Japan  (FSC Japan Issuance Date  18-07-2018) | | | Uniever  Disposable Epidural Anesthesia Minitray  Class B  Shelf Life: 5 Years | | | | | Disposable Epidural Anesthesia Minitray | **Approved.** | | | |
|  | -do- | | | **Manufacturer:** M/s UNISIS Corp., 4-11-4 Taito, Taito-ku, Tokyo 110-0016, Japan  (FSC Japan Issuance Date  18-07-2018) | | | Uniever Disposable Spinal Anesthesia Needle  Class D  Shelf Life: 5 Years | | | | | Disposable Spinal Anesthesia Needle | **Approved.** | | | |
|  | -do- | | | **Manufacturer:** M/s UNISIS Corp., 4-11-4 Taito, Taito-ku, Tokyo 110-0016, Japan  (FSC Japan Issuance Date  18-07-2018) | | | Uniever Disposable Epidural Anesthesia Needle  Class B  Shelf Life: 5 Years | | | | | Disposable Epidural Anesthesia Needle | **Approved.** | | | |
|  | M/s Sadqain Healthcare (Pvt) Ltd., Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi  (ELI-00020) | | | **Manufacturer:** M/s Intersurgical Limited., Crane House, Molly Millars Lane, Wokingham, Berkshire, UK  (FSC UK Issuance Date  01-03-2016) | | | Hydro-Trach T MK II HME  Class B  Shelf Life: 5 Years  Code: 1874000 | | | | | HME filter with Oxygen Tubing | **Approved.** | | | |
|  | -do- | | | **Manufacturer:** M/s Intersurgical Limited., Crane House, Molly Millars Lane, Wokingham, Berkshire, UK  (FSC UK Issuance Date  01-03-2016) | | | Hydro-Guard Mini Breathing Filter  Class B  Shelf Life: 5 Years  Code: 1745000 | | | | | Breathing Filter | **Approved.** | | | |
|  | -do- | | | **Manufacturer:** M/s Intersurgical Limited., Crane House, Molly Millars Lane, Wokingham, Berkshire, UK  (FSC UK Issuance Date  01-03-2016) | | | Clear-Therm Micro HMEF with Luer Port  Clear-Therm Mini HMEF with Luer Port  Class B  Shelf Life: 2 Years  1441000, 1831000 | | | | | Heat and Moisture Exchanging Filter | **Approved.** | | | |
|  | M/s Briogene Private Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi  (ELI-00015) | | | **Manufacturer:** M/s Qiagen GmbH Qiagen Str. 1, 40724 Hilden, Germany  (FSC Germany Issuance Date  02-06-2015) | | | Artus R  HBV QS-RGQKit-(24) CE4506363  HBV QS-RGQ Kit (72),CE4506366  Class C  Shelf Life: 23 Months | | | | | HBV Kit | **Approved.** | | | |
|  | -do- | | | **Legal Manufacturer:** M/s Maco Pharma Rue Lorthiois 59420 Mouvaux (France)  **Manufacturing Sites:**  (i) M/s MacoProductions 1-200 Chaussee Fernand Forest, 59200 Tourcoing, France  (ii) M/s MacoProductions Pologne SP Z.o.o. ul Szwajcarska 54405 Wroclaw, Polongne  (iii) M/s Maco MD Lot 99 Zone Industrielle Chotrana 2, 2056 Raoued, Ariana, Tunisie  (FSC France Issuance Date  25-04-2016) | | | Macopharma  Double Blood Bag with Leukodepletion Filter  Class D  Shelf Life: 02 Years  Code: | | | | | Double Blood Bag with CPDA1 | **Approved** subject to clarification of codes on Free Sale Certificate. | | | |
|  | -do- | | | **Legal Manufacturer:** M/s Maco Pharma Rue Lorthiois 59420 Mouvaux (France)  **Manufacturing Sites:**  (i) M/s MacoProductions 1-200 Chaussee Fernand Forest, 59200 Tourcoing, France  (ii) M/s MacoProductions Pologne SP Z.o.o. ul Szwajcarska 54405 Wroclaw, Polongne  (iii) M/s Maco MD Lot 99 Zone Industrielle Chotrana 2, 2056 Raoued, Ariana, Tunisie  (FSC France Issuance Date  25-04-2016) | | | Macopharma  Triple Blood Bag with Leukodepletion Filter  Class D  Shelf Life: 02 Years  Codes: MRE6506LO, MRE7506LO | | | | | Triple Blood Bag with CPDA1 | **Approved** subject to clarification of codes on Free Sale Certificate. | | | |
|  | -do- | | | **Legal Manufacturer:** M/s Maco Pharma Rue Lorthiois 59420 Mouvaux (France)  **Manufacturing Sites:**  (i) M/s MacoProductions 1-200 Chaussee Fernand Forest, 59200 Tourcoing, France  (ii) M/s MacoProductions Pologne SP Z.o.o. ul Szwajcarska 54405 Wroclaw, Polongne  (iii) M/s Maco MD Lot 99 Zone Industrielle Chotrana 2, 2056 Raoued, Ariana, Tunisie  (FSC France Issuance Date  25-04-2016) | | | Macopharma  Single Blood Bag with Leukodepletion Filter  Class D  Shelf Life: 02 Years  Code: MSE6501LO  Fee: 50000/- | | | | | Single Blood Bag with CPDA1 | **Approved** subject to clarification of codes on Free Sale Certificate. | | | |
|  | -do- | | | **Legal Manufacturer:** M/s Maco Pharma Rue Lorthiois 59420 Mouvaux (France)  **Manufacturing Sites:**  (i) M/s MacoProductions 1-200 Chaussee Fernand Forest, 59200 Tourcoing, France  (ii) M/s MacoProductions Pologne SP Z.o.o. ul Szwajcarska 54405 Wroclaw, Polongne  (iii) M/s Maco MD Lot 99 Zone Industrielle Chotrana 2, 2056 Raoued, Ariana, Tunisie  (FSC France Issuance Date  25-04-2016) | | | Macopharma  Multiple Blood Bag with Leukodepletion Filter  Class D  Shelf Life: 02 Years  Code: MQE6506LO, MQE7506LO  Fee: 50000/- | | | | | Quadruple Blood Bag with CPDA1 | **Approved** subject to clarification of codes on Free Sale Certificate. | | | |
|  | M/s Saving Life Technologies (SLT), 427-K Block, Model Town, Lahore  (ELI-00053) | | | **Manufacturer:** M/s Eucatech AG Rebgartenweg 27, 79576 Weil am Rhein/ Germany  (FSC Germany Issuance Date  27-04-2016) | | | Eucalimus  (Sirolimus Eluting Coronary Stent System)  Class D  Shelf Life: 3 Years  Sizes | | | | | Sirolimus Eluting Coronary Stent System (Rapamycin Derivative) | **Approved** subject to provision of valid Quality Management System Certificate ISO:13485. | | | |
| 8mm  ELM22508  ELM25008  ELM27508  ELM30008  ELM32508  ELM35008  ELM40008  10mm  ELM22510  ELM25010  ELM27510  ELM30010  ELM32510  ELM35010  ELM40010  13mm  ELM22513  ELM25013  ELM27513  ELM30013  ELM32513  ELM35013  ELM40013  16mm  ELM22516  ELM25016  ELM27516  ELM30016  ELM32516  ELM35016  ELM40016  18mm  ELM22518  ELM25018  ELM27518  ELM30018  ELM32518  ELM35018  ELM40018 | 23mm  ELM22523  ELM25023  ELM27523  ELM30023  ELM32523  ELM35023  ELM40023  28mm  ELM22528  ELM25028  ELM27528  ELM30028  ELM32528  ELM35028  ELM40028  33mm  ELM25033  ELM27533  ELM30033  ELM32533  ELM35033  ELM40033  38mm  ELM25038  ELM27538  ELM30038  ELM32538  ELM35038  ELM40038  43mm  ELM25043  ELM27543  ELM30043  ELM32543  ELM35043  ELM40043  48mm  ELM27548  ELM30048  ELM32548  ELM35048  ELM40048 | | | |
|  | -do- | | | **Manufacturer:** M/s Eucatech AG Rebgartenweg 27, 79576 Weil am Rhein/ Germany  (FSC Germany Issuance Date  27-04-2016) | | | Euca VI  (PTCA Balloon Catheter)  Class D  Shelf Life: Not Mention  SIZES: | | | | | PTCA Balloon Catheter | **Approved** subject to provision of valid Quality Management System Certificate ISO:13485. | | | |
| 10mm  euca VI 15010  euca VI 20010  euca VI 22510  euca VI 25010  euca VI 27510  euca VI 30010  euca VI 35010  euca VI 40010  15mm  euca VI 15015  euca VI 20015  euca VI 22515  euca VI 25015  euca VI 27515  euca VI 30015  euca VI 35015  euca VI 40015  20mm  euca VI 15020  euca VI 20020  euca VI 22520  euca VI 25020  euca VI 27520  euca VI 30020  euca VI 35020  euca VI 40020 | 25mm  euca VI 15025  euca VI 20025  euca VI 22525  euca VI 25025  euca VI 27525  euca VI 30025  euca VI 35025  euca VI 40025  30mm  euca VI 15030  euca VI 20030  euca VI 22530  euca VI 25030  euca VI 27530  euca VI 30030  euca VI 35030  euca VI 40030  40mm  euca VI 22540  euca VI 25040  euca VI 27540  euca VI 30040  euca VI 35040  euca VI 40040 | | | |
|  | -do- | | | **Manufacturer:** M/s Eucatech AG Rebgartenweg 27, 79576 Weil am Rhein/ Germany  (FSC Germany Issuance Date  27-04-2016) | | | CC Flex  (Cobalt Chromium Coronary Stent System)  Class D  Shelf Life: 3 Years  Sizes: | | | | | Cobalt Chromium Coronary Stent System | **Approved** subject to provision of valid Quality Management System Certificate ISO:13485. | | | |
| 08mm  CCF 22508  CCF 25008  CCF 27508  CCF 30008  CCF 32508  CCF 35008  CCF 40008  10mm  CCF 22510  CCF 25010  CCF 27510  CCF 30010  CCF 32510  CCF 35010  CCF 40010  13mm  CCF 22513  CCF 25013  CCF 27513  CCF 30013  CCF 32513  CCF 35013  CCF 40013  CCF 45013  CCF 50013  16mm  CCF 22516  CCF 25016  CCF 27516  CCF 30016  CCF 32516  CCF 35016  CCF 40016  CCF 45016  CCF 50016  CCF 55016  CCF 60016  18mm  CCF 22518  CCF 25018  CCF 27518  CCF 30018 | CCF 32518  CCF 35018  CCF 40018  CCF 45018  CCF 50018  CCF 55018  CCF 60018  23mm  CCF 22523  CCF 25023  CCF 27523  CCF 30023  CCF 32523  CCF 35023  CCF 40023  CCF 45023  CCF 50023  CCF 55023  CCF 60023  28mm  CCF 25028  CCF 27528  CCF 30028  CCF 32528  CCF 35028  CCF 40028  CCF 45028  CCF 50028  CCF 55028  CCF 60028  33mm  CCF 27533  CCF 30033  CCF 32533  CCF 35033  CCF 40033  CCF 45033  CCF 50033  CCF 55033  CCF 60033  38mm  CCF 30038  CCF 32538  CCF 35038  CCF 40038  CCF 45038  CCF 50038  CCF 55038  CCF 60038 | | | |
|  | Ms Sakuf Trading, 2nd Floor, G-34, Phase-I, Commercial Area, DHA, Lahore  (ELI-00126) | | | **Manufacturer:** Ms EMBO Flussigkeiten A.G., Route des Avouillons 30, 1196 Gland, Switzerland  (FSC Switzerland Valid Till  26-03-2021) | | | Squid Liquid Embolic Agent  Class D  Shelf Life: 3 Years  Model: SQUID12, SQUID12LD, SQUID18, SQUID18LD, SQUID34, SQUID34LD. | | | | | Liquid Embolic Device | **Approved.** | | | |
|  | M/s. Cor-Med, , 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi. | | | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630  (FSC USFDA Valid Till  01-07-2020) | | | Embosphere(R) Microspheres in Syringe  Class D  Shelf Life: 3 Years  S010GH, S020GH, S110GH, S120GH, S210GH, S220GH, S410GH, S420GH, S610GH, S620GH, S810GH, S820GH, S1010GH, S1020GH | | | | | Embosphere Microsphere are indicated for use in the embolization. Hypervascular tumar including symptomatic uterine fibroids. Prostatic arteries for symptomatic benign prostatic hyperplasia. Atriovenous malformations. | **Approved.** | | | |
|  | -do- | | | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630  (FSC USFDA Valid Till  01-07-2020) | | | HepaSphereTM Microspheres  Class D  Shelf Life: 3 Years  V225HS, V250HS, V325HS, V350HS, V525HS, V550HS,  V725HS, V750HS | | | | | Hepasphere Microsphere are indicated for use in the embolization.  Of blood vessels with or without delivery of Doxirubicin Hcl therapeutic preoperative purposes in the following procedures.  Embolization of hepatocellular carcinoma. Embolisation of metastases to the liver. | **Approved.** | | | |
|  | -do- | | | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630  (FSC USFDA Valid Till  01-07-2020) | | | ASAP Aspiration Catheter Kit  Class D  Shelf Life: 3 Years  ASAP 100  ASAPLP TM Low Profile Aspiration Catheter Kit  ASAPLP | | | | | It is used for delivering radio opaque media to selected sites in the vascular system | **Approved.** | | | |
|  | -do- | | | M/s MERIT MEDICAL, USA,  1600 West Merit Parkway, South Jordan UT 84095  **Manufacturing Site**:  Merit Maquiladora Mexico, S, DE, R, L, DE C.V Avenida Sor Juana Ines de laCruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California Mexico 22630  (FSC USFDA Valid Till  01-07-2020) | | | EN Snare ® Endovascular Snare System  Class D  Shelf Life: 3 Years  EN 1003004, EN 2007030  EN 2006015, EN 2007045  EN 1003008, EN 2006010  EN 2006020 | | | | | The En Snare Endovascular Snare and catheter is intended use in the cardiovascular system or hallow viscous to retrieve and manipulate objectes manipulation procedure include indwelling venous catheter fibrin stripping and central venous access venipuncture procedure assistance. | **Approved.** | | | |

**Item No.IV. 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 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** | | **Decision** |
|  | M/s Royal Enterprises, SHS, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Legal Manufacture:**  M/s Foshan Tonghe Medical Technology Co., Ltd., F3 Building, 10th of Plan B, Central Technology Industrial Area, Leping Town, Sanshui District, Foshancity, Guangdong Province, China  (FSC China Valid Till  21-12-2019) | Wheel Chair (All Sizes)  Class A | Wheel Chair | | **Approved.** |
| **MODEL**  SYIV100-THL802, SYIV100-TH809, SYIV100-THL809Y  SYIV100-THL868, SYIV100-THL874Y, SYIV100-THL871  SYIV100-THL873, SYIV100-THL874, SYIV100-THL875  SYIV100-THL901, SYIV100-THL902C, SYIV100-THL902GC  SYIV100-THL903, SYIV100-THL903GC, SYIV100-THL908A  SYIV100-THL980AC, SYIV100-THL908LAH,  SYIV100-THL954LGC, SYIV100-THL980LA,  SYIV100-THL874LAH, SYIV100-THL864LJ,  SYIV100-THL864LY, SYIV100-THL868L J,  SYIV100-THL872LAJ, SYIV100-THL863LAJ,  SYIV100-THL953LQXC, SYIV100-THL869LAJ  SYIV100-THL958LBCJ, SYIV100-THL871LBJ  SYIV100-THL870LBJ, SYIV100-THL973LAH  SYIV100-THL907LABJ, SYIV100-THL955LB  SYIV100-THL863LABJ, SYIV100-THL865LABJ  SYIV100-805LABJ, SYIV100-THL867LBH  SYIV100-THL959L, SYIV100-THL606LABJ  SYIV100-Q01LABJ, SYIV100-Q02LABJ  SYIV100-G03LAJ, SYIV100-G02LAJ | | |  |
|  | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore  (ELI-00094) | **Legal Manufacture:** M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA  **Manufacturing Sites:** (i) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA  (ii) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA  (FSC USFDA Valid Till  16-05-2020) | DOC Guide Wire Extension  Class : A  Shelf Life: 2Years  22260 | | Guide Wire Extension is intended to provide the necessary length to allow the exchange of one balloon dilatation catheter, stent, or other interventional device for another while maintaining the position of the guide wire in the desired position | **Approved.** |
|  | M/s Royal Enterprises, SHS, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Legal Manufacture:**  M/s Foshan Dongfang Medical Equipment Manufactory (Ltd.), 5 Xingfu Rd., Zone A, Shishan Industrial Park, Nanhai District, Foshan City, P.R China  (FSC China Valid Till  13-04-2019) | Unika Plus (Electric Hospital Bed)  Class A  Shelf Life: Not Applicable  Model: FS3238WGZF4, FS3239WGZF4 | | Electric Hospital Bed | **Approved.** |
|  | -do- | **Legal Manufacture:**  M/s Foshan Dongfang Medical Equipment Manufactory (Ltd.), 5 Xingfu Rd., Zone A, Shishan Industrial Park, Nanhai District, Foshan City, P.R China  (FSC China Valid Till  13-04-2019) | Unika Plus (Electric Wheel Chair)  Shelf Life: Not Applicable  Class A  Model: FS110A, FS111A, FS112, FS121, FS123, FS124, FS125, FS127, FS129 | | Electric Wheel Chair | **Approved.** |
|  | -do- | **Legal Manufacture:**  M/s Guangdong Dayang Medical Technology Co., Ltd., Changhongling Industrial Park (2nd Phase), Shishan Nanhai District, Foshan, Guangdong, China  (FSC China Valid Till  20-12-2018) | Nebicare (Manual Wheel Chair)  Class A  Shelf Life: Not Applicable  Model:  DY01201LQ, DY01700LQ,  DY01802E, DY01809, DY01863, DY01864, DY01868, DY01872, DY01875, DY019001, DY01903  DY01908, DY01902GC, DY019051, DY01950, DY01953, DY01954, DY01980, DY01958, DY01959, DY01973, DY01990, DY02608, DY02609, DY02608GC, DY02609GC, DY02681, DY02683, DY01805, DY01871 | | Wheel Chair Manual  Free Sale Certificate Expire on 20-12-2018 | **Approved.** |
|  | -do- | **Legal Manufacture:**  M/s Foshan Dongfang Medical Equipment Manufactory (Ltd.), 5 Xingfu Rd., Zone A, Shishan Industrial Park, Nanhai District, Foshan City, P.R China  (FSC China Valid Till  13-04-2019) | Unika Plus Wheel Chair (Manual)  Class A  Shelf Life: Not Applicable  Model: FS809, FS802, FS871, FS874, FS875, FS901, FS869, FS903, FS908, FS909, FS873, FS972, FS975, FS864L, FS251L, FS869L, FS872L, FS874L, FS903L, FS868L, FS908L, FS974L, FS955L, FS957L, FS959L, FS980L | | Wheel Chair Manual | **Approved.** |
|  | M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi  (ELI-00011) | **Manufacture:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  (FSC Germany, Issuance Date 23-10-2018) | Leukomed® T Plus  Class A  Shelf Life: 5 Years  5cm x 7.2 cm  8cm x 10 cm  8cm x 15 cm  10cm x 20 cm  10cm x 25 cm  10cm x 30 cm  Fee submitted: Rs 5000/- | | Transparent Adsorbent Wound Dressing | **Approved.** |
|  | -do- | **Manufacturer:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  **Manufacturing Plant:**  M/s BSN Medical GmbH Heykenaukamp 10 21147 Hamburg, Germany  (FSC Germany,  Issuance Date 24-04-2017) | Leukomed®  Class A  Shelf Life: 5 Years  5cm x 7.2 cm  8cm x 10 cm  8cm x 15 cm  10cm x 20 cm  10cm x 25 cm  10cm x 30 cm  Fee submitted: Rs 5000/- | | Adsorbent Wound Dressing | **Approved.** |
|  | -do- | **Manufacturer:**  M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany  **Manufacturing Plant:**  M/s BSN Medical GmbH Heykenaukamp 10 21147 Hamburg, Germany  (FSC Germany Issuance Date 24-04-2017) | Fixomull® Stretch  Class A  Shelf Life: 5 Years  5cm x 10 m  10cm x 10 m  Fee submitted: Rs 5000/- | | Adhesive Tape | **Approved.** |
|  | M/s Royal Enterprises, SHS, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Manufacturer:**  M/s Guangdong Kaiyang Medical Technology Group Co., Ltd., (Ercun Industrial Area) Fushenggang, Yanfeng, Shishan Town, Nanhan District, Foshan City, China  (FSC China Valid Till  27-05-2020) | UNIKA + Wheel Chair  Class A  Shelf Life: Not Mentioned  KY809, KY638Q, KY681Y, KY608, KY609, KY607-17, KY689BQ, KY868, KY875, KY874, KY607GCJ, KY609GC, KY610GCJ, KY608GC, KY608GCE, KY681-51, KY605, KY980AC, KY951B56, KY863LAJ, KY908LAH, KY909LAH, KY903LQ-A, KY958LAC, KY958LC, KY959L, KY863LABJ-12, KY9001L, KY9003L, KY976LAQ, KY871LVJ, KY973LAH, KY982LBGC,  KY955LB, KY957BGC, KY976A-43, KY870ABJ, KY940BJ, KY871, KY954LGC, KY968LI, KY972LAJ, KY969LB-A, KY974L, KY903LG, KY903LB, KY988LAQ, KY950LBQ, KY903LACX, KY951LQ, KY953LQXC, KY903LQA, KY608L, KY608LGCJ, KY902GC, KY903B, KY902C, KY901, KY909B, KY972B, KY986BQ, KY956X, KY903GCJ | | Wheel Chair | **Approved.** |
|  | M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi  (ELI-00011) | **Legal Manufacturer:**  M/s BSN Medical Inc., 5825 Carnegie Blvd, Charlotte, NC 28209, USA  **Manufacturing Facility:**  M/s BSN Medical SA de CV Av. Parque SN Villa Florida Reynosa, Tamaulipas 88715, Mexico  (FSC USFDA Valid Till  13-06-2019) | Flashcast® Fiberglass Cast Bandage Tape  Class A  Shelf Life: 5 Years  5cm X 3.6m  7.5cm X 3.6m  10cm X 3.6m  12.5cm X 3.6m | | Fiberglass Cast Tape manufactured from a heat cleaned fiberglass kintted cloth. The fabric coated with hydrophilic polyurethane resin  Brand Name is not provided on Free Sale Certificate | **Approved.** |
|  | M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi  (ELI-00011) | **Legal Manufacturer:**  M/s BSN Medical Inc., 5825 Carnegie Blvd, Charlotte, NC 28209, USA  **Manufacturing Facility:**  M/s BSN Medical SA de CV Av. Parque SN Villa Florida Reynosa, Tamaulipas 88715, Mexico  (FSC USFDA Valid Till  13-06-2019) | Delta-Dry® Fiber Glass Cast Bandage Tape  Class A  Shelf Life: Not Defined  5cmx2.4m  7.5cmx2.4m  10cmx2.4m | | Fiber Glass Cast Bandage Tape made of water resistant material with synthetic on one side designed to allow water to pass through material  Stability Studies Not Provided  Brand Name is not provided on Free Sale Certificate | **Approved** subject to provision of complete stability studies**.**  The firm will be given the name on Free Sale Certificate. |
|  | M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi  (ELI-00011) | **Legal Manufacturer:**  M/s BSN Medical Inc., 5825 Carnegie Blvd, Charlotte, NC 28209, USA  **Manufacturing Facility:**  M/s BSN Medical SA de CV Av. Parque SN Villa Florida Reynosa, Tamaulipas 88715, Mexico  (FSC USFDA Valid Till  13-06-2019) | Dynacast® Prelude Synthetic Splint System  Class A  Shelf Life: Not Provided  2.5cmx4.6m  5cmx4.6m  7.5cmx4.6m  10cmx4.6m  12.5cmx4.6m  15cmx4.6m  20cmx2.3m | | The product is a knitted fiber glass single layer substrate impregnated with a polyurethane resin and enclosed within a polyurethane padding material  Brand Name is not provided on Free Sale Certificate | **Approved** subject to provision of complete stability studies**.**  The firm will be given the name on Free Sale Certificate. |
|  | M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi  (ELI-00011) | **Legal Manufacturer:**  M/s BSN Medical Inc., 5825 Carnegie Blvd, Charlotte, NC 28209, USA  **Manufacturing Facility:**  M/s TWE Meulebeke BVBA marialocpsteenweg 51, Meulebeke, West-Viaanderen B-8760, Belgium  (FSC USFDA Valid Till  13-06-2019) | Soffban® Plus  Class A  Shelf Life: 5 Years  5cm x 2.7m  7.5cm x 2.7m  10cm x 2.7m  15cm x 2.7m | | Synthetic Orthopedic Padding  Name of Product is different on Free Sale Certificate | **Approved** subject to provision of complete stability studies**.**  The firm will be given the name on Free Sale Certificate. |
|  | M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051) | **Manufacturer:**  M/s Xiantao Daoqi Plastic Co., Ltd., No.83, Wagou New District, Pengchang Town, Xiantao City, China  (FSC China Valid Till  29-09-2019) | Classic Disposable Surgical Mask  Class A  Shelf Life: 5 Years  17. 5x9. 5cm (Adult) | | Disposable Surgical Mask | **Approved.** |
|  | M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051) | **Manufacturer:**  M/s Xiantao Daoqi Plastic Co., Ltd., No.83, Wagou New District, Pengchang Town, Xiantao City, China  (FSC China Valid Till  29-09-2019) | Classic Disposable Surgical Gown  Class A  Shelf Life: 5 Years  Model: Standard 110x130cm(M)  115x137cm(L), 115x140cm(XL), 120x140cm(XXL) | | Disposable Surgical Gown | **Approved.** |
|  | M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051) | **Manufacturer:**  M/s Jiaxing Meson Medical Materials Co., Ltd., 1F, Building 5, 1880 Renmin Road, Wutong Street, Tongxiang, Jiaxing, ZheJiang Province, China  (FSC China Valid Till  10-05-2020) | Meson Disposable Sterile Wound Dressing  Class A  Shelf Life: 4 Years  Size: 9 x 10cm, 10 x 10cm,  9 x 15cm, 10 x 15cm,  9 x 20cm, 10 x 20cm,  9 x 10cm, 10 x 25cm  9 x 30cm, 10 x 30cm | | Wound Dressing Sterile | **Approved.** |
|  | M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051) | **Manufacturer:**  M/s Jiaxing Meson Medical Materials Co., Ltd., 1F, Building 5, 1880 Renmin Road, Wutong Street, Tongxiang, Jiaxing, ZheJiang Province, China  (FSC China Valid Till  10-05-2020) | Meson Disposable Sterile IV Wound Dressing  Class A  Shelf Life: 5 Years  Size: 6x8cm | | IV Wound Dressing Sterile | **Approved.** |
|  | M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi  (ELI-00051) | **Manufacturer:**  M/s Xiantao Daoqi Plastic Co., Ltd., No.83, Wagou New District, Pengchang Town, Xiantao City, China  (FSC China Valid Till  29-09-2019) | Classic Disposable Surgical Cap  Class A  Shelf Life: 5 Years  Size:17”, 18”, 19”, 20”, 21”, 24” | | Disposable Surgical Cap | **Approved.** |
|  | M/s Royal Enterprises, SH5, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Manufacturer:**  M/s Guangdong Kaiyang Medical Technology Group Co., Ltd., ErcunIndustrial Area) Fushenggang, Yanfeng, Shishan Town, Nanhai District, Foshan City, China  (FSC China Valid Till  10-10-2020) | UNIKA+ Manual Hospital Bed  Class A  Shelf Life: Not Mentioned | | Manual Hospital Bed | **Approved.** |
|  | M/s Royal Enterprises, SH5, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Manufacturer:**  M/s Guangdong Kaiyang Medical Technology Group Co., Ltd., ErcunIndustrial Area) Fushenggang, Yanfeng, Shishan Town, Nanhai District, Foshan City, China  (FSC China Valid Till  10-10-2020) | UNIKA+ Walker  Class A  Shelf Life: Not Mentioned  KY Series, KY970, KY971, KY972, KY973, KY913L(S),  KY913L, KY915L (S), KY915L  KY916L, KY917L, KY918L, KY919L, KY960L, KY961L,  KY962L, KY9144L, KY9145L, KY9146L, KY9147L, KY9148L  KY912L-2.5, KY912L-3, KY912L-4, KY912L-5, KY914L,  KY963L, KY964L, KY965L, KY966L(S)-2.5, KY966L(S)-3,  KY966L(S)-4, KY966L(S)-5  KY966L | | Walker | **Approved.** |
|  | M/s Royal Enterprises, SH5, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Manufacturer:**  M/s Guangdong Kaiyang Medical Technology Group Co., Ltd., ErcunIndustrial Area) Fushenggang, Yanfeng, Shishan Town, Nanhai District, Foshan City, China  (FSC China Valid Till  10-10-2020) | UNIKA+ Air Mattress  Class A  Shelf Life: Not Mentioned  Air Mattress (All Sizes) | | Air Mattress | **Approved.** |
|  | M/s Matrix Medical Care, Flat No. 55/5, First Floor, Shadman, Lahore  (ELI-00124) | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till  28-05-2020) | Qraymed Sterile Vaginal Dilators for single use  Class A  Shelf Life: 5 Years  QR10-0101, QR10-0102,  QR10-0103, QR10-0201,  QR10-0202, QR10-0203,  QR10-0301, QR10-0302,  QR10-0303, QR10-0401,  QR10-0402, QR10-0403 | | Vaginal Dilator | **Approved.** |
|  | M/s Matrix Medical Care, Flat No. 55/5, First Floor, Shadman, Lahore  (ELI-00124) | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till  28-05-2020) | Qraymed Urine Bags  Class A  Shelf Life: 5 Years  QR09-0101, QR09-0102,  QR09-0103, QR09-0104,  QR09-0201, QR09-0202,  QR09-0203, QR09-0204,  QR09-0301, QR09-0302,  QR09-0303, QR09-0304,  QR09-0401, QR09-0402,  QR09-0403, QR09-0404 | | Urine Collection Bags | **Approved.** |
|  | M/s 3A Nutra, 12-F1 Block, Johar Town, Lahore  (ELI-00134) | **Manufacturer:**  M/s Jiangmen New Era External Use Drug Co., Ltd., No. 8, Beiyuan Road, Jianghai District, Jiangmen, Guangdong, China  (FSC China Valid Till  28-08-2020) | Cool Baby Cooling Gel Sheet  Class A  Shelf Life: 1 Years  Model: 140mm\*100mm,  120mm\*70mm , 120mm\*50mm  110mm\*50mm, 110mm\*40mm  105mm\*45mm, 100mm\*70mm  100mm\*40mm, 90mm\*40mm  70mm\*40mm | | Cooling Gel Sheet | **Approved.** |
|  | M/s Royal Enterprises, SH5, Karimji Building, Opp HBL North Napier Road, Karachi  (ELI-00062) | **Manufacturer:**  M/s Guangdong Kaiyang Medical Technology Group Co., Ltd., ErcunIndustrial Area) Fushenggang, Yanfeng, Shishan Town, Nanhai District, Foshan City, China  (FSC China Valid Till  10-10-2020) | UNIKA+ Medical Crutches  Class A  Shelf Life: Not Mentioned  KY925L (S) KY925L (M)  KY925L (L), KY935L,  KY935M, KY9351S, KY935M,  KY9351L, KY9352, KY9353, KY9354, KY9355, KY933L, KY9331L, KY9332L, KY9333L, KY9334L, KY9335L, KY9336L, KY9337L, KY9338L, KY9339L, KY937L, KY937L-A, KY910L, KY911M, KY911L-A, KY920L, KY9201L, KY921L, KY922L, KY923L, KY924, KY924L, KY926L, KY927L, KY928L, KY929L, KY930L, KY932, KY932L, KY933LR, KY934, KY935, KY936L, KY938L, KY938L-A, KY938L-B, KY939L, KY940L, KY941L, KY942L, KY942L-A, KY943L, KY944L, KY945L, KY946L, KY947, KY948, KY949 | | Medical Crutches | **Approved.** |
|  | M/s Matrix Medical Care, Flat No. 55/5, First Floor, Shadman, Lahore  (ELI-00124) | **Manufacturer:**  M/s Zibo Qray International Co., Ltd., No.77, Zhanghuan Road, 255000, Zibo City, Shandong, China  (FSC China Valid Till  28-05-2020) | Qraymed Infusion Connector and Accessory  Class A  Shelf Life: 5 Years  QR05-0101, QR05-0102,  QR05-0103, QR05-0104,  QR05-0105, QR05-0106,  QR05-0107, QR05-0108,  QR05-0109, QR05-0110,  QR05-0201, QR05-0202,  QR05-0203, QR05-0204,  QR05-0205, QR05-0206,  QR05-0207, QR05-0208,  QR05-0209, QR05-0210,  QR05-0301, QR05-0302,  QR05-0303, QR05-0304,  QR05-0305, QR05-0306,  QR05-0401, QR05-0402 | | Infusion Connector and Accessory | **Approved.** |

**Item No.V. APPLICATIONS FOR GRANT OF ENLISTMENT OF MEDICAL DEVICES FOR LOCAL MANUFACTURE.**

Secretary MDB informed the Board that the following applications for grant of enlistment of medical devices for local manufacture under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No.** | **Name of Establishment** | **Name of Medical Device/Generic Name** | **Brief Description** | **Medical Device Class** | **Shelf Life** |
| **1** | M/s Uniferoz (Pvt) Ltd  32/8 Sector 15, Korangi Industrial Area, Karachi. | Dermapore  Non-Woven Fabric Surgical Tape | For Retention of post operative wound dressing, gauze and absorbent pads to secure catheter and drainage tube | Class-A | Stability claim 4 years but stability data 1.5 years provided |
|  | Size Rolls  1. Dermapore Non-Woven Fabric Surgical Tape 2.5cm x 10 cm 4 Rolls  2. Dermapore Non-Woven Fabric Surgical Tape 5cm x 10M 2 Rolls  3. Dermapore Non-Woven Fabric Surgical Tape 10cm x 10M 1 Roll  4. Dermapore Non-Woven Fabric Surgical Tape 7.5cm x 10M 2 Rolls  5. Dermapore Non-Woven Fabric Surgical Tape 15cm x 10M 1 Rolls  DML No. 000515  Issue date: 23-06-2013 (Renewal Applied) | | | | |
|  | **Decision: Approved subject to submission of stability data and GMP inspection.** | | | | |
|  | M/s Kohinoor Industries,  160/B, Small Industries Estate, Sahiwal. | Band Aid  Extensible Bandage | Cotton & Rubber elastic Bandage consists of characteristics fabric of pain weave. The wrap threads consists of single cotton Threads with the count not finer than 13 tex and of combined rubber and two single cotton threads with a count, after spiral folding, not finer than 98 tex: the spiral folded threads contains not less than 8 turns per cm. | Class-A | 3 Years |
| **Size**  5cm x 3cm, 7.5 cm x 3m, 10cm x 3cm, 12.5 x 3m  5 cm x 4cm, 7.5 cm x 4m, 10cm x by 4m, 12.5 cm x 4m  5cm x 4.5m. 7.5 cm x 4.5m, 10cm by 4.5m, 12.5cm x 4.5  Stability Undertaking Not Provided | | | | |
|  | **Decision: Approved subject to GMP inspection.** | | | | |
|  | M/s Kohinoor Industries,  160/B, Small Industries Estate, Sahiwal. | Tri Band  Calico Triangular Bandage | For supporting or immobilizing injured shoulders, arms, wrists and hands. Versatile, it can be used in many emergency situations such as typing legs or ankles together to immobilize, or to compress wounds to stop bleeding | Class-A | 3 Years |
| **Size**  90cm x 90 cm, 95 cm x 95 cm  DML No. 000197  Issue date: 25-10-2010 (GMP Report 08-12-2017 Attached) | | | | |
|  | **Decision: Approved subject to GMP inspection.** | | | | |
|  | M/s BSN Medical (Pvt) Ltd, A/69, S.I.T.E, Manghopir Road, P.O. Box 3659, Karachi | Gypsona ®  Plaster of Paris Bandage | N/a | Class-A | 5 Years |
| **Size**  7.5 cm x2.7m  10cm x 2.7m  15cm x 2.7m | | | | |
|  | **Decision: Deferred the product as it is already registered as as drug.** | | | | |
|  | M/s Karim Industries, 1/2 Km Lahore Raiwind Road Lahore. | Medi Triangular Bandage | For supporting or immobilizing injured shoulders, arms, wrists and hands. Versatile, it can be used in many emergency situations such as typing legs or ankles together to immobilize, or to compress wounds to stop bleeding | Class-A | 3 Years |
| **Description Size**   1. Triangular Bandage 36x36x51 Inches     DML No. 000254  Issue Date: 08-12-2015 (GMP Certificate 23-06-2015 Attached) | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | |

**Item No.VI. APPLICATIONS FOR GRANT OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE.**

Secretary MDB informed the Board that the following applications for grant of registration of medical devices for local manufacture under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **S.No.** | **Name of Establishment** | | **Name of Medical Device/Generic Name** | | | **Brief Description** | | **Medical Device Class** | | | **Shelf Life** |
|  | M/s Kohinoor Industries,  160/B, Small Industries Estate, Sahiwal. | | Oval Eye Pad  Eye Pad with Bandage | | | An Oval eye pad, measuring 5cm x 7.5 cm attached lengthwise, continuous stitching across its narrow ends, to the outer surface of the rolled open-woven Bandage, approximately 20cm from one end. The pad consists of the absorbent cotton wool, which complies with the standard for the absorbent cotton wool. | | | Class B | | 3 Years |
|  | **Size**  5cm x 7.5 cm | | | | | | | | | | |
|  | **Decision: Approved subject to GMP inspection.** | | | | | | | | | | |
|  | M/s Karim Industries, 1/2 Km Lahore Raiwind Road Lahore. | | Medi Sofra Tulle  Framycetin sulphate 1% B.P | | | It is used to treat infected or potentially infected burns, wounds, ulcers, and skin grafts. | | | Class C | | 5 Years |
| **Product Strength/Size**   1. Fraymycetin Sulphate Tulle 5cm x 5cm (1x5) 2. Fraymycetin Sulphate Tulle 10cm x 10cm (1x10) 3. Fraymycetin Sulphate Tulle 10cm x 40cm (1x40) 4. Fraymycetin Sulphate Tulle 15cm x 20cm (1x20) 5. Fraymycetin Sulphate Tulle 15cm x 20cm (1x15) 6. Fraymycetin Sulphate Tulle 15cm x 20cm (Roll)   DML No. 000254  Issue Date: 08-12-2015 (GMP Certificate 23-06-2015 Attached) | | | | | | | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | M/s Karim Industries, 1/2 Km Lahore Raiwind Road Lahore. | | Medi-plast Bandage  Plaster or Paris Bandage | | | It is used in surgical dressing to make plaster casts to immobilize broken bones while they heal, though many modern orthopedic casts are made of fibre glass or thermoplastic. | | | Class C | | 5 Years |
| **Product Strength/Size**   1. Medi-Plast Bandage (POP Bandage) (2") 5cm x 2.70m 2. Medi-Plast Bandage (POP Bandage) (3") 7.5cm x 2.70m 3. Medi-Plast Bandage (POP Bandage) (4") 10cm x 2.70m 4. Medi-Plast Bandage (POP Bandage) (5") 12.7cm x 2.70m 5. Medi-Plast Bandage (POP Bandage) (6") 15cm x 2.70m 6. Medi-Plast Bandage (POP Bandage) (8") 20cm x 2.70m   DML No. 000254  Issue Date: 08-12-2015 (GMP Certificate 23-06-2015 Attached) | | | | | | | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | M/s Karim Industries, 1/2 Km Lahore Raiwind Road Lahore. | | Medi lint Gauze BPC  Lint gauze BPC | | | Medi-Lint can be used for cleansing, packing, scrubbing, covering and securing in a variety of wounds. | | | Class C | | 5 Years |
| **Product Strength/Size**   1. Medi Lint BPC 25g 2. Medi Lint BPC 50g 3. Medi Lint BPC 100g 4. Medi Lint BPC 250g 5. Medi Lint BPC 500g   DML No. 000254  Issue Date: 08-12-2015 (GMP Certificate 23-06-2015 Attached) | | | | | | | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | M/s Karim Industries, 1/2 Km Lahore Raiwind Road Lahore. | | Medi lap sponges  Lap sponges swabs x-rays detectable | | | An X-ray detectable Lap Sponges consists of absorbent cotton gauze which is folded in such a manner that no cut edges are exposed and stitches round the open sides. Lap sponges with x-ray tape and loop is produced from 100% gauze. | | | Class C | | 5 Years |
| **Product Strength/Size**   1. Medi Lap Sponges 30 cm x 30 cm (4ply) X-ray detectable. 2. Medi Lap Sponges 45 cm x 45 cm (4ply) X-Ray detectable.   DML No. 000254  Issue Date: 08-12-2015 (GMP Certificate 23-06-2015 Attached) | | | | | | | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | M/s Uniferoz (Pvt) Ltd  32/8 Sector 15, Korangi Industrial Area, Karachi. | | Dermapore Surgical Wound Dressing | | | Dermapore Surgical Wound Dressing is the Sterilize dressing made from porous flexible non woven fabric its porous structure allows skin moisture to permeate skin to breathe. its hypoallergenic adhesive will not irritate the skin | | | Class C | | 4 Years |
|  | **Product Strength/Size**   1. Dermapore Surgical Wound Dressing 6 cm x 7 cm (10 Sheet/Box) 2. Dermapore Surgical Wound Dressing 9 cm x 10 cm (25 Sheet/Box)   DML No. 000515  Issue date: 23-06-2013 (Renewal Applied) | | | | | | | | | | |
|  | **Decision: Approved subject to GMP inspection.** | | | | | | | | | | |
|  | M/s Uniferoz (Pvt) Ltd  32/8 Sector 15, Korangi Industrial Area, Karachi. | | Front Line Adhesive First Aid Bandage  Contains:  Elastic Fabric Tape  Non Medicated Wound Pad | | | Adhesive Bandages (Sterile) | | | Class-B | | 4 Years |
| **Strip Size: Pack Size:**   1. Frontline Adhesive Large Bandages 25mm x 76mm 100 Strips 2. Frontline Adhesive Knuckle Bandages 38mm x 76mm 40 Strips 3. Frontline Adhesive Fingertip Bandages 44mm x 76mm 100 Strips   DML No. 000515  Issue Date: 23-06-2013 (GMP Report 23-05-2018 Attached) | | | | | | | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | M/s Uniferoz (Pvt) Ltd  32/8 Sector 15, Korangi Industrial Area, Karachi. | | Saniplast Aqua Bandage  Saniplast Aqua Bandage contains:  Polyurethane (PU) Tape  Bnzalkonium chloride (0.5% W/W) | | | First Aid Bandage | | | Class-B | | Stability claim 4 years but stability data 2 years provided Firm applied in Class A but as per MDR, 2017 it is classified is Class B. The Case may be subject to submission of differential fee and provision of Form 7 |
| **Size Strips**  1. Saniplast Large 25mm x 72 mm 20 strips  2. Saniplast square 38 mm x 38mm 20 strips  3. Saniplast Assorted 2 in 1 (Large + Square) 20 strips  DML No. 000515  Issue date: 23-06-2013 (Renewal Applied) | | | | | | | | | | | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | | M/s, Crespak Medical Industries,  8 th KM Manga Raiwind Road, Lahore.  (ELM-0004) | | Engel Plus Disposable  Syringe  50 ml  60 ml | Disposable Syringe for single use. | | Class B | | | 3 Years | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |
|  | | Kohinoor Industries.  159-160, Small Industrial Estate, Sahiwal, Pakistan  (DML No. 000197) | | Oval Eye Pad Bandage  5 cm x 7.5 cm  GMP certificate issue date 08-12-2017.  Sterilization by Gamma Rays from PARAS  (Sterilization facility is not available at manufacturing premises).  Sterlization validation protocol not provided) | An oval eye pad, measuring 5 cm by 7.5 cm attached lengthwise, by continuous stitching across its narrow ends, to the outer surface of the rolled open-wove bandage, approximately 20 cm from one end. This pad consist of absorbant cotton wool, which complies with the standard for the absorbant cotton wool. | | Class B | | | 3 Years | |
| **Decision: Approved subject to GMP inspection.** | | | | | | | | | | | |

**Item No.VII. APPLICATIONS FOR GRANT OF RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE.**

Secretary MDB informed the Board that the following applications for grant of renewal of registration of medical devices for local manufacture under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S. No.** | **Name of Establishment with Licence Number** | **Brand Name of Medical Devices with Class and Shelf life** | **Description of Medical Device** | **Remarks** |
|  | M/s, Crespak Medical Industries,  8 th KM Manga Raiwind Road,  Lahore.  (ELM-0004) | Crescon I.V Disposable  Cannula with wings  (Butterfly type)  1’s/18G  1’s/20G  1’s/22G  1’s/24G  Class B  Shelf Life: 3 Years  Drug Registration No. 070399 | Disposable I.V Cannula for single use. | **Approved.** |
|  | M/s, Crespak Medical Industries,  8 th KM Manga Raiwind Road,  Lahore.  (ELM-0004) | DispojektDisposable IV  infusion set  1’s/20G  1’s/21G  1’s/22G  Class B  Shelf Life: 3 Years  Drug Registration No.  071604 | Disposable I.V Infusion Set for single use | **Approved.** |
|  | M/s, Crespak Medical Industries,  8 th KM Manga Raiwind Road,  Lahore.  (ELM-0004) | Engel PlusDisposable  Syringe  1ml/26G  1ml/27G  3ml/22G  3ml/23G  3ml/24G  5ml/22G  5ml/23G  5ml/24G  10ml/21G  10ml/22G  20ml/21G  20ml/22G  Class B  Shelf Life: 3 Years  Drug Registration No.  070400 | Disposable Syringe for single use. | **Approved.** |
|  | M/s, Crespak Medical Industries,  8 th KM Manga Raiwind Road,  Lahore.  (ELM-0004) | Vasocath I.V Disposable  Cannula without wings  and without port.  1’s/18G  1’s/20G  1’s/22G  1’s/24G  Class B  Shelf Life: 3 Years  Drug Registration No.  071601 | Disposable I.V  Cannula without wings  and without port. | **Approved.** |
|  | M/s, Crespak Medical Industries,  8 th KM Manga Raiwind Road,  Lahore.  (ELM-0004) | Vaygon I.V Disposable  Cannula with wings and  with port  1’s/18G  1’s/20G  1’s/22G  1’s/24G  Class B  Shelf Life: 3 Years  Drug Registration No.  070398 | Disposable  I.V Cannula with wings and with port | **Approved.** |

**Item No.VII**. **CONCURRENCE OF MDB REGARDING PEC AND PROVISIONAL REGISTRATION OF MEDICAL DEVICES PROVIDED IN SCHEDULE-D OF MDR, 2017.**

It is submitted that the subject case was placed before the MDB in its 8th meeting held on 13th February, 2018 for concurrence of the MDB for issuance Provisional Eestablishment Certificates (PECs) and Provisional Registration Certificates (PRCs) for Schedule-D medical devices. The MDB decision is as under:-

*"The MDB gave its concurrence for issuance of PEC and provisional registrations for Schedule-D medical devices. However, the list of issued PEC and provisional registrations shall be placed before the Board in next meeting for its information".*

In the light of above decision, this Division has issued 12 Provisional Registration Certificates (PRCs) to different importers of medical devices uptil 26-11-2018. The list of PRCs is annexed at Annexure-I for information of MDB please.

**Decision:- The MDB went through the Annex-I, gave its concurrence and appreciated the efforts of the MDMC Division.**

**Item No.V**. **ISSUANCE OF REGISTRATION LETTERS UNDER MDR, 2017.**

M/s Sciencies (Pvt) Limited, Lahore have stated that their following products of M/s Becton Dickinson and Company has been registered in favour of M/s Asto Life Sciences (Pvt) Limited, Lahore on 5th July, 2017 and requested for issuance of registration notification under Medical Devices Rules, 2017:-

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.#** | **Regn.No.** | **Brand Name of Medical Device** | **Shelf Life** | **Name of Manufacturer** |
| (i) | 074663 | BD SoloShot TM Mini Auto Disable Syringes  (0.5 ml & 0.05 ml) | 5 years | M/s Becton Dickinson, S.A. Ctra, Mequinenza, Fraga (Huesca), Spain. |
| (ii) | 074685 | BD Emerald TM Pro (Reuse Prevention) Luer Slip Syringes  (2ml, 5ml & 10ml) | 5 years | -do- |
| (iii) | 059218 | BD Disposable Syringes  (3ml,5ml, 10ml, 20ml) | 5 years | M/s Becton Dickinson Medical (Singapore) Tuas Avenue, Singapore. |
| (iv) | 059219 | BD Venflon TM Pro IV Cannulas  (G16, G18, G20 & G22). | 5 years | **Product Owner**: M/s Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631, SE. 251 06, Helsingborg, Sweden.  **Manufacturing Site**: M/S Becton Dickinson Medical (S) Pte Ltd, 30 Taus Avenue-2, Singapore 639461. |

It is submitted that the Medical Device Board in its 8th meeting held on 13th February, 2017 decided that the medical devices, previously declared as drug and registered as drug under the drugs Act, 1976 and rules thereunder shall be deemed to be registered as medical device under Medical Devices Rules, 2017 till their registration is valid subject to Establishment Licence under new rules. Thereafter, at the time of renewal of registration, the firms shall apply on prescribed forms under the Medical Devices Rules, 2017 and accordingly fresh registration number shall be allotted.

Keeping in view the above, letters under MDR, 2017 has been isued.

Submitted for ratification of the MDB please.

**Decision: The Board ratified / approved the issuance of registration letter with new registration numbers.**

**Item No.VI**. **CANCELLATION OF ESTABLISHMENT LICENSE TO IMPORT OF M/S ALERE MEDICAL PAKISTAN (PVT) LIMITED, KARACHI.**

M/s Alere Medical Pakistan (Private) Limited, Karachi has requested for deregistration/ closure of their Establishment License No.ELI-00283 dated 19-10-2018 voluntarily. They further stated that registration of products manufactured by M/s Alere Medical will be registered by M/s Abbot Laboratories (Pakistan) Private Limited, Karachi.

It is submitted that under Rule 10 of MDR, 2017 the matter shall be presented before Medical Devices Board for Cancellation of the Establishment Licence to import medical devices.

Submitted for consideration and decision by MDB.

**Decision: The Board acceded to the request of the firm and cancelled the Establishment Licence to import medical devices.**

**Item No.VII**. **PERSONAL HEARING OF M/S UDL DISTRIBUTION (PVT) LIMITED, KARACHI AD M/S IQBAL AND COMPANY, ISLAMABAD.**

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. **Furthermore, M/S UDL (Pvt) Ltd will furnish in writing to the Board that it will fulfill all the liabilities / commitments of M/S Iqbal & Company (previuos authorized agent of M/s Arrow USA) in tender business before taking any further action regarding concerned items.**

**Item No.VIII**. **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

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

**Item No. IX**. **ISSUANCE OF REGISTRATION LETTER UNDER MDR, 2017 OF ALREADY APPROVED PRODUCT BY REGISTRATION BOARD.**

M/s Mission Pharmaceuticals, Karachi have stated that their applied product for dialysis was deferred by the Registration Board in the 254th meeting (deferred reason: not proper specification as compared to me-too),in 269th meeting they were asked to submit file with proper me-too and international references and registered products references but their wrong formulation was submitted in agenda 269th meeting and price calculated lowest side. After long discussion with DRAP authorities once again was submitted case with new fee challan in 282nd Board meeting and the case was approved. At the end time of issuance of registration letter, their case was forwarded to MDMC for clarification whether this product is a medical device or drug.

It is submitted that Registration Board in its 282nd meeting held on 14th - 15th May, 2018 approved the following formulations of M/s Mission Pharmaceuticals, Karachi. The minutes of the said meeting are reproduced as under:-

|  |  |  |
| --- | --- | --- |
| **Name of Drug (s) & Composition** | **Detail of Submissions / Fee Demanded Packs / Price** | **Approval Status by RRA/Me Too Status / Last Inspection Report** |
| **Renal Cure Concentrate 35X (RC-102-R)**  Part-A (solution) + Part-B (Powder)  For Bicarbonate Haemodialysis.  After finally mixing/diluting 35X Haemodialysis machines with De-ionized water, the strength of active ingredients of Part-A & Part-B Haemodilysis concentrate are:  **Part A**  Sodium..................80-110 m.mol/L  Potassium..............0-3 m.mol/L  Calcium............... ..0-2 m.mol/L  Magnesium............0-1.2 m.mol/L  Chloride................90-120 m.mol/L  Acetic Acid...........2.5-10 m.mol/L  Glucose.................0-12 m.mol/L  **Part B**  Sodium....Not more than 45 m.mol/L  Bicarbonate........Not more than 45 m.mol/L | Form-5, Rs: 20,000/- vide Dy. # (R&I), dated 08-05-2018 Pack size: Part-A 4.0 L Soln. Part-B Powder, Part-A 5.0 L Soln. Part-B Powder, Part-A 10.0 L Soln. Part-B Powder Price as per DRAP SRO | Monograph for Haemodialysis Solutions is available on official web-site of Health Canada that confirms availability/ approval status of applied formulation. Furthermore, BP monograph is available for Haemodialysis Solutions stating similar formulation. Me Too: Renacarb Concentrate by M/s Renacon, Lahore. Last GMP Inspection Report dated 01-01-2018. |

The shelf life was not mentioned in the minutes of Registration Board. The firm had requested shelf life of 2 years. Furthermore, the firm has DML (DML No. 000809) by way of Formulation with sections approved for liquid dialysis solution and powder for dialysis. Internationally haemodialysis concentrate/ haemodialysis dialysate solutions are medical devices. They fall in Class C as per Rule 3 of Schedule-A (Classification of Medical Devices) of the Medical Devices Rules, 2017 .

The case is being placed before the MDB for its ratification please.

**Decision: The MDB ratified and approved the letter issued to M/s Mission Pharmaceuticals, Karachi.**

**Item No. X**. **REGISTRATION OF MEDICAL DEVICES OF M/S SEARLE COMPANY LIMITED, KARACHI.**

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) | 062257 | Medco Inject Insulin 100U | 1 ml | 5 years | M/s Abu Dhabi Medical Devices Co., United Arab Emarates. |
| (ii) | 059096 | Medeco Auto-disable Syringes | 0.05 ml  0.1 ml  0.5 ml | 5 years | -do- |
| (iv) | 062256 | Medeco Inject | 2 ml  3 ml  5 ml | 5 years | -do- |

The firm has submitted following documents:-

1. Application dossier alongwith Form 7-A for the above products.
2. Legalized Letter of Authorization regarding above products to M/s Searle Company Limited, Karachi from the foreign manufacturer, namely, M/s Abu Dhabi Medical Devices Co., United Arab Emirates.
3. Copy of Letter of Termination of Authorization of M/s Vertex Enterprises, Lahore from the M/s Abu Dhabi Medical Devices Co., United Arab Emirates.
4. No Objection Certificate (NOC) from M/s Vertex Enterprises, Lahore regarding transfer of registration of above products to M/s Searle Company Limited, Karachi.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sr No.** | **Name of Importer** | **Name of Manufacturer** | **Name of Medical Device** | **Brief Description** | **Remarks** | **Evaluated by** |
|  | M/s Searle Company Limited.  1st Floor, NICL Building, Abbasi Shaheed Road, Karachi. | **Manufacturer:** Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi, UAE  (FSC valid till 23-01-2019) | Medeco Auto Disable Syringe  Class B  Shelf Life: 5 years  0.5 ml with needle size 23 G, length 1''  0.5 ml with needle size 24 G, length 1''  0.5 ml with needle size 24 G, length 3/4''  0.5 ml with needle size 25 G, length 1''  0.5 ml with needle size 25 G, length 5/8''  Fee submitted: Rs 100,000/- | For administration of medication generally through intra-muscular or intra-venous route. Sterile, single-use. | (1) Sizes or codes not mentioned on Free Sale Certificate | Mrs. Unum Zia Shamsi |
| 1. - | -do- | **Manufacturer:** Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi, UAE  (FSC valid till 23-01-2019) | Medeco Inject Insulin Syringe  Class B  Shelf Life: 3 years  1.0 ml for U-100 with needle 29 G  1.0 ml for U-100 with needle 30 G  1.0 ml for U-100 with needle 31 G  Fee submitted: Rs 100,000/- | Sterile, single-use syringe for insulin administration | (1) Sizes or codes not mentioned on Free Sale Certificate | -do- |
|  | -do- | **Manufacturer:** Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi, UAE  (FSC valid till 23-01-2019) | Medeco Inject Syringes  Class-B  Shelf Life: 5 Years  Sizes: 2ml, 3ml & 5ml  Fee submitted: Rs 100,000/- | Sterile Single Use hypodermic syringe | (1) Sizes or codes not mentioned on Free Sale Certificate | Mr. Hafiz Asif Iqbal |

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.

Submitted for consideration of MDB please.

**Decision:** **The MDB cancelled the above products in the name of M/s Vertex Enterprises, Lahore and approved them in the name of M/s Searle Company Limited, Karachi.**

**Item No. XI**. **REGISTRATION OF HYPODERMIC NEEDLES.**

It has been brought into the notice of QA&LT and Medical Devices Divisions, DRAP that Hypodermic needles are avilable in the market without registration and are being used or have a misuse potential in clinical settings or by quacks by reusing syringes and replacing only needles. Resultantly could be one of the causes or have a potential in spreading of Hepatitis and other bloodborne diseases.

The arguments put forward by the importeres in favour of registration /availablity of hypodermic needles are :-

1. that the tip of the needle could get damaged while penetrating rubber stopper of vial or touching the base of ampoule, thus cannot be used for injecting in human / animals or be painful, while replacing with a needle is cost effective.
2. In poultry and livestock practice, replacement of needles from 17 to 22 Gauges are used in huge quantity while the sterilized glass syringes remain the same.

1. In children upto age of 3 years, needle with guage size 25-27 is used, requiring replacement in syringes.

The argument put forward against the registration/availability of hypodermic needle is manily:-

1. the replacement of needle in reuse syringe has the potential of spread of Hepatitis and other bloodborne diseases.

The misuse of replacement of needles by reusing syringe in clinical settings or by quacks is a malpractice. One of the solutions to curb this malpractice is usage of registered Auto-disable syringes but they are not in common use, are expensive and could not meet the approx. 2 billion annual syringes requirement. The requirement of syringes is being met by 14 manufacturers and 47 importers who have registered their syringes with DRAP.

DRAP has registered syringes without needles and with needles as drug, however, only needles were never registered by DRAP, but the needle remained available in the market before and after registration of syringes since it was never declared as drug. Only one manufacturer, namely NISA-S.F has got registration of hypodermic needles of 17 to 27 G by the MDB which has not yet manufacturered /marketed.

Hypodermic needle falls in class-B of medical devices and is exempted from registration till 15th July, 2019 under Rule 52 of Medical Devices Rules, 2017 notified on 16th January, 2018. The un-registered needles available are enjoying the exemption given in MDR, 2017.

**Decision:** The matter was discussed at length by the Board. Mr.Khawaja Asim Omar of M/s Asto Life Sciences (Pvt) Ltd, Lahore presented his views regarding potential hypodermic needle in spread of blood borne diseases.

Mr. Tahir Aziz Mughal, COO, Shaukat Khanum, Peshawar was of the opinion that banning hypodermic needle is not a solution. The needles are registered world over and are commonly used in the hospital settings. The misuse of hypodermic needle is a practice related issue which needs a mix of regulatory and managerial interventions rather than banning. Therefore a separate meeting is required for more deliberations / discussions involving all stakeholders to come up with a stategy to tackle the matter of misuse of needle involving Provincial Healthcare Commissions and awareness campaign. The matter shall be again placed before the MDB after deliberations of meeting.

**Agenda Item XII** : **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** is placed before the MDB for consideration (Annexure II).

**Decision:** The Board was of the opinion that the Division should focus on Enlistment or Registration of medical devices for import and local manufacture and deferred the matter of formulation of Enlistment or Registration form for Contract Manaufacturing of medical devices.

**Agenda Item XIII:** **CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR EXPORT PURPOSE ONLY**

Under rule 15 of Medical Devices Rules, 2017, manufacturers may apply for enlistment or registration of medical devices for export purpose. Form-8 is provided for enlistment or registration of locally manufacture of medical devices. However, it does not provide option for export only medical devices enlistment or registration . 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-8C Certificate of Enlistment or Registration of a medical device or accessory or component for Export Purpose only”** is placed before the MDB for consideration. (Annexure III).

**Decision:** The Board approved the form and recommended the Authority for the approval of **“Form-8C Certificate of Enlistment or Registration of a medical device or accessory or component for Export Purpose only.**

**Agenda Item XIV :** **INSPECTION BOOK FOR MANUFACTURER OF LOCAL MANUFACTURER AND IMPORTERS**

Under Rule 6(2)(b) of Medical Devices Rules, 2017 the licensee shall maintain the inspection book provided by the MDB at the time of the issuance of the licence on which a member of the MDB or an Inspector shall record proceedings of each of his visit, his comments and the defect or irregularities noticed, if any, by him and such inspection book shall be signed by him as well as the licensee or his authorized agent. In case any defect or irregularity is recorded in the inspection book, the licensee shall take steps to remove such defect or irregularity.

For this purpose a draft design of Inspection book is place below for consideration of the MDB. (Annexure IV).

**Decision: The Board approved the format/design of inspection book.**

**ITEM NO. XV: POWER DELEGATION: COSTITUTION OF PANEL FOR LOCAL AND FOREIGN INSPECTIONS AND MINOR CORRECTIONS**

The Board in its 8th meting held on 13th February, 2018 and in its 10th Meeting held on 09-10-2018 delegated its power to Director MDMC Division for constitution of panel for local and foreign inspections and for minor corrections respectively. It was decided that the Secretary, MDB shall constitute panel for local and foreign inspections and amend minor corrections with the approval of CEO, DRAP.

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**Annexure-I**

**LIST OF PROVISIONAL REGISTRATION OF MEDICAL DEVICES FOR IMPORT PROVIDED IN SCHEDULE-D OF MDR, 2017.**

**Issued after 10th Meeting**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.#** | **PR.No.** | **Issue Date** | **Name of Importer** | **Product Name** | **Name of Manufacturer** |
|  | 00599-PR-MD | 19-10-2018 | M/s Ferozsons Laboratories Limited,  P.O Ferozsons Amangarh,  Nowshera, KPK. | Comet TM Pressure Guidewire | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.  **Manufacturing Site:** M/s Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. |
|  | 00600-PR-MD | 26-10-2018 | M/s A.H Distributors,  House No. CB-708, Lane No.5, Peshawar Road,  Rawalpindi. | Introducer Sets | **Manufactured By:** M/s Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinlong 1st Road, Baolong Industrial Zone, Longgang District, Shenzhen, China. |
|  | 00601-PR-MD | 26-10-2018 | -do- | Guide Wires | -do- |
|  | 00602-PR-MD | 26-10-2018 | -do- | TR-Closure Band | -do- |
|  | 00603-PR-MD | 26-10-2018 | -do- | Connecting Tubing | -do- |
|  | 00604-PR-MD | 26-10-2018 | -do- | Introducer Needle | -do- |
|  | 00605-PR-MD | 26-10-2018 | -do- | Balloon Inflation Device | -do- |
|  | 00606-PR-MD | 26-10-2018 | M/s Alliance Medical,  12-B, 1st Floor, Agro Flats, Shadman,  Lahore. | Transradial Introducer Set | **Manufactured By:** M/s SCW Medicath Ltd., No.4 Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen 518116, P.R China. |
|  | 00607-PR-MD | 26-10-2018 | -do- | Introducer Sets (Femoral) |  |
|  | 00608-PR-MD | 26-10-2018 | M/s Digital Imaging Systems,  121-Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore. | TorqMax Sheath Grip Accessory | **Manufacturer:**M/s Spectranetics Corp., 9965 Federal Drive, Colorado Springs, CO 80921,USA |
|  | 00609-PR-MD | 26-10-2018 | -do- | LLD (Lead Locking Device) | **-do-** |
|  | 00610-PR-MD | 26-11-2018 | M/s JK Traders,  Suite No. 13, 2nd Floor Majeed Plaza Bank Road, Saddar,  Rawalpindi. | Introducer Sheath Set | M/s Anntom Medica Limited, 5/F, Building A6 Yinlong Industrial Zone, 92 Shenshan Road, Longgang District Shenzhen, China |

**Annexure II**

**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:

**Annexure III**

**DRUG REGULATORY AUTHORITY OF PAKISTAN**

**FORM-8C**

***[****See rule 15(5), 63(3)****]***

**CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR EXPORT PURPOSE ONLY**

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

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

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

M/s ………………..

The medical device as per details given below has been registered/enlisted for export purpose only 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 Manufacturer** |  |
| **Address of Manufacturing Site** |  |

2. Products specified on this certificate are for export only and shall not be sold in Pakistan.

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

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

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

6. This certificate is not taken as Government endorsement of any product that is referred on this certificate.

Secretary

Medical Device Board

Seal:

**Annexure IV**

**Government of Pakistan**

**DRUG REGULATORY AUTHORITY OF PAKISTAN**



**Medical Devices &**

**Medicated Cosmetics Division**

|  |  |
| --- | --- |
| **Name of Establishment** |  |
| **Address of Establishment** |  |
|  |
| **Licence Number** |  |
| **Validity** |  |

**ACKNOWLEDGEMENT OF RECIEPT OF INSPECTION BOOK**

I, ………………………………………… Designation …………………. , CNIC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ of M/s ……………………………………..…. Hereby acknowledge the receipt of this inspection book on ( Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ containing 100 pages.

Name of Receiving Person

Stamp of the Firm or thumb impression of Receiving person.

|  |  |
| --- | --- |
| **Inspection Book Maintained by Manufacturer M/s** |  |
| **Address** |  |
| **Establishment Licence Number** |  |
| **Section approved for Manufacturing** |  |

**Instructions:-**

1. This book is the property of the Drug Regulatory Authority of Pakistan and the holder is responsible for returning it to the Medical Devices Board/ Issuing Authority when no longer valid and produce at the of renewal of licence.
2. This is to be kept at the premises approved for manufacturing of medical devices and the holder shall produce it on demand by the Competent Authority.
3. No Alteration is permitted in any of the recordings.

**Secretary**

Seal and Signature of Issuing Authority

Medical Devices Board

Medical Devices & Medicated Cosmetics Division

|  |  |
| --- | --- |
| **Name and Designation of of person(s) inspecting the premises** |  |
| **Name of Quality Control Incharge present at the time of inspection** |  |
| **Name of Production Incharge present at the time of inspection** |  |
| **Name of Quality Assurance Incharge present at the time of inspection** |  |
| **Date of Inspection** |  |

Details of Proceeding of inspection, observations, comments and action taken if any:-

|  |  |  |
| --- | --- | --- |
| Signature of the licensee or the Officer for the time being incharge of the Section/Firm |  | Signature of the person who inspected the premises |