**Government of Pakistan**

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

**Drug Regulatory Authority of Pakistan**

**\*\*\*\*\*\*\*\*\*\*\***

**MINUTES OF THE 9TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 5TH JULY, 2018**

 9th meeting of the Medical Device Board (MDB) was held in the office of Chief Executive Officer, Drug Regulatory Authority of Pakistan, TF Complex, G-9/4, Islamabad on 5th July, 2018. The meeting was chaired by Dr. Sheikh Akhter Hussain, Director Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan and was attended by the following:-

|  |  |  |
| --- | --- | --- |
| **S.No**. | **Name and Designation / Department** | **Position in the MDB** |
|  | Director Medical Devices & Medicated Cosmetics, DRAP, Islamabad. | Chairman |
|  | Dr. Alamgir Rao, Director (Pharmacy Services), Health Department, Lahore. | Member |
|  | Dr. Safi Ullah, Drug Inspector, Health Department, Peshawar. | Member |
|  | Dr. Sajid Bashir, Prof. of Pharmaceutics, Dean Department of Pharmacy, University of Sargodha, Sargodha. | Member |
|  | Prof. Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi.  | Member |
|  | Brig.(R) Dr. Waqar Azim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Golra Mor, Islamabad. | Member |
|  | Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar. | Member |
|  | Muhammad Asghar, CEO, Cyber Soft Technologies, Lahore. | Member |
|  | Dr. Abdul Haleem Khan, Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore.  | Member |
|  | Dr. Mohammad Farid Khan, Director Emergency Services, District Kasur. | Member |
|  | Additional Director (MD&MC), 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 8TH MEDICAL DEVICE BOARD MEETING**

**Decision:** The Board confirmed the minutes of the 8th meeting of MDB.

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

 Secretary MDB informed that the case was placed before the MDB in its 8th meeting held on 13th February, 2018 for taking concurrence of the MDB for issuance of Provisional Establishment Certificates (PECs) and Provisional Registration Certificates (PRCs) for Schedule-D medical devices. The MDB decided 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 of MDB**,** he informed that the Division of MDMC has issued 79 PECs and 550 PRCs to different importers of medical devices uptil 27-06-2018. The lists of PECs and PRCs are annexed at Annexure-I &II respectively for information of MDB.

**Decision:-** The MDB went through the Annex-I & II and appreciated the efforts of the MDMC Division.

**Item No. III**. **APPLICATIONS FORGRANT 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 placed at Annexure-III.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No.** | **Name of Establishment** | **Director/Proprietor/****partners** | **Name of panel Inspector (s)** | **Cold Chain****(Yes/No)** | **Decision** |
|  | M/s Roche Pakistan Limited, **Head Office:** 37-C, Block-6, P.E.C.H.S, Karachi.**Godown Address:**R-Pl, Plot No 56, Sector 15, K.I.A, Karachi. | 1. Mr. Farruk Rehan(Managing Director)2. Ms Hafsa Shamsie.3.Mr. Badaruddin F. Vellani.4. Dr. Peter Hug5. Mr. Robert Ferraro6. Mr. Dieter F. Heinis7. Mr. Olaf Schulzeck | Mrs. Unum Zia Shamsi,A.D-IV (MDMC).Hafiz Muhammad Asif Iqbal, A.D-V (MDMC) | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s OBS Pakistan Pvt.) Ltd, **Head Office:** C-14, Mangopir Road, S.I.T. E Karachi.**Godown address:**Same as above | 1.Mr. Muhammad Arslan  Batla. 2. Mr. Mirza Anjum  Fahim (Managing Director) 3. Mr.Saeed ur Rehman | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s ACP Systems, **Head Office:** 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi**Godown address:**Same as above | 1. Mr. Jawed Akhtar2. Mr. Shaikh Tahir Mahmood | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Briogene (Pvt) Limited,**Head Office:** 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e- Faisal, Jamshed Town, Karachi.**Godown address:**Same as above | 1. Javed Ghulam  Mohammad  (CEO) 2.Mr. Kamran  Nishat.3. Mr. Raymond Simkins. | -do- | Limited Capacity both for refrigeration products and freezing products. | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Ghazi Brothers, **Head Office:** Ghazi House, D-35, K.D.A Scheme No I, Meiran M Shah Road, Karachi.**Godown Address:**Ghazi House, B 32, Al Hilal Society K.D.A Scheme No, 7, University Road Karachi. | Mohammad Irfan GhaziFMuller | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Ali Gohar & Company (Private) Limited.**Head Office:** State Life Building I-B, I.I Chundrigar Road, Karachi.**Godown address**: B-23, SITE, Karachi | 1.Mrs. Naiyar Zamani Gohar 2.Mr. Arshad Ali  Gohar (CEO) | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s B. Braun Pakistan (Pvt) Ltd., **Head office:** The Forum, Suite 216, Khayaban e Jami, Clifton, Block 9, Karachi.**Godown address:** Ground floor, Plot No. C-153, Sector 6F, Mehran Town, Karachi | 1. Mr. Syed Muhammad Zafar Hashmi (CEO)2. Mr. Wasif Sajjad3. Christian Joachim Rainer Hildebrandt4. Andreas Walde |  -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s BSN Medical (Pvt) Ltd, **Head office**: A-69, SITE, Mangopir Road, Karachi.**Godown address:**Same as above | 1. Mr. Rehman Ghani. (CEO)2. Mr. Erik Trock  Jansen.3. Ms. Yik Hing Ping. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s ONCOGENE Pharmaceuticals.**Head office:**Mezzanine Floor 246/B, P.E.C.H.S, Block 6, Karachi.**Godown address:**Same as above | Jahan Ara. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Noor International, **Head office:**Noor House, 29- D, Block-6 PECHS Karachi.**Godown address:**Same as above | 1. Farooq ul Islam2. Zia ul Islam3.Qamar Ul Islam | -do- | Yes, with Limited capacity. | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Med Art Pakistan,**Head office:**A-175 Block 13-C KDA Scheme 24,Gulshan- e- Iqbal Karachi.**Godown address:**Same as above | 1. Sarah Ali 2. Nazish Zehra3. Noreen Mudassir | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Gene-Tech Laboratories, 246/B, P.E.C.H.S Block- 6, Karachi. | Dr. Zubair Khalil khan | Muhammad Ayub Naveed, Assistant Director-II (MDMC), DRAP. Islamabad.Ms. Hira Bhutto, Assistant Director-I (MDMC), DRAP, Islamabad. | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Premier Agencies, 60, Muslimabad, Jamshed Quarters, M.A Jinnah Road Extension, Karachi. | 1. Ebrahim Qasim
2. M.Salman Qasim
3. M. Idrees.
 | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Noesis Pvt. Limited, SCB Main, I.I Chundrigar Road, Karachi. | 1. Adnan Ahmad 2.Waqar Ahmad Malik  | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Johnson & Johnson Pakistan (Pvt) Limited, Office No, 806, 8th floor Horizon Towers, Block 3, Scheme No 5, Clifton. Karachi. | 1. Khalid Shabban  Mansour Bakar 2. Ramez Ezzat Aziz  Louca.3. Ramez Ezzat Aziz  Louca. | -do- | No | **Rejected due to following reasons:-****1. Qualified staff is outsourced.****2. Storage is out sourced to M&P.****3.Management details not provided.** |
|  | M/s A- Feroz & Co, Medicine Street No.1, Marriot Road, Karachi.**Godown Address:**Plot No.330/3, DMCHS, Alamgir Road, Karachi. | Mr. Feroz Ahmad Chothai | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s PharmEvo (Pvt) Ltd, A- 29, North Western Industrial Zone, Port Qasim, Karachi. | 1. M. Haroon 2.Zamiruddin Ahmad. 3. Derek-A-Evans. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Muller & Phipps Pakistan (Pvt) Limited, Uzma Court, Main Clifton Road, Karachi.**Godown Address:**Plot No, 208 & 208 /1, Sector No. 23, Korangi industrial Area, Karachi. | 1. Mujeeb Ali Khan 2. Jahanzeb Saeed.3. Munaf Lakda. | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Advance Cardiology System, 12, Al-Sehat Centre, Rafique H.J. ShaheedRoad, Hotel Regent Plaza, Karachi. | Mohammad Sadiq | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s S. Ejazuddin & Co, Zia Plaza Altaf Hussain Road Karachi.**Godown Address:**Plot No.20 Sr, Serin Quarter Off.Altaf Hussain Road, Karachi. | 1. M. Taufiq Feroz2.Mumtazuddin Feroz3.Nazimuddin Feroz 4. Sultan Ahmad Feroz.5. Rizwan Feroz. | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Sorabjee Patel & Co, 45 Badri Building I.I Chundrigar Road, Karachi. | Romina Mansoor | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Mars Enterprises, Office No 4, Jason Center, 2nd floor, BC-8, Block 9, Clifton, Karachi. | 1.Sanjay Kumar. 2.Pawan Kumar3. Subhash Kumar. | -do- | No | Approved for warm range (above 30°C) medical devices. without cold chain facility. |
|  | M/s Medco Healthcare, 155, Block -3 C.P Barar Society, Alamgir Road Karachi. | Asif Ahmad Khan | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Searle Company Limited, First Floor N.I.C.L Building Abbasi Shaheed Road. Karachi.**Godown Address:**F-2/Q SITE Karachi. | 1. Zubair Razzak  Palwala, 2. Mobeen Alam, 3.Muhammad Sajid.4. Tahir Ahmed5. Moujood ul Hasan6. Irfan Akram7. Dr. Saeed Sarwar8. Fakhr-e-Alam9. Dr. Imtiaz Haider10. Athar Iqbal | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s IBL Health Care, First Floor N.I.C.L Building Abbasi Shaheed Road. Karachi.**Godown Address:**F-2 Q, PTC Factory SITE Karachi. | 1. Mr. Rashid Abdullah2.Mr.Adnan Asdar Ali.3.Mr.Syed Nadeem Ahmad4. Mr. Zubair Razzak Palwala5. Mr. Shahid Abdullah6. Mr. Ayaz Abdullah7. Ms. Shaista Khaliq | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Iqbal & Company, **Head office:**Alfalah Manzil, Opposite National Police Foundation, Street No. 26, E-11/4, Islamabad.**Godown Address:**Same as above | 1. Mr. Arshad Iqbal Malik2. Mrs. Saira Arshad Malik | Mrs. Unum Zia Shamsi,Assistant Director-IV (MDMC), DRAP, Islamabad.Hafiz Muhammad Asif Iqbal,Assistant Director-V (MDMC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Dora Enterprises, **Head office:**54-B, Model Town Lahore.**Godown Address:**1st floor, Office No.2, 35-M Civic Centre, Model Town Extension, Lahore. | 1.Tashbeeb Gulzar 2.Andleeb Gulzar 3. Faiza Tashbeeb | Mr. Muhammad Ayub Naveed, Assistant Director-II(MD&MC),DRAP, Islamabad.Mrs. Unum Zia Shamsi, Assistant Director-IV (MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Schazoo SPL Consumer Healthcare, 71-B/C2, Gulberg-III, Lahore.**Godown Address:**Same as above | 1. Mujtaba Shuja urRehman.
2. Mian Ahmad Shuja ur Rehman
3. Mian Asad Shuja
4. Mr. Ansar Sohail Malik
5. Mr. Ahmer Mallick
 | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Mubarik Vision, Baserment 32-A Usman Center, Shah Alam Market, Lahore | Mr. Nazir Ahmad Chowhan. | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Alam Medix, 9/1 Hanan Plaza, Mayo Hospital Road, Lahore.**Godown Address:**Basement, Hanan Plaza, 19-Rattan Chand Road, Mayo Hospital Road,Lahore | Mr. Muhammad Naeem Ahmed | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Shamco Trader (Pvt) Ltd., 174-A, Ahmed Block, New Garden Town, Lahore. | 1. Mr. Shahid Mahmood Cheema2. Ms. Naila Shahid3. Mr. Mashood Mahmood Cheema | Hafiz Muhammad Asif Iqbal,Assistant Director-V (MDMC), DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Digital Imaging Systems, HO Address: 121- Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore. | 1. Mr. Faiz Yaqub2. Mr. Muhammad Wajid Ali | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Healthline Pharmaceuticals Pvt. Limited, 65-D-I , Ofice No.402, Al-Hafeez Heights, 4th Floor, Gulberg-3, Lahore. | 1. Aman ullah 2. Musarat Aman. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Asto Life Sciences, 44/1.Block -K, Model Town Lahore. | 1.Rao Tofique Ahmad. 2.Khajwa Asim Omer | -do- | Limited capacity | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Ison Medical Corporation, Plot No.18- B, Block-D (Commercial) Valencia, Lahore. | 1. Mr Mohsin Ijaz Ch 2. Mrs Naila Ijaz.  | -do- | Limited capacity | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi | Mr. Ahmed Ali Aslam. | 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 Promed International, **Importing Address**: CB-6349, Amarpak Plaza, Jhelum Road,Rawalpindi. **Corr Address**: Office No. 310, 3rd Floor, ISE Towers, Islamabad. | Mr. Ahmed Jamal. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Sadqain Healthcare (Pvt) Limited, Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi.**Godown Address:**Plot No 11-A, Street No.3, RCCI Industrial Area Rawat. | Mr. Zahid Javeed. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s 4A International, Plot 7, street No 11,lawyers Society, Chaklala, Rawalpindi. | Sana ullah Nasir. | Hafiz Muhammad Asif Iqbal,Assistant Director-V (MDMC), DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Global Marketing Services, 111-B, Hali Road, Westridge 1, Rawalpindi. | 1. Mr. Zafar Mahmood2. Mr. Muhammad Ayub3. Mr. Fahad Ahmed Khan | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s SBK International, 23, Valley Road, Street 3, Westridge 1, Rawalpindi | 1. Mr. Saad Bin Kamil2. Mr. Muhammad Kamil | Muhammad Ayub Naveed, Assistant Director-II(MDMC),DRAP, Islamabad.Hafiz Muhammad Asif Iqbal, Assistant Director-V(MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Raffay Associates, **Head Office**:Office No 04, 2nd Floor, Ahmed Plaza Range Road, Rawalpindi.**Godown Address:**Same as above | Mr. Naveed Aslam. | Mr. Muhammad Ayub Naveed, Assistant Director-II(MD&MC),DRAP, Islamabad.Mrs. Unum Zia Shamsi, Assistant Director-IV (MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Global Healthcare, **Head Office**:Office No 41-A. Street No 15,Near Foundation School Race Course Road, Westridge, Rawalpindi.**Godown Address:**House No 245, Street 11, Race Course Road, Westridge 1, Rwp. | Mr. Asif Mahmood. | -do- | Yes. | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Mezan International, 59 BR II, Opp. DCO House, Haji Meherban Road, Jhelum.**Godown Address:**Same as Above | Rehan ur Rehman. | Muhammad Ayub Naveed, Assistant Director-II (MDMC), DRAP, Islamabad.Hafiz Muhammad Asif Iqbal, Assistant Director-V(MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Pharma Plus International, H# 9A, Opp. Qayyum Stadium, Rafiqui Lane,Old Bara Road, Peshawar. | 1.Muhammad Imran Khan 2.Mr Aamir Rauf. | Hafiz Muhammad Asif Iqbal,Assistant Director-V (MDMC), DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Sudais Associates, Sudais House, Street No.7, House No. 1, Khan Bahadur Colony Duran Pur Peshawar. | Mr, Shaker Khan. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Hashir Surgical Services, Office No 16, Street 1, F-2,Phase 6, Hayatabad, Peshawar.**Godown Address:**1. Office No 5, 2nd Floor, Syed,s Tower, University Road, Peshawer.2. House No.2, St. No.1, Gulshan Colony, G.T. Road, Peshawar. | Mr. Asghar Ali Shah. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Moon Enterprises, 1-CD, Mouj Darya (Edward) Road, Lahore.**Godown Address:**Saggain Road New Khurshid Manzil, Saggain, Lahore. | 1. Muhammad Afzal. 2. Muhammad Murslin. 3.Zaeema Murslin | Mr. Muhammad Ayub Naveed, Assistant Director-II(MDMC),DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MDMC), DRAP, Islamabad. | No. | **Rejected due to poor storage conditions.** |
|  | M/s Trowmedic International, Building No 117, Sagian T No 4, Opposite Sanda Stop Band Road, Lahore. | Mr. Hassan Saleem | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Cardiac Care, 848-C Shadman -1, Lahore. | Waseem Aslam Chatta. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Universal Dental (Pvt) Ltd., 17-Mcleod Road, Lahore | 1. Saleem Hayee2. Waqar Hayee3.Saima Waqar. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Humayun Dental Supplies, 43, Mozang Road, Lahore | Mr. Liaqat Ali | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Matrix Medical Care, Flat No.55/5, Fist Floor, Shadman Market, Lahore. | 1. Syed Mohsin Raza.2. Syed Muhammad Naeem. | -do- | No. | Approved subject to provision of evidence for application for DSL. |
|  | M/s Save on Health Care, **Head Office**:101- B, Panjpeer Road, Lalpur Mughalpura, Lahore.**Godown Address:**Same as Above | 1. Mr.Muhammad Jamil Hassan 2. Mr.Shahbaz idrees Khan 3. Mr.Muhammad Amir  | Mrs. Unum Zia Shamsi,Assistant Director-IV (MDMC), DRAP, Islamabad.Hafiz Muhammad Asif Iqbal,Assistant Director-V (MDMC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s La-Vie (Pvt) Ltd., **Head Office:**Behind PSO Petrol Pump, Peco More, Peco Road, Kot Lakhpat, Lahore.**Godown Address:**First Floor BMC Building, Opposite Micro Electronic, Peco Road, Kot Lakhpat, Lahore  | 1. Mr.Pervaiz Iqbal Awan(CEO)2. Mr. Aslam Khan3. Ms.Bushra Yasmeen.4. Ms.Sukeina Hadi. | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Concept Pharma (Pvt) Ltd., **Head Office:**825-E, Johar Town, Lahore.**Godown Address:**Same as Above | 1.Mr.Naeem Ahmad(CEO)2.Mr. Faizan Ahmad.3.Mr. Usman Ahmad.4.Mr.Shafiq Ahmad. | -do- | Limited capacity. | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Bionext Pharmaceutica**Head Office:**251-A, Karim Block, Allama Iqbal Town, Lahore.**Godown Address;**Same as Above | 1. Mr.Kashif Iqbal. 2. Ms.Hina Kashif. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Sharif Trading Company, **Head Office**:20/3A Al-Hamd Colony Opp. 691-D, Neelam Block, Allama Iqbal Town, Lahore.**Godown Address:**Same as Above | Mr.Muhammad Nauman Sharif. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s. Progressive Corporation,**Head Office**:147 -D, Commercial Broadway, Phase- 8 DHA, Lahore.**Godown Address:**Same as Above | Mr. Irfan Ayaz. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Al-Yahya Enterprises, **Head Office**:203, Sana Plaza Garrison, Golf Club, Bahar Shah Road, Al- Faisal Tower, Lahore.**Godown Address;**206, Sana Plaza Garrison, Golf Club, Bahar Shah Road, Al- Faisal Tower, Lahore. | Mr. Khawaja Shujat Ali. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s. A & E Medical, **Head Office**:323-Ata Turk Block, New Gardan Town, Lahore.**Godown Address:**Same as Above | 1.Mr. Muhammad Ihtsham Ul Haq.2. Ms. Shama Ihtsham | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Gulfam Brothers, **Head Office:**Office No 702, 7th Floor, Land Mark Plaza Jail Road, Lahore.**Godown Address:**Same as Above | Ms. Al-Kausar Sarfraz. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Ferozsons Laboratories Ltd, Amangah, Nowshera-KPK. | 1. Mr Akhtar Khalid Waheed.2. Mr Osman Khalid Waheed 3. Mrs Munize Azhar Peracha.4.Mrs. Amna Peracha Khan.5. Mr. Arshad Saeed Hussain.6. Mr. Nihal F. Cassim.7.Mr. Shahid Anwar. | Hafiz Muhammad Asif Iqbal,Assistant Director-V (MDMC), DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Standard Supply Agencies, Shop No 20,21&22, Khyber Bazar, Peshawer. | Waseem Shahzad | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Quality Medical Services, H-49, Gordon College Road, Rawalpindi. | Aleem Shahzad. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Bio Medics Medical System, F -597, F- Block, Statelite Town, Rawalpindi. | Mr. Sohail Ahmad. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s FW Distributer, FW Building, Opposite Poonch House, Adamjee Road, Saddar, Rawalpindi. | 1. Muhammad Yunus.2.Muhammad Faisal Ali. | -do- | No | Rejected due to poor and inadequate storage facility and SOPs not prepared as per checklist  |
|  | M/s 3M Surgicals, Plot. 5/172 Sarwar Road, Rawalpindi. | Syed Munawer Rashid Shah | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Intek Corporation, Office No 30, First Floor Al Amin Plaza, The Mall Rawalpindi.**Godown Address:**(i) 25 A Nagi Road Westridge 1, Rawalpindi(ii) 22-C Greenwood Homes,New Muslim Town, Lahore. | Mr. Irfan-ul-Az eem. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Anwar & Sons, Apartments No 10, Safari Villas -2, Commercial Complex Phase-7, Bahria Town, Rawalpindi.**Godown Address:**asian business center shop LG I & 2 Gt. Road Main Gate Bahria Town Phase 7 Rawalpindi. | Tahir Mahmood Khan. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Bay-G Pharma, House No.103-A, A-Block Satelite Town, Rawalpindi. | 1. Abdul Farooq 2. Abdul shakoor Awan. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s JK Traders, Suit No 13, 2nd Floor Majeed Plaza Bank Road Saddar, Rawalpindi. | 1. Jehanzeb Khan2. Ehsan Khan. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Genus, **Head office:**No 220, Block-3, DMCHS, S. Abdul Tawwab Road, Karachi.**Godown Address:**41- H-B, Block 6, PECHS, Mehmood Hussain Road, Karachi. | Haseeb Qamer. | Mrs. Unum Zia Shamsi, Assistant Director-IV (MDMC), DRAP, Islamabad.Hafiz Muhammad Asif Iqbal, Assistant Director-V (MDMC), DRAP, Islamabad. | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Oriental Sales Corporation, **Head office:** 327,DMCHS, Block -3, Haider Ali Road, Karachi.**Godown address:**Same as above | 1.Mr. Muhammad Younus 2.Mr. Mansoor Younus3.Mr. Faisal Masood.4.Ms. Fatima Masood.5.Mr. Anas Masood.6.Mr. Saad Masood. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Matrix Pharma Pvt Ltd, Plot No 12, Sector 15, Korangi Industrial Area, Karachi. | 1. Liquat Ali Malik.2. Sameer Liaqat Malik. | 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 Allmed Solutions, A-21/3, KDA Scheme 1 (Ext). Opposite National Stadium Karachi. | Sadaf Mirza. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s. Parazelsus Pakistan (Pvt) Ltd. Office No 201-204, 2nd Floor, Park Towes, Shahra -Firdousi, Karachi.**Godown Address:**Shed #F-9, Plot No.51, Survey No.239, Sec No.2, Road 4000, Korangi Industrial Area, Karachi.  | 1. Parazelsus Orient  Limited2. Markus Haefeli.3.Mujtaba Rahim.4. Zia Shams. | -do- | No | **Rejected as they have no dedicated storage area for medical devices.** |
|  | M/s Hoora Pharma (Pvt) Ltd., WH-01 20-A7-A8, Korangi Creek Industrial Park, Karachi. | 1.Mr Adbul Rasheed.2. Mrs Aysha Rasheed Chohan3. Zulqarnain Rasheed Chohan | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Abbott Laboratories(Pakistan) Ltd., Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi. | 1. Mr. Anis Ahmed2. Mr. Munir Ahmed Shaikh3. Mr. Kamran Y Mirza4. Mr. Shamim Ahmed Khan5. Mr. Ehsan Ali Malik6. Ms. Zehra Naqvi7. Ms. Seema Khan | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s. Medinostic Healthcare (Pvt) Ltd., B-18, S.I.T.E, Karachi. | 1.Tariq Allawala. 2. Syed Waqar Hussain. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s. Sindh Medical Stores, 13- B, Block 6, PECHS, Shahrah -e- Faisal Karachi. | 1. Mr. M Younus Billo2.Mrs Kishwar Billo.3.Dr Tasmia Abeer Billo. | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Usmanco International, 220,Block -3,DMCHS, S.Abdul Tawwab Road, Karachi.**Godown Address:**41-H, Block-6, PECHS, Karachi | Qammar Usman. | -do- | No | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Hospital Supply Corporation, 42 Darul Aman Housing Society, Block 7 & 8, Karachi. | 1.Mehtabuddin Feroz.2. Muhammad Yahya Feroz 3.Sohail Feroz. | -do- | No | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Lab Link Enterprises, M-203, Block 2, P.E.C.H.S Opp Ghousiya Masjid, Karachi.**Godown Address:**B-40, S.I.T.E, Karachi | Mr Arshad Awan. | -do- | No | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Ham International, Mezzenine Floor Plot No. LS-2, St,9 Block-15 KDA Scheme, 36 Gulistan-e-Johar, Karachi.**Godown Address:**S-29 Mateen Shoppers Galary. Main Tariq Road, PECHS. Karachi. | Ms. Mina Jahan. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Life Care, M-20 Mezzanine Floor Falaknaz Plaza Main Shahra e faisal Karachi**Godown Address:**House No. 104/A-102, Area Asifabad Shah Faisal Town, Karachi | Mr. Imtiaz ur Rehman. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Hospital Services & Sales, 13 C Annex , Block 6, PECHS, Shahrah e Faisal, Karachi. | 1. Mr Younus Billo2.Mrs Kishwar Billo.3.Dr Tasmia Abeer Billo. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s UDL Distribution (Pvt) Ltd., I-D -13, Sector 30, Korangi Industrial Area, Karachi.**Godown Address:**S-8/A, Translyari Quarters, SITE Near Gul Bai, In Line of Meezan Bank, Head Office, Karachi | 1. Mr Arshad Abdullah2.Mr Nasir Abdullah3.Mr Tahir Khaliq4.Mr Ahsan Khaliq. | -do- | No | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Mana & Co., Office No 401. 4th floor, Masood Chamber, Shahrah -e- Liaquat, Karachi.**Godown Address:**SHED No, 2.Plot No. F-2, AJ, SITE, Karachi. | Mr Imran. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Nisa Impex(Pvt) Ltd, Maxim Arcade, Plot No 13-14, Usman Block, Jeddah Town, Phase-1, Opp. DHA -II, G.T Road, Islamabad. **Godown Address:**Office No 2,First Floor Akber Khan, Plaza College Road, Tehsil & Distt Rawalpindi. | 1.Mohammad Inayat Ullah 2.Mohammad Wassi Shan.3.Rakshanda Anjum. | Hafiz Muhammad Asif Iqbal, Assistant Director-V (MDMC),DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Atco Pharma International (Pvt) Ltd., B-18, S.I.T.E. Karachi. | 1. Shaikh Mohammad Naseem Allawala,2.Mr Saeed Allawala.3. Mr. Aslam Usman Allawala | 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 Bayer Pakistan (Pvt) Ltd., C-21,S.I.T.E, Karachi | 1. Mr Imran Ahmad Khan2.Mr Muhammad Shafiq | -do- | No | Rejected as they have no dedicated storage area for medical devices. |
|  | M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, Manghopir Road, S.I.T.E, Karachi. | 1. Mr. Pervez Hayat Noon2. Dr. Shahida Qaiser | -do- | No | Rejected due to very poor and unhygienic storage area. |
|  | M/s Hakimsons (Pvt) Ltd., Hakimsons House, A-58 /B, S.I.T.E.Mangophir Road, Karachi. | 1.Nawazish Ali Hakim.2.Nayyar Jahan Hakim.3.Naveed Nawish Ali Hakim. | -do- | No | Rejected due to poor storage conditions. |
|  | M/s CKD Pharmaceuticals Pakistan (Pvt) Ltd, Plot 50/28, Korangi Industrial Area, Karachi. | 1. Mr. Syed Mustafa Hussain Kazmi2. Ms. Naureen Liaqat | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Excel Corporation, 435, BYJ Society Bahadurabad Karachi. | Mr. Ather Feroz. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Sure Bio Diagnostics & Pharmaceutical, EE -10 Defence View Phase 11, Near Iqra University Shaheed-e-Millat Express Way, Karachi. | Shaikh Shakeel Ahmad. | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s TraMax Health Systems, A-337 Block -D, North Nazimabad, Karachi. | Syed Shakeel Ahmed | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Biogenics Pakistan (Pvt) Ltd., 201, Fartune Centre, PECHS Block No 6, Sharae Faisal, Karachi.**Godown Address:**19 G/2 Block 6 PECHS,Karachi | Mrs. Azra Rehana Karrar.Mr. Hassan Haider KarrarMr Hussain Haider Karrar.Mr Rubbab Haider Karrar. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Macro Medical Systems, B-10A, Abdullah Terrace Block-16, Gulistan-e-Jauhar, Karachi.  | Nasir A Qureshi. | -do- | No | **Rejected as they have no dedicated storage area for medical devices.** |
|  | M/s Meher Traders,**Head Office**:Office A 21-22 First Floor, Zeenat Medicine Market, North Napier Road, Karachi.**Godown Address:**Muhammad Bukhsh& Sons Building 23, West Wharf Road, P.O.B No. 4459 Karachi. | Mr. Jamal Idrees. | Mrs. Unum Zia Shamsi, Assistant Director-IV (MDMC),DRAP, Islamabad.Hafiz Muhammad Asif Iqbal, Assistant Director-V (MD&MC), DRAP, Islamabad. | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s MSB Medical, **Head office:**F-2, 1st floor, 51-1/C, Block-6, PECHS, Karachi.**Godown address:**Same as above | Attaullah Bhatti. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Pharma Supply Corporation,**Head Office:**49 J, Annexe, Block-6, PECHS Karachi.**Godown Address:**Same as Above | Mr. Muhammad Ali. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Meximp Technologies, **Head office:**B-62, Block 5, Gulshan-e- Iqbal, Karachi.**Godown Address:**Same as above | Mr. Faiyaz Ahmad.2.Mr. Mudassir Ahmed Inamdar | -do- | Limited capacity | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Popular International (Pvt) Ltd., **Head office:**141 Justice Inamullah Road, Block 7 & 8, KMCHS, Karachi.**Godown Address:**Same as above | 1.Mr. Iqbal Billo(CEO)2.Mr. Nasima Billo3.Mr. Umer Billo.4.Mr. Saqib Billo.5.Mr. Abdul Rehman Billo.6.Mr.Abdul Rahim Billo. | -do- | Yes | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Coral Pharmaceuticals**Head Office**:A-85, SCHMS, Karachi.**Godown Address:**Same as Above | 1. Mr. Atif Ali.2.Mr. Amin Ul Haque.3.Ms. Fatima Haseeb. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s FM Health Care,**Head Office**:203, Al Rehman Center, Block 7/8 KCHS, Shaheed e Millat Road, Karachi.**Godown Address:**Same as Above | 1. Mr Sheikh Masood Ahmad Chhabra2.Mr. Sheikh Zafar Masood Chhabra3.Mr. Muhammad Tariq Masood. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Nasir Brothers, **Head Office**:Office No 22B, 2nd Floor, Zeenat Medicine Market, North Napier Road, Karachi.**Godown Address:**Plot No 149 150, Ground Floor , Block 7/8, Memon Cooperative Housing Society Karachi. | Mr. Nasir Ahmed | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Prism Health Pakistan, **Head Office:**705-706, Anum Blessings, Block 7/8, KCHSU, Karachi.**Godown Address:**Same as Above | Mr. Muhammad Asif Ghafoor. | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Zenith International, **Head Office**:Room No 104, Tahir Plaza, A/20, Block 7 & 8, KCHSU, Karachi.**Godown Address:**Shop no 1, Ground Floor, Plot No-4 D, 17th Comm. St. Phase 11 Ext. DHA, Karachi. | Mr. Kashif Shakeel | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Labserv,**Head Office**:House No B- 165/2 , Block 3A Gulistan-e-Jauhar, Scheme 36, Karachi.**Godown Address:**Same as Above | Mrs. Irshad Bano. | -do- | Yes.-10°C to -40°C facility also available. | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Anthro Pharmaceuticals (Pvt) Limited, **Head Office:**C-19D, Badar Commercial Lane 5, Phase 5 Ext. DHA Karachi.**Godown address:**1st Floor Plot No. c-125, 126 Sec. 6F, Mehran Town Korangi, Karachi | 1. Ms. Sunila Zaidi (CEO)2. Mr. Syed Muhammad Abbas Zaidi | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Creative Network Solution, **Head Office:**Shop No. G-170, Naz Plaza, M.A Jinnah Road, Karachi.**Godown address:**G-199 Naz Plaza, M.A Jinnah Road, Karachi. | Mr. Jawaid Hussain | -do- | No | **Rejected due to very poor and unhygienic storage area .** |
|  | M/s Universal Enterprises, **Head Office:**29, Block-3, Overseas Co-Operative Housing Society, Stadium Road, Karachi.**Godown address:**Same as above | Mr. Muhammad Aleem Mirza | -do- | No | Approved for room temperature medical devices without cold chain facility. |
|  | M/s National Enterprises, **Head Office**:Office No. 409, 4th Floor, Al-Sehat Center, Annexe Regent Plaza, Shahrah-e-Faisal, Karachi.**Godown Address:**Same as Above | Mr. Muhammad Zubair | -do- | Limited capacity. | Approved for room temperature medical devices alongwith cold chain facility. |
|  | M/s Sky Traders,**Head Office:**A-11, Ground Floor, Al-Hilal Co-Operative Housing Society, Block No.IV & V, KDA Scheme No.7, Karachi**Godown Address:**Same as above | 1. Mr. Asim Hameed2. Ms. Uzma Asim | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Royal Enterprises, **Head Office**:Shop No.5, Karimji Building, Opposite HBL, North Napier Road, Karachi.**Godown Address:**1. M-4 , Asghar Ali Building, Campbell Street , Karachi.2. 201, Union Chambers, North Napier Road, Karachi | Tausif Jamil | -do- | No. | Approved for storage of room temperature medical devices without cold chain facility, subject to provision of DSL. |
|  | M/s Sultan Sons, **Head office:**133, Kutchi Gali No.1, Marriot Road, Karachi.**Godown Address:**1. M-2, Mez floor, Asghar Ali Bldg., Karachi2. 2nd floor #29, Sadaf centre, Serai road, Karachi3. 2nd floor 27/28 Sadaf centre, Serai Road, Karachi4. 2-A Pt# 07/15 N.Napier Road, Karachi | 1. Mr. Mohammad Aslam2. Mr Shakil Ahmad.3.Mr Jamil Sultan | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Intra Health, **Head office:**56-A, UnitNo.1, Justice Inamullah Road, Block 7/8, K.C.H.S, Karachi.**Godown Address:**Plot No. 37/1, Sector 15, Korangi Industrial Area, Karachi | Muhammad Kamran Muddasir | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Saving Life Technologies (SLT), **Head office:**427-K, Block Model Town, Lahore.**Godown Address:**Same as above | Mr. Arsalaan Bajwa | Mrs. Unum Zia Shamsi, Assistant Director-IV (MDMC),DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Verizon **Head office:**60-D F.C.C Zahoor Elahi Road Gulberg- IV, Lahore.**Godown Address:**Same as above | Ms. Humaira Farooq Sohail. | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Apsta International, **Head office:**38-A , Johar Town, Lahore.**Godown Address:**Same as above | Mr. Amer Yousuf | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s K.M Enterprises, **Head office:**605, D Block, M.A Johar Town, Lahore.**Godown Address:**Same as above | Mr. Khalid Mahmood | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Optimus Entrepot, **Head office:**194- F/1 - Block, Johar Town, Lahore.**Godown Address:**Same as above | 1.Mr. Muhammad Hamid2.Mr. Muhammad Ahsan Shafique3.Mr. Saeed Ahmad Bajwa4.Mr. Asadullah5.Mr. Sajjad Latif.6. Mr. Farooq Azam Khan7. Mr. Nasreen Rao Zulfiqar8. Ms. Rubina Ishaq9. Mr. Umer Farooq Niazi10. Mr. Akhtar Hussain Abbasi | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s SES Associates, **Head office:**148-Ejaz Park, Model Town Link Road, Lahore.**Godown Address:**1st Floor, 148-Ejaz Park, Model Town Link Road, Lahore. | Mr. Muhammad Shahid Ikram | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Tech Zone, Ground Floor, Weal House 8, Faiz Road, Old Muslim Town Lahore. | Ali Hassan Qadri. | Muhammad Ayub Naveed, Assistant Director-II (MDMC),DRAP, Islamabad.Hafiz Muhammad Asif Iqbal, Assistant Director-V (MD&MC), DRAP, Islamabad. | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Healthline Pharma, 170-D, Johar Town, Lahore. | 1. Mr. Mohammad Rashid Khan2. Mr. Faisal Mahmood Khan3. Ms. Amna Israr | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Matora Digionics Pvt Ltd., 130-C, Scotch Corner Upper Mall, Lahore. | Shahid Bashir | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Sakuf Trading, 2nd Floor, G-34 Phase-I Commercial Area DHA, Lahore. | Mr. Muhammad Usman Malik | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Bristol Mayer Biotech Pakistan (Pvt) Ltd, 73-B, Guldasht Town, Lahore. | 1.Mr. Munawer Ali Tariq2. Mr. Zaheer Ahmed Khan3. Mr. Abdul Razzaq Khan | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Chiesi Pharmaceuticals (Pvt) Ltd, 60/1A, XX, Phase III, Commercial Zone, Khayaban-e-Iqbal, DHA, Lahore.**Godown Address:**Khewat No. 55, 14KM Multan Road, Thokar Niaz Baig Lahore | Mr. Umar Masood | -do- | No. | Approved for room temperature medical devices without cold chain facility. |
|  | M/s Hope Pharma, 1-B, Guldasht Town, Zarar Shaheed Road, Lahore. | Mr. Kashif Amin | -do- | No. | Rejected due to unsatisfactory and inadequate store and storage conditions. |
|  | M/s Unique Pharma, House No 1775/21, Street No.1, Tariqabad , MDA Road,Multan. | Mr. Muhammad Arshad. | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Latif Instuments Pvt Ltd, M/s Latif Instuments Pvt Ltd14, Commercial Building Shahrah e Quaid e Azam Lahore | 1.Mian Tahir Rasheed 2.Mian Khalid Rashid3.Mian Arif Mushtaq4.Mian Amer Rashid | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility, subject to provision of DSL. |
|  | M/s Ameer Sons, 305-A, Upper Mall, Lahore. | 1. Musleh Uddin Sheikh.
2. Fasih Ud Din
3. Zaheer Uddin Babar
4. Vajih Uddin
 | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility, subject to provision of DSL. |
|  | Haji S. Ameer Din & Sons, 305-A, Upper Mall, Lahore. | 1. Musleh Uddin Sheikh.
2. Fasih Ud Din
3. Zaheer Uddin Babar
4. Vajih Uddin
 | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility, subject to provision of DSL. |
|  | Al-Ameen Associates, 125-Habitates Flats, Shadman-II, Lahore. | 1. Dr. Mian Khalid Rashid.
2. Mian Tahir Rashid.
3. Mian Amer Rashid.
 | -do- | No. | Approved for warm range (above 30°C) medical devices without cold chain facility, subject to provision of DSL. |
|  | M/s Med Lab Services, **Head Office:**office no 1, 1st floor ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi.**Godown Address:**Office No.4, 2nd Floor, ABC, Plaza, Commercial Center, Satellite Town, Rawalpindi. | Chudhry Muhammad Naeem | Mrs. Unum Zia Shamsi, Assistant Director-IV (MDMC), DRAP, Islamabad.Ms. Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | YesAlso has limited capacity for freezing products.  | Approved for room temperature medical devices alongwith cold chain facility, subject to provision of DSL. |

**Item No. IV**. **APPLICATIONS FOR GRANT OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.**

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

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **S.No** | **Name of Establishment** | **Address** | **Name of Qualified Person** | **Name of QC Incharge** | **Inspection panel & date of inspection** | **Recommendation of Panel.** |
| 1. | M/s Nisa.SF (Private) Limited. | **HO Address:** Office No.1, 1st Floor, Maxim Arcade, Usman Block Jeddah Town , Phase 1, Opp DHA Phase II, GT Road, Islamabad, Pakistan.**Factory Address:** 10-KM Muridke Sheikhupura Road, Muridke Distt Sheikhupura, Punjab. Pakistan | Dr. Amir Hameed (Production Incharge) | Mr. Shahid Hussain | **Prof. Dr. Abdul Haleem,** Chairperson Faculty of Pharmacy, F.C College, Lahore.**Dr. Ghazanfar Ali Khan,** Additional Director MDMC, DRAP.**Mr. Muhammad Ayub Naveed,** Assistant Director MDMC, DRAP | Based on the inspection, the panel of experts are of the opinion that the firm has sufficient facilities with respect to Production, Quality Control/Quality Assurance, Storage and Technical Staff, therefore, recommended to MDB for grant of Establishment Licence to Manufacture Medical Devices in Syringe, I.V. Cannula and I.V Products Section |
| **Decision: Approved the Establishment License to Manufacture Medical Devices alongwith following Sections:-**1. **Syringe Section.**
2. **I.V. Cannula Section.**
3. **I.V Products Section**
 |
| 2.  | M/s Unisa (Pvt) Ltd. | Main G.T. Road, Adam Zai, Akora Khattak, District Nowshera, KPK, Pakistan | Mr. Adil Ghaffar(Production Incharge) | Mr. Ihsanullah | **Prof. Dr. Sajid Bashir,**Dean, Dept. of Pharmacy, UOS, Sargodha/ Member MDB.**Dr. Ghazanfar Ali Khan,** Additional Director MDMC, DRAP.**H.M. Asif Iqbal**Assistant Director, MDMC, DRAP | The management of the firm is very cooperative and willing to make improvements to the non-conformities and observations. The management has undertaken to comply with the non-conformities and observations in the shortest possible time. The panel of experts is of the opinion that unit is meeting the basic requirements of building, personnel, documentation, warehouse, sterilization, HVAC, microbiology testing and quality control and therefore recommends the MDB to grant the Establishment License to Manufacture Medical Devices (Syringes & IV sets).  |
| **Decision: Approved the Establishment License to Manufacture Medical Devices alongwith following Sections:-**1. **Syringe Sections.**
2. **I.V Set Section**
 |
| 3.  | M/s Medical Devices Development Centre (MDDC) | Medical Devices Development Centre (MDDC), School of Mechanical & Manufacturing Engineering (SMMER), National University of Science & Technology (NUST), Sector H-12, Islamabad, Pakistan | Dr. Murtaza Najabat Ali(Production Incharge) | Marium Mir | **Mr. Muhamad Tahir Aziz,**COO, SKMH, Peshawar/ Member MDB.**Brig. Dr. Waqar Azeem Niaz,** Member MDB.**Dr. Ghazanfar Ali Khan,** Additional Director MDMC, DRAP.**Mr. Muhammad Ayub Naveed,** Assistant Director MDMC, DRAP | For Manufacturing of Bare Metal Coronary Stent System for clinical and safety evaluation only. |
| **Decision: Allowed the MDDC, NUST to manufacture Bare Metal Coronary Stent System for clinical and safety evaluation only and submit the established clinical safety and performance profile to MDB. The MDB if satisfied, may grant approval for commercial batches.** |

 **Item No. V**. **DELEGATION OF POWERS REGARDING IMPORT OF MEDICAL DEVICES.**

 Secretary MDB informed the Board that grant of clearance for commercial import of raw material and finished drugs is a routine procedure performed at field offices and since the medical devices have now come under regulation so that clearance will also be required. He submitted that rule 25 (c) of Medical Device Rules, 2017 states as under:

(c) intimate on Form-11 of arrival of the consignment of imported medical devices or components or raw materials, other than those imported for personal use or hospital’s patient’s use, alongwith three copies of the invoices to the officer authorized to grant clearance on receipt of information at the port of importation;

**Decision:** The Board delegated the powers for performance of above function under the Medical Device Rules, 2017 to Additional Directors of DRAP’s field offices or officers authorized by them.

**Item No. VI**. **Registration of Medical Devices for Local Manufacture.**

 Secretary MDB informed the board that the following firms have applied for registration of their medical devices for local manufacture. The MDB considered the applications and decided as mentioned against each:-

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sr. No** | **Name and Addresses of Estasblishment** | **Name of medical device** | **Product Details** | **MD Class** | **Shelf Life** | **Decision** |
| 1 | M/s Nisa.SF (Private) Limited, **HO Address:** Office No.1, 1st Floor, Maxim Arcade, Usman Block Jeddah Town, Phase 1, Opp DHA Phase II, GT Road, Islamabad, Pakistan.**Factory Address:** 10-KM Muridke Sheikhupura Road, Muridke Distt Sheikhupura, Punjab. Pakistan | BM Disposable Infusion set TPE N.S.009 | With 21G X 1 ½ " (0.8mm X 38mm) | Class B | 5 Year | Approved with shelf life of 3 years subject to confirmation of the manufacturing facility / processes by Dr. Abdul Haleem Khan, Member MDB and Prof.Dr. Sajid Bashir, Member MDB for the applied products. |
| 2 | -do- | BM Disposable Blood Transfusion Sets  | NormalWith Leucocytes Filter | Class B | 5 Year | do |
| 3 | -do- | BM Auto Disable Syringe | 0.05ml with 26G X ½ " (0.45mm X 13mm)0.05ml with 23G X 1 " (0.6mm X 25mm)0.5ml with 26G X ½ " (0.45mm X 13mm)0.5ml with 23G X 1" (0.6mm X 25mm)1ml with 26G X ½ " (0.45mm X 13mm)1ml with 23G X 1" (0.6mm X 25mm)3ml with 23G X 1" (0.6mm X 25mm)3ml with 21G X 1 ½ " (0.8mm X 38mm)5ml with 23G X 1" (0.6mm X 25mm)5ml with 21G X 1 ½ " (0.8mm X 38mm)10ml with 21G X 1 ½" (0.8mm X 38mm) | Class B | 5 Year | do |
| 4 | -do- | BM Disposable Syringe | 1ml with 26G X ½ " (0.45mm X 13mm)1.5ml with 26G X ½ " (0.45mm X 13mm)2ml with 24G X 1" (0.55mm X 25mm)2.5ml with 24G X 1" (0.55mm X 25mm)3ml with 24G X 1" (0.55mm X 25mm)3ml with 23G X 1" (0.6mm X 25mm)5ml with 23G X 1" (0.6mm X 25mm)10ml with 21G X 1 ½ " (0.8mm X 38mm)20ml with 20G X 1 ½" (0.9mm X 38mm)30ml with 20G X 1 ½" (0.9mm X 38mm)50ml with 20G X 1 ½ " (0.9mm X 38mm)60ml with 20G X 1 ½ " (0.9mm X 38mm) | Class B | 5 Year | do |
| 5 | -do- | BM Disposable Infusion set N.S.007 with precision dose filter | With 21G X 1 ½ " (0.8mm X 38mm) | Class B | 5 Year | do |
| 6 | -do- | BM Disposable Infusion Set N.S.002 | With 21G X 1 ½ " (0.8mm X 38mm) | Class B | 5 Year | do |
| 7 | -do- | BM Disposable Infusion Set (TOTM) N.S. 022 | With 21G X 1 ½ " (0.8mm X 38mm) | Class B | 5 Year | do |
| 8 | -do- | BM Disposable Light Protective Infusion Set N.S. 018With precision dose filter. | With 21G X 1 ½ " (0.8mm X 38mm) | Class B | 5 Year | do |
| 9 | -do- | BM Disposable Hypodermic Needles | 18G X 1 ½" (1.2mm X 38mm)19G X 1 ½" (1.1mm X 38mm)20G X 1 ½" (0.9mm X 38mm)21G X 1 ½" (0.8mm X 38mm)22G X 1 ½" (0.7mm X 38mm)23G X 1" (0.6mm X 25mm)24G X 1" (0.55mm X 25mm)25G X 1" (0.5mm X 25mm)26G X 1/2" (0.45mm X 13mm)27G X 1/2" (0.4mm X 13mm) | Class B | 5 Year | do |
| 10 | -do- | B.M Disposable I.V Burette Set | 100ml150 ml | Class B | 5 Year | do |
| 11 | -do- | BM Disposable Single winged Scalp Vein Set. | 21G X 0.75" (0.8mm X 19mm)23G X 0.75" (0.6mm X 19mm) | Class B | 5 Year | do |
| 12 | -do- | BM Disposable Light Protective Infusion set N.S.018 with precision dose filter | With 21G X 1 ½ " (0.8mm X 38mm) | Class B | 5 Year | do |
| 13 | -do- | BM disposable Dialysis Tube ArterialBM disposable Dialysis Tube Venous | With Red ColorWith Blue Color | Class B | 5 Year | do |
| 14 | -do- | BM Disposable I.V. Catheter B,D,J,Y- Type | 18G X 1.16" (1.3mm X 32mm)20G X 1.16" (1.3mm X 32mm)22G X 1" (0.9mm X 25mm)24G X 0.75" (0.7mm X 19mm) | Class B | 5 Year | do |
| 15 | -do- | BM Disposable suction tubesFR4, FR5, FR6, FR8, FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24 | With Standard length 40cm(FR4, FR5, FR6, FR8, FR10)With Standard length 120cm(FR12, FR14, FR16, FR18, FR20, FR22, FR24) | Class B | 5 Year | do |
| 16 | -do- | BM Disposable Feeding TubesFR4, FR5, FR6, FR8, FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24 | With Standard length 40cm(FR4, FR5, FR6, FR8, FR10)With Standard length 120cm(FR12, FR14, FR16, FR18, FR20, FR22, FR24) | Class B | 5 Year | do |
| 17 | -do- | BM Disposable Nasal Oxygen Tube | Infants & Adults | Class B | 5 Year | do |
| 18 | -do- | BM Disposable Nelaton Catheter FR4, FR5, FR6, FR8, FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24 | With Standard length 40cm & 20cm | Class B | 5 Year | do |
| 19 | -do- | BM Disposable A.V. Fistula Needle | 14G X 1"15G X 1"16G X 1"17G X 1" | Class B | 5 Year | do |
| 20 | M/s Unisa Pvt Ltd., Main G.T Road , Adamzai, Akora Khattak, Distt Nowshera. | Uniflow set for transfusion of Blood and Blood Component. | UNIFLOW (Blood Transfusion Set)With Standard 150 cm length, Double Bulb with Nylo Filter | Class B | 5 Year | Approved with shelf life of 3 years subject to confirmation of the manufacturing facility / processes by Dr. Abdul Haleem Khan, Member MDB and Prof.Dr. Sajid Bashir, Member MDB for the applied products. |
| 21 | -do- | Unilin -1 Disposable Insulin Syringe | Insulin Syringe - 1Sterile use insulin syringe with 30G 8mm extra Fine needle | Class B | 5 Year | do |
| 22 | -do- | Sterile Single Use Hypodermic Needle. | UNIDLE (14G,16G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,) Sterile ss tube with hub and cap made of pp Packed in blister Paper  | Class B | 5 Year | do |
| 23 | -do- | Sterile single use Plastic Syringes. | Syringe 1ml/CCSyringe 2.5ML/CCSyringe 3ML/CCSyringe 5ML/CCSyringe 10ML/CCSyringe 20ML/CC | Class B | 5 Year | do |
| 24 | -do- | Sterile Single Use Adminisation Set For Gravity Infusion.Uniset with y -Port Without Y- Port | 1.UNISET sterile single use intravenous infusion set (Gravity infusion) 150 cm in Length with latex tune2.UNISET (WITH Y-PORT)Sterile single use intravenous infusion set (Gravity Infusion) 150cm ub length with Y- Port for injection | Class B | 5 Year | do |

**Item No. VII: HARDSHIP OF DISPOSABLE SYRINGE MANUFACTURERS CAUSEDTHROUGH SRO DATED 15-03-2017.**

 Secretary MDB informed the Board that the Pakistan Medical Disposable Manufacturers Association (PMDMA) has written the following letter addressed to the Director (Medical Devices & Medicated Cosmetics) DRAP, wherein they have requested that raw material imported for manufacturing of disposable syringe, IV Sets, IV Products (IV Burette, Feeding Tube, Stomach Tubes, Suction Tubes, Nelton Tubes, Scalp Vein Set), IV Canula, Hypodermic Needles be exempted from sales tax:

*“This is with reference to notification No. SRO 167 of 2017 dated 15-03-2017 issued by the Federal Government in exercise of its powers under section 36 and all other enabling provisions of Drug Regulatory Authority of Pakistan Act, 2012 whereby certain notifications/SROs including notification No. SRO 324(I)/1994 dated 19-04-1994 were repealed under rules 145 of Medical Devices Rules, 2015.*

*Pakistan Medical Disposable Manufacturers Association is the manufacturers of disposable syringes are heavily suffered due to the said repeal on the following grounds:*

1. *Disposable syringe was brought under the Drugs Act, 1976 through notification No. SRO 324(I)/1994 dated 19-04-1994. The said notification can only be repealed/amended in exercise of powers conferred under section 3 of the Drugs Act, 1976 whereas the same was repealed under the law not being the one under which it was issued.*
2. *After declaring the disposable syringes as drug, the supply of syringes was exempted under Sixth Schedule to the Sales Tax Act, 1990. Due to the repeal of the said SRO dated 19-04-1994, the exemption from sales tax shall be ceased and supply of syringes shall come under the tax net, which shall cause great damage to the industry as raw material for the manufacturers of syringes is also exempt under the Sixth Schedule to the said Act of 1990.*
3. *The local industry of syringe manufacturing being run in accordance with the law, rules and regulations administered by the Ministry of Health, shall not be able to compete with the commercial importers of syringes, it shall not only cause great damage to the ailing economy of the country by way of remittance of foreign exchange but also cause serious threat to the patient health with regard to its quality control and observance of protocols.*
4. *The directions of the Honorable Supreme Court is required to be followed in a manner whereby the local manufacturers of syringes may not be affected who made investments in this country, created employment, making value addition and saving foreign exchange as against commercial importers having far less contribution than the manufacturers of syringes and the unscrupulous elements of our society shall have a chance to misuse the incentive provided by virtue of the directions of the Honorable Supreme Court of Pakistan.*

 *Keeping in view above submissions, the plight of the local syringe manufacturers may be considered and suggested that the Federal Government may like to issue another notification with retrospective effect under the drugs Act to place syringe, Insulin Syringe 100 unit, IV sets, IV Products, (IV Burette, Feeding Tube, Stomach Tubes, Suction Tubes, Nelton Tubes, Scalp Vain Set) IV Cannula, Hypodermic needles in the category of drug and therapeutic enabling the manufacturers to continue to avail exemption under the Sales Tax law like other pharmaceutical manufacturers.”*

The matter was placed before the MDB for consideration. The representative of PMDMA also gave presentation to the Board members regarding the hardships of disposable syringe manufacturers.

**Decision: The MDB constituted the following committee to give recommendations on the subject case. The committee can also co-opt any member for assistance and complete their recommendations in 15 days and submit in next MDB meeting:-**

1. **Dr. Abdul Haleem Khan, Member MDB.**
2. **Dr. Sajid Bashir, Member MDB.**
3. **Miss. Hira Bhutto, Assistant Director-I (MDMC), DRAP, Islamabad (Focal Person).**

**Item No. VIII: PRESENTATION BY SURGICAL INSTRUMENTS MANUFACTURERES ASSOCIATION OF PAKISTAN (SIMAP) REGARDING PROBLEMS FACED BY THEIR INDUSTRY**

 Secretary MDB informed the Board that SIMAP had a meeting with CEO, DRAP on 27-06-2018regarding bottlenecks and problems faced by the surgical industry of Sialkot and the future negative implications of Medical Device Rules, 2017 on their industry. Their representative Mr. Jehangeer Babar Bajwa presented the following in the meeting. CEO, DRAP gave them an opportunity to present their point of view before the MDB.

*i) “The SIMAP was established in 1958 with an aim to protect and promote the art of surgical instruments manufacturing and to help solving the problems of surgical manufacturing community. It is one of the oldest trading organization. SIMAP has around 3800 members firms and more than 150,000 workers are engaged in manufacturing of Surgical Instruments to meet the export commitments in the International Market. The value of exports of surgical instruments for the financial year 2015-2016 is US$ 358 Million. However, the share obtained from the international market of US$ 18 Billion is far less than the potential of the surgical industry.*

*ii) Surgical Industry of Pakistan holds a history of more than 100 years. Pakistani Surgical Instruments are the most economical in the world with the finest quality. The Surgical Industry represents manufacturers and exporters of Surgical Instruments, Electro Medical Instruments, Body External Fixation Systems and Implants, Micro Surgery Instruments, Cardiovascular Instruments, Endoscopic and Gynecological Instruments, ENT Instruments, Respiratory Aid Instruments, Orthopedic Instruments, Holloware, Anesthesia Products, Hospital Furniture, Dental Instruments, Veterinary Instruments, Personal Beauty care Items and Beauty Saloon instruments.*

*iii) Surgical Industry is an export oriented vendor based industry manufacturing mostly Class A (non-invasive) medical devices. The supply chain connected to this industry is very complicated, since; different processes are performed at different places by various vendors. All the manufacturers depend on these vendors for carrying out one or more process. No manufacturer performs all the processes under one roof, therefore, there is a dire need to study the different processes of industry and then regulate accordingly; otherwise it would result in severe adverse consequences.*

*iv) Businesses of vendors are of small scale light engineering nature and it would be very difficult for DRAP to license and regulate such a huge number of vendors (approx. 3800). In case if a vendor does not apply for license and his business is stopped, then it would result in stoppage of connected surgical industry, even if one is willing to be regulated.*

*v) It would be impossible for vendors to hire a pharmacist / bio-medical engineer as a production and quality control in-charge and sustain their small businesses.*

*vi) Surgical Instruments or Class A (non-invasive) medical devices be exempted from Medical Device Rules, 2017 and cautious approach be taken in regulation.*

*vii) A roadmap for regulation may be framed after proper study of processes of surgical industry and connected vendors.*

*viii) There is a need to conduct workshops / seminars by DRAP to create awareness among the surgical industry regarding Medical Device Rules, 2017, which would also alleviate fear among the industry created by few consultants through emails and telephones.”*

The representative of SIMAP gave presentation to the MDB regarding problems faced by the surgical industry of Sialkot.

**Decision**: **The MDB constituted the following committee to discuss the subject case with SIMAP representatives in detail and come up with the recommendations for MDB:-**

1. **Dr. Abdul Haleem Khan, Member MDB.**
2. **Dr. Mohammad Farid Khan, Member MDB.**
3. **Dr. Ghazanfar Ali Khan, Additional Director (MDMC/Secretary MDB) DRAP, Islamabad (Focal Person).**
4. **Mrs. Unum Zia Shamsi, Assistant Director-IV (MDMC), DRAP, Islamabad.**

 **The first meeting of the Committee was held in DRAP Office immediately after the MDB meeting. Representatives of SIMAP Mr. Jehangeer Babar Bajwa, Ch. Qaiser Mehmood and Mr. Faizan-ul-Haq were present. Mr. Jehangeer Babar Bajwa on behalf of SIMAP reiterated the problems faced by the vendor based cottage Surgical Industry in the context of Medical Device Rules, 2017 and requested for exemption in rules for one year.**

 **The Committee is of the opinion that Establishment License to Manufacture medical devices of these surgical manufacturers processed by different vendors for a single product cannot be given under the Rules. The Surgical Industry is an export oriented vendor based industry manufacturing mostly Class A (non-invasive) medical devices and is of complex nature involving multiple steps performed by various vendors. All the manufacturers depend on these vendors for carrying out one or more process. No manufacturer performs all the processes under one roof, therefore, it cannot be regulated as such as it would be very difficult for DRAP to license and regulate such a huge number of vendors (approx. 3800). The Committee decided to visit the Industry for proper understanding, study of processes and connected vendors before finalizing recommendations and proposals for facilitation and regulation of Industry and subsequent amendments of Forms as per Rule 63(3) of Medical Device Rules, 2017.**

**Annexure-I**

**LIST OF PROVISIONAL ESTABLISHMENT CERTIFICATES ISSUED UNDER MEDICAL DEVICES RULES, 2017**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr No** | **File No** | **License No** | **Establishment Name** | **Issuance Date** |
|  | F-12-17/2013-MD (Vol II) | 0001-MD | M/s Atco Pharma International (Pvt) Limited, B-18, S.I.T.E Karachi. | 19-02-2018 |
|  | F.12-18/2017-MD  | 0002-MD | M/s Tek Enterprises, Office No. MZ-9, Al Hafeez Heights, 65- D, Sir Syed Road, Gulberg-III, Lahore. | 20-02-2018 |
|  | F.12-3/2016-MD | 0003-MD | M/s Cardiovascular Medical System, Office No 210-J-II, M.A Johar Town Lahore | 22-02-2018 |
|  | F.12-6/2016-MD (Pt) | 0004-MD | M/s Pak Punjab Cardex Medical System, Office No.202-2nd Floor, Eden Heights Jail Road Lahore.  | 22-02-2018 |
|  | F.12-19/2017-MD  | 0005-MD | M/s A.H Distributors, KH-1183 Lane No.5 Peshawar Road Rawalpindi. | 22-02-2018 |
|  | F.12-20/2017-MD | 0006-MD | M/s A&E Medical, 323, Ata Turk Block, New Garden Town, Lahore | 22-02-2018 |
|  | NO.F.12-50/2017-MD | 0007-MD | M/s Imtiaz Brothers, Suite No. 7B, 2nd Floor Abrar Business Center 25 Main Wahdat Road, Lahore -54600  | 22-02-2018 |
|  | F-12-9/2012-MD (Pt) | 0008-MD | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore. | 22-02-2018 |
|  | NO.F.12-54/2017-MD | 0009-MD | M/s Fresenius Medical Care Pvt Ltd, 137-A Faisal Town, Lahore | 22-02-2018 |
|  | F-12-18/2011-MD | 0010-MD | M/s B. Braun Pakistan (Pvt) Ltd. The Forum, Suite 216, Khayaban-e-Jami, Clifton Block 9, Karachi – 75600. | 22-02-2018 |
|  | F.12-21/2017-MD | 0011-MD | M/s Health Care International, Office No. 1st Floor H.# 42, St.#171, Shahbaz Park Madina Colony Baghbanpura Lahore. | 23-02-2018 |
|  | F.12-9/2017-MD  | 0012-MD | M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore.  | 23-02-2018 |
|  | F.12-1/2015-MD | 0013-MD | M/s Hashir Surgical Services situated at Head Office:# 16, Street 1, Sector F-2, Phase 6, Hayatabad, Peshawar. | 23-02-2018 |
|  | F.12-4/2013-MD | 0014-MD | M/s Iqbal & Company, Alfalah Manzil, Street 26, E-11/4, Islamabad. | 23-02-2018 |
|  | NO.F.12-4/2016-MD | 0015-MD | M/s Trans Angio System, 507, Progressive, Square, Block 6, PECHS, Shahra-e-Faisal, Karachi | 23-02-2018 |
|  | F.12-16/2017-MD | 0016-MD | M/s Bio Medics Medical System, F-597, F-Block, Satellite Town, Rawalpindi | 23-02-2018 |
|  | F.12-2/2018-MD | 0017-MD | M/s Ham International, Mezzanine Floor Plot No. LS2, St No. 9, Block No. 15, KDA Scheme 36, Gulistan e Johar, Karachi | 23-02-2018 |
|  | F.12-44/2017-MD | 0018-MD | M/s Life Care, M-20 Mezzanine floor Falaknaz Plaza Main shahra e faisal Karachi | 23-02-2018 |
|  | F.12-30/2017-MD | 0019-MD | M/s Advance Cardiology System, House: 12, Al-Sehat Centre, Rafique H.J. Shaheed Road, Hotel Regent Plaza, Karachi. | 23-02-2018 |
|  | F.12-13/2017-MD | 0020-MD | M/s Sakuf Trading, 2nd Floor, G-34 Phase-1, Commercial Area, DHA, Lahore. | 23-02-2018 |
|  | F.12-11/2017-MD | 0021-MD | M/s Al-Waali Care Concepts, 86 Allama Iqbal Road, Street Chah Baba Shadi Waal, Near Meraj Masjid, Lahore | 23-02-2018 |
|  | F.12-3/2018-MD | 0022-MD | M/s Safe Health Pakistan Bizcon, Office # 25 2nd Floor Dilkusha Chamber Marton Road, Karachi.  | 23-02-2018 |
|  | F.12-37/2017-MD (Vol-I) | 0023-MD | M/s Global Marketing, Services 111, Hali Road Westridge 1, Rawalpindi | 05-03-2018 |
|  | F-12-5/2013-MD(Vol-II) | 0024-MD | M/s Intek Corporation, Office # 30, First Floor, Al-Amin Plaza, The Mall, Rawalpindi. | 05-03-2018 |
|  | F.12-3/2017-MD  | 0025-MD | M/s Genus, 220, Block 3, D.M.C.H.S, S.Abdul Tawwab Road, Karachi. | 05-03-2018 |
|  | F.12-25/2017-MD | 0026-MD | M/s Mars Enterprises Office # 4 Jason Centre 2nd Floor, BC-8, Block No. 9, Clifton, Karachi. | 05-03-2018 |
|  | F-12-6/2011-MD (Vol-II) | 0027-MD | M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road Karachi. | 05-03-2018 |
|  | F.12-28/2017-MD | 0028-MD | M/s Noor International, Noor House 29-D, Block 6, P.E.C.H Society Karachi.  | 05-03-2018 |
|  | F.12-17/2017-MD | 0029-MD | M/s Maxims Medical, (i) 210 2nd Floor Land Mark Plaza Jail  Road Lahore. (ii) 534 H Block St # 13 Phase-V DHA  Lahore. | 07-03-2018 |
|  | F.12-42/2017-MD | 0030-MD | M/s Physiomed (Pvt) Ltd, 268/3, Kamal Road, Saddar, Rawalpindi | 07-03-2018 |
|  | F.12-23/2013-MD | 0031-MD | M/s Health Tec, 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi.  | 07-03-2018 |
|  | NO.F.12-3/2014-MD | 0032-MD | M/s Muller & Phipps Pakistan (Pvt) Ltd, Uzma Court, Main Clifton Road, Karachi | 07-03-2018 |
|  | F-12-5/2014-MD | 0033-MD | M/s Cardiac Care, 848-C, Shadman- I, Lahore. | 07-03-2018 |
|  | F.12-22/2011-MD  | 0034-MD | M/s Oriental Sales Corporation, 327 DMCHS, Block-3, Haider Ali Road Karachi. | 07-03-2018 |
|  | F.12-45/2017-MD | 0035-MD | M/s Sadqain Health Care Pvt Ltd, Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town; Phase-7, Rawalpindi. | 07-03-2018 |
|  | F.12-4/2018-MD | 0036-MD | M/s Health Care Corporation, Office No. 257-K, 1st Floor, Phase-I DHA, Cantonment, Lahore | 07-03-2018 |
|  | F.12-1/2014-MD (Vol-I) | 0037-MD | M/s Cor-Med, 2nd Floor 38/62 Rehman Plaza Bank Road Saddar, Rawalpindi. | 08-03-2018 |
|  | F-12-2/2017-MD | 0038-MD | M/s 4S International, Suite # 205, 2nd Floor Al-Fiza Glass Tower, main Rashid Minhas Road, Block 10-A, Gulshan-e-Iqbal, Karachi. | 08-03-2018 |
|  | F-12-5/2018-MD | 0039-MD | M/s National Enterprises, 409, 4th Floor, Al-Sehat Centre, Annexe Regent Plaza, Shahrah-e-Faisal, Karachi | 08-03-2018 |
|  | F-12-8/2017-MD | 0040-MD | M/s Anwar & Sons, Apartment No.10, Safari Villas-2, Commercial Complex Phase -7, Bahria Town, Rawalpindi. | 08-03-2018 |
|  | F.12-4/2014-MD | 0041-MD | M/s Universal Enterprises, 29, Block – 3 Overseas Co-Operative Housing Society, Stadium Road Karachi. | 08-03-2018 |
|  | F.12-21/2011-MD (Vol-II) | 0042-MD | M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh Nowshera, KPK. | 13-03-2018 |
|  | F.12-31/2017-MD | 0043-MD | M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi | 15-03-2018 |
|  | F.12-6/2018-MD | 0044-MD | M/s Meditron Medical Systems, 369-E, Johar Town, Lahore | 03-04-2018 |
|  | F.12-38/2017-MD | 0045-MD | M/s S.J Traders, Office No. 14, 3rd Floor Majeed Plaza, Bank Road, Saddar, Rawalpindi | 03-04-2018 |
|  | F.12-16/2011-MD (Vol-I) | 0046-MD | M/s Otsuka Pakistan Limited, 30-B, S.M.C.H.S, Karachi | 03-04-2018 |
|  | F.12-33/2017-MD | 0047-MD | M/s Healthline Pharmaceutical Pvt. Ltd, 30 Office No. 402, Al - Hafeez Heights, Ghalib Road, Gulberg 3, Lahore | 03-04-2018 |
|  | No.F.12-61/2017-MD | 0048-MD | M/s Quality Health Care Services, 148-Ejaz Park, Model Town Link Road, Lahore. | 03-04-2018 |
|  | F.12-1/2013-MD | 0049-MD | M/s SES Associates, 61-Bank Square Model Town Lahore | 03-04-2018 |
|  | F.12-14/2017-MD | 0050-MD | M/s Flowtronix Systems, Flat 2, 1st Floor Al-Asharaf Plaza Range Road, Rawalpindi | 03-04-2018 |
|  | F.12-36/2017-MD | 0051-MD | M/s Medco Health Care, 155, Block-3, C.P. Barar Society, Alamgir Road Karachi | 04-04-2018 |
|  | F.12-29/2017-MD | 0052-MD | M/s Easha Enterprises, 376-Pak Khaleej Center, Saidpur Road, Rawalpindi | 04-04-2018 |
|  | No.F.12-22/2017-MD | 0053-MD | M/s A.M Distributors, 4th Floor, Plot No.37-C, Bukhari Commercial Lane-8, Phase-VI DHA, Karachi | 06-04-2018 |
|  | No.F.12-8/2018-MD | 0054-MD | M/s Dora Enterprises, 54-B, Model Town Lahore (Head Office):: Sale Office: Suit # 02 First Floor 35-M, Block Civic Centre Model Town, Lahore | 06-04-2018 |
|  | No.F.12-05/2017-MD | 0055-MD | M/s Hakimsons (Pvt) Limited, Hakimsons House, A-58/B, S.I.T.E, Manghopir Road, Karachi | 13-04-2018 |
|  | No.F.12-15/2017-MD | 0056-MD | M/s Verizon, 60-D F.C.C Zahoor Elahi Road Gulburg IV, Lahore | 13-04-2018 |
|  | No.F.12-29/2017-MD | 0057-MD | M/s 3M Surgicals situated at Plot 5/172, Street 172, Sarwar Road, Rawalpindi  | 13-04-2018 |
|  | No.F.12-34/2017-MD(Vol-I) | 0058-MD | M/s Medisurg Innovatives Health Care, 1/6-N, Block-6, PECHS, Shahrah-e-Faisal, Karachi | 18-04-2018 |
|  | No.F.12-56/2017-MD | 0059-MD | M/s Claris Medical, Unit # 27, 3rd Floor, Twin City Plaza, I-8 Markaz, Islamabad | 26-04-2018 |
|  | No.F.12-27/2017-MD | 0060-MD | M/s Safeway Systems Pakistan situated at House No. 741/11 Lane 6, Range Road Rawalpindi | 26-04-2018 |
|  | No.F.12-10/2017-MD | 0062-MD | M/s SLT (Saving Life Technologies), 427-K Block Model Town, Lahore | 27-04-2018 |
|  | No.F.12-62/2018-MD | 0063-MD | M/s Arfi International, Suit No. 904, Al Rahim Tower, I.I. Chundrigar Road, Karachi | 30-04-2018 |
|  | No.F.12-9/2011-MD | 0064-MD | M/s Intra Health, 56-A, Unit No.1, Justice Inamullah Road, Block 7/8 K.C.H.S., Karachi | 08-05-2018 |
|  | No.F.12-63/2018-MD | 0065-MD | M/s Iqbal Enterprise, 1/4-C, Block-6, PECHS, Karachi | 08-05-2018 |
|  | No.F.12-6/2012-MD | 0066-MD | M/s Usmanco International situated at 220, Block # 3, DMCHS, S.Abdul Tawwab Road, Karachi. | 08-05-2018 |
|  | No.F.12-2/2014-MD (Pt) | 0067-MD | M/s Promed International situated at CB-6349, Amarpak Plaza, Jhelum Road, Rawalpindi. | 08-05-2018 |
|  | No.F.12-10/2018-MD | 0068-MD | M/s Ali Gohar & Company (Pvt) Ltd, State Life Building 1-B, I.I. Chundrigar Road, Karachi. | 15-05-2015 |
|  | No.F.12-54/2017-MD | 0069-MD | M/s Fresenius Medical Care Pakistan (Private) Ltd, TAMC, First Floor, 273 III, M.M. Alam Road Gulberg III, Lahore. | 15-05-2015 |
|  | No.F.12-51/2017-MD | 0070-MD | M/s Popular International (Pvt) Ltd situated at 141, Justice Inamullah Road Block 7 & 8 KMCHS Karachi | 24-05-2018 |
|  | No.F.12-7/2017-MD | 0071-MD | M/s Surgi World, Office # 303, Muhammadia Plaza College Road, Rawalpindi | 24-05-2018 |
|  | No.F.12-52/2017-MD | 0072-MD | M/s JK Traders, Suite No. 13, 2nd Floor Majeed Plaza Bank Road Saddar, Rawalpindi | 05-06-2018 |
|  | No.F.12-59/2017-MD | 0073-MD | M/s Guardian Pharmacy, 9-E Ground Floor, Rehman Tower, Mian Market, Gulberg II, Lahore | 05-06-2018 |
|  | No.F.12-8/2016-MD | 0074-MD | M/s Hope Pharma, Office #1-B, Guldasht Town, Zarar Road Cantonment, Lahore | 05-06-2018 |
|  | No.F.12-14/2018-MD | 0075-MD | M/s Oscartech Pakistan, Opposite Union Council, Kotla Arab Ali Khan, District Gujrat, Tehsil Kharian | 05-06-2018 |
|  | No.F.12-11/2018-MD | 0061-MD | M/s UDL Distribution (Pvt), Ltd, 1-D-13, Sector 30, Korangi Industrial Area Karachi | 12-06-2018 |
|  | No.F.12-42/2017-MD | 0076-MD | M/s Sapphire International, Room No. 903, 9th Floor UNI- Centre I.I. Chundrigar Road Karachi | 12-06-2018 |
|  | No.F.12-15/2018-MD | 0077-MD | M/s Nismedical, Mashriq Centre, 3rd Floor, Suite 315 Block 14, Gulshan-e-Iqbal, Karachi | 12-06-2018 |
|  | No.F.12-16/2018-MD | 0078-MD | M/s Gulfam Brothers, Office No.702, 7th Floor Land Mark Plaza Jail Road, Lahore | 12-06-2018 |
|  | No.F.12-46/2017-MD | 0079-MD | M/s Save On Health Care, Building No. 101-B, Panjpeer Road, Lalpul Mughalpura, Lahore | 12-06-2018 |

**Annexure-II**

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

**Upto 18-04-2018**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.#** | **PR.No.** | **Issue Date** | **Name of Importer** | **Product Name** | **Name of Manufacturer** |
|  | 00001-PR-MD | 07-03-2018 | M/s Atco Pharma International (Private) Limited, B-18, S.I.T.E, Karachi | CRE8 Amphilimus Eluting Coronary Stent” | M/s CID S.p.A Strada per Crescentino sn, 13040 Saluggia (VC), Italy |
|  | 00002-PR-MD | 07-03-2018 | -do- | Avantgarde Chrono Carbostent | -do- |
|  | 00003-PR-MD | 07-03-2018 | -do- | Pro HP Pegaso (PTCA Balloon Catheter) | -do- |
|  | 00004-PR-MD | 07-03-2018 | -do- | Fluydo Pegaso (PTCA Balloon Catheter) | -do- |
|  | 00005-PR-MD | 08-03-2018 | M/s Digital Imaging Systems, 121-Habitat Apartments, Shadman II, Ghaus-ul-Azam Road,Lahore. | Copilot Bleedback Control Valve | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Dr Santa Clara, CA 95054 USA.**Contract Manufacturers:** 1. M/s AVAILMED S.A. DE C.V. (MEXICO) Ave. Paseo Reforma No. 8950 Interior (C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa TIJUANA, Baja California 22116 MEXICO.
2. 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.
 |
|  | 00006-PR-MD | 08-03-2018 | -do- | Guide Wire Accessory Kit with Copilot 1003330 | -do- |
|  | 00007-PR-MD | 08-03-2018 | -do- | 20/30 Priority Pack with Copilot Bleedback Control Valve 1003327 | -do- |
|  | 00008-PR-MD | 08-03-2018 | -do- | Hi-Torque Cross -IT 100XT, 200XT, 300XT, 400XT Guide Wire with Hydrocoat Hydrophilic Coating | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Dr Santa Clara, CA 95054 USA**Manufacturing Sites:** 1. M/s ABBOTT VASCULAR CASHEl ROAD CLONMEL, Tipperary IRELAND.
2. M/s ABBOTT VASCULAR, 26531 YNEZ RD., Temecula, CA 92591 USA
3. M/s Abbott Vascular Costa Rica, 52 Calle 3 B31 Coyol Free Zone El Coyol, Alajuela COSTA RICA
4. M/s ABBOTT VASCULAR, Road # 2, km 58.0, Cruce Davila BARCELONE TA, PR 00617 USA
 |
|  | 00009-PR-MD | 08-03-2018 | -do- | Hi-Torque Whisper 0.014 (LS, MS, ES) Guide Wire | -do- |
|  | 00010-PR-MD | 08-03-2018 | -do- | Hi-Torque Balance Middle Weight 0.014 Guide Wire | -do- |
|  | 00011-PR-MD | 08-03-2018 | -do- | Hi-Torque Powerturn Guide Wires | -do- |
|  | 00012-PR-MD | 08-03-2018 | -do- | Hi-Torque Balance Heavyweight 0.014 Guide Wire with Hydrocoat Hydrophilic Coating | -do- |
|  | 00013-PR-MD | 08-03-2018 | -do- | Hi-Torque Progress PTCA Guide Wires | -do- |
|  | 00014-PR-MD | 08-03-2018 | -do- | Hi-Torque Pilot 50,150,200 Guide Wire with Hydrophilic Coating | -do- |
|  | 00015-PR-MD | 08-03-2018 | M/s Physiomed (Pvt) Limited, 268/3, Kamal Road, Saddar,Rawalpindi. | Endurity MRI (PM 1172, PM 2172) | **Legal Manufacturer**: M/s ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION, 15900 Valley View Ct SYLMAR, CA 91342, USA.**Contract Manufacturers**: 1. M/s ST. JUDE MEDICAL. PUERTO RICO, LLC, LOT A INTERIOR- No.2 St KM 67.5 SANTANA INDUSTRIAL PARK, Arecibo, PR 00612, USA.
2. M/s ST. JUDE MEDICAL OPERATIONS (M) SDN BHD, Bayan Lepas Industiral Zone Penang, Pulau Pinang11900 MALAYSIA.
 |
|  | 00016-PR-MD | 08-03-2018 | -do- | SJM Confirm Implantable Cardiac Monitor (DM 2102) | **Legal Manufacturer/ Manufacturer:** M/s ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION, 15900 Valley View Ct SYLMAR, CA 91342, USA. |
|  | 00017-PR-MD | 08-03-2018 | -do- | Endurity Core (PM 1152, PM2152) | **Manufacturer(s):**1. M/s ST. JUDE MEDICAL, CARDIAC RHYTHM MANAGEMENT DIVISION, 15900 Valley View Ct SYLMAR, CA 91342, USA.
2. M/s ST. JUDE MEDICAL. PUERTO RICO, LLC, LOT A INTERIOR- No.2 St KM 67.5 SANTANA INDUSTRIAL PARK, Arecibo, PR 00612, USA.
3. M/s ST. JUDE MEDICAL OPERATIONS (M) SDN BHD, Bayan Lepas Industiral Zone Penang, Pulau Pinang11900 MALAYSIA.
 |
|  | 00018-PR-MD | 08-03-2018 | -do- | Quadra Allure MPTM RF (PM 3262) | -do- |
|  | 00019-PR-MD | 08-03-2018 | -do- | Quadra AssuraTM (CD3367-40-C) | -do- |
|  | 00020-PR-MD | 08-03-2018 | -do- | Fortify AssuraTM (CD2359-40C, CD2359-40QC) | -do- |
|  | 00021-PR-MD | 08-03-2018 | -do- | EllipseTM VR  | -do- |
|  | 00022-PR-MD | 08-03-2018 | -do- | II SR+ 2525T, K SR 2535K (Microny) | -do- |
|  | 00023-PR-MD | 08-03-2018 | M/s Tek Enterprises, Office No MZ-09, Mezzanine Floor Al Hafeez Heights,65-D, Sir Syed Road Gulberg III,Lahore. | ASAHI ZenyteEX PTCA Guiding Catheter | **Manufacturer:** M/s ASAHI Intecc Co., Ltd., 1703 Wakita cho, Moriyama-ku, Nagoya, Aichi 463-0024, Japan**Manufacturing Sites:** 1. M/s ASAHI Intecc Co., Ltd., 3-100 Akatsuki-cho, 489-0071 Seto, Aichi Japan.
2. M/s Asahi Intecc Thailand, Thai Factory 158/1 M005 Bangkadi Industrial Park, Tiwanon Road, Tambol, Bangkadi Amphur Muang, Pathumthani 12000, Thailand
 |
|  | 00024-PR-MD | 08-03-2018 | -do- | ASAHI PTCA Guide Wire | -do- |
|  | 00025-PR-MD | 08-03-2018 | -do- | ASAHI Hypersion Corony Guide Catheter | -do- |
|  | 00026-PR-MD | 08-03-2018 | -do- | ASAHI Corsair Microcatheter | -do- |
|  | 00027-PR-MD | 08-03-2018 | -do- | ASAHI Caravel Microcatheter | **Manufacturer:** M/s ASAHI Intecc Co., Ltd., 1703 Wakita cho, Moriyama-ku, Nagoya, Aichi 463-0024, Japan**Manufacturing Site:** M/s Asahi Intecc Thailand, Thai Factory 158/1 M005 Bangkadi Industrial Park, Tiwanon Road, Tambol, Bangkadi Amphur Muang, Pathumthani 12000, Thailand |
|  | 00028-PR-MD | 13-03-2018 | M/s Pak Punjab Cardex Medical System, 202, 2nd Floor, Eden Heights, Jail Road,Lahore. | DESyne Novolimus Eluting Coronary Stent System | **Legal Manufacturer:** M/s Elixir Medical Corporation-870 Hermosa Drive, Sunnyvale, California 94085, USA.**Manufactured By:** M/s VistaMed Limited, IDA Business and Technology Park, Carrick-on-Shannon, Co., Leitrim, Ireland |
|  | 00029-PR-MD | 13-03-2018 | -do- | DESyne X2 Novolimus Eluting Coronary Stent System | -do- |
|  | 00030-PR-MD | 13-03-2018 | -do- | Disposable Pressure Transducer | **Manufactured By:** M/s Zheijiang Haisheng Medical Device Co., Ltd., No.8 Zhenyuan Road, Paojiang Industrial Zone, Shaoxing City, Zhejiang Province, China. |
|  | 00031-PR-MD | 13-03-2018 | -do- | Breathing Circuit (Disposable Breathing Filter) | -do- |
|  | 00032-PR-MD | 13-03-2018 | -do- | DESolve Novolimus TM Eluting Bioresobable Coronary Stent System | **Manufactured By:** M/s Elixir Medical Corporation-870 Hermosa Drive, Sunnyvale, California 94085, USA. |
|  | 00033-PR-MD | 13-03-2018 | -do- | BIOTEQ Angiography Catheter | **Manufactured By:** M/s Bioteque Corporation, 5f-6, No.23, Sec1, Chang-An E. Road, Taipei104, Taiwan, R.O.C. |
|  | 00034-PR-MD | 13-03-2018 | M/s A&E Medical, 323-Ata Turk Block New Garden Town,Lahore. | Electrocatheters for temporary endocardial pacing and electrophysiological studies "SPIKE LC S" 2-poles | **Manufactured By:** M/s FIAB S.p.A., Via P. Costoli 4, 50039 Vicchio (FI) Italy. |
|  | 00035-PR-MD | 13-03-2018 | -do- | External Cardiac Stimulator "Easypace" and provided related accessories | **-do-** |
|  | 00036-PR-MD | 13-03-2018 | -do- | NIC 1.1 PTCA Balloon Catheters | **Manufactured By:** M/s SIS Medical Distribution AG, Hungerbuelstrasse 12a, 8500 Frauenfeld, Switzerland. |
|  | 00037-PR-MD | 13-03-2018 | -do- | Inflation Device | -do- |
|  | 00038-PR-MD | 13-03-2018 | -do- | OPN NC PTCA Balloon Catheters | -do- |
|  | 00039-PR-MD | 13-03-2018 | -do- | TIN PTCA Balloon Catheters | -do- |
|  | 00040-PR-MD | 13-03-2018 | -do- | BEO NC PTCA Balloon Catheters | -do- |
|  | 00041-PR-MD | 13-03-2018 | -do- | NIC Nano PTCA Balloon Catheters | -do- |
|  | 00042-PR-MD | 13-03-2018 | -do- | Haemofilter | **Manufactured By:** M/s ALLMED MEDICAL GmbH Mittelbacher Str. 18 01896 Pulsnitz, Germany. |
|  | 00043-PR-MD | 15-03-2018 | M/s ACP Systems, 13 & 23 Navel Fleet Club, Iqbal (SJ) Shaheed Road, Karachi. | Hancock TM II Bioprosthesis, Model T510 (Mitral) | **Name of Owner Operator:** M/s MEDTRONIC INC. 710 Medtronic Parkway, Minneapolis, MN 55432, USA**Name of Manufacturer/ Distributor:** M/s Medtronic Heart Valves Division 1851 EAST DEERE AVE. Santa Ana, CA 92705, USA |
|  | 00044-PR-MD | 15-03-2018 | -do- | Hancock TM II Bioprosthesis, Model T505 (Aortic) | -do- |
|  | 00045-PR-MD | 15-03-2018 | -do- | Tsmics1\_Octopus Nuvo Tissue Stabilizer | **Name of Owner Operator:** M/s MEDTRONIC INC. 710 Medtronic Parkway, Minneapolis, MN 55432, USA**Name of Manufacturer/ Distributor:** M/s Medtronic Perfusion Systems 7611 Northland Dr Minnespolis, MN 55428, USA**Name of Manufacturer/ Contract Manufacturer:**M/s Vention Medical Inc 620 WATSON SW GR. MI 49504, USA |
|  | 00046-PR-MD | 15-03-2018 | -do- | TS2000\_Octopus Evolution Tissue Stabilizer | -do- |
|  | 00047-PR-MD | 15-03-2018 | -do- | 29700\_Urchin Heart Positioner | -do- |
|  | 00048-PR-MD | 15-03-2018 | -do- | 29800\_Starfish 2 Heart Positioner | -do- |
|  | 00049-PR-MD | 15-03-2018 | -do- | HP102\_Starfish NS Heart Positioner | -do- |
|  | 00050-PR-MD | 15-03-2018 | -do- | HP3000\_Starfish Evo Heart Positioner | -do- |
|  | 00051-PR-MD | 15-03-2018 | -do- | HP3500\_Urchin Evo Heart Positioner | -do- |
|  | 00052-PR-MD | 15-03-2018 | -do- | Clearview Intracoronary Shunts | -do- |
|  | 00053-PR-MD | 15-03-2018 | M/s Alliance Medical,12-B, 1st Floor, Agro Flats, Shadman,Lahore. | Central Venous Catheters and Catheterization Kit | **Manufactured By:** M/s Biosensors International Pte. Ltd. 36 Jalan Tukang 619266 Singapore. |
|  | 00054-PR-MD | 15-03-2018 | -do- | Biosensors Accutrans Pressure Monitoring System | -do- |
|  | 00055-PR-MD | 15-03-2018 | -do- | Biosensors Thermodilution Catheters and Biotrays | -do- |
|  | 00056-PR-MD | 15-03-2018 | -do- | Biosensors (Embolectomy) Catheters | **Manufactured By:** M/s Biosensors International Pte. Ltd. 36 Jalan Tukang 619266 Singapore. |
|  | 00057-PR-MD | 15-03-2018 | -do- | PTCA Balloon Catheter Clever (Semi-Compliant) | **Manufactured By:** M/s Conic Vascular Technology SA, Via Carlo Maderno 23, CH-6901 Lugano, Switzerland. |
|  | 00058-PR-MD | 15-03-2018 | -do- | PTCA Balloon Catheter NC Clever (Non-Compliant) | -do- |
|  | 00059-PR-MD | 15-03-2018 | M/s Health Care International, Office No.42, Street No. 171, Mohallah Shehbaz Park,Medina Colony, Baghbanpura, Lahore. | Option Retrievable Vena Cava Filter System (IVC Filter) | **Manufactured By:** M/s Argon Medical Devices, 5151 Headquarters Drive, Suite 210 Plano, Texas 75024, USA |
|  | 00060-PR-MD | 15-03-2018 | -do- | Atrieve TM Vascular Snare Kit | -do- |
|  | 00061-PR-MD | 15-03-2018 | -do- | PTFE Coated Guidewire | -do- |
|  | 00062-PR-MD | 15-03-2018 | -do- | Vesolock Surgical Clips & Appliers | **Manufactured By:** M/s Vesocclude Medical, LLC 7429 ACC Blvd, Suite 101 Raleigh, NC 27617 USA |
|  | 00063-PR-MD | 15-03-2018 | -do- | Small, Narrow, Medium, Large, Wide, Titanium Ligation Clips | -do- |
|  | 00064-PR-MD | 15-03-2018 | -do- | Delivery Sheath | **Manufactured By:** M/s Oscor Inc. Dessoto Boulevard No. 3816 Palm Harbor, Florida, USA |
|  | 00065-PR-MD | 15-03-2018 | -do- | Steerable Guiding Sheaths Destino® | -do- |
|  | 00066-PR-MD | 15-03-2018 | -do- | Angiographic Catheters Classic­ | -do- |
|  | 00067-PR-MD | 15-03-2018 | -do- | Boosting Catheter | **Manufactured By:** M/s Qxmedical. LLC 2820 Patton Rd Roseville, MN 55113 USA |
|  | 00068-PR-MD | 16-03-2018 | M/s Cor-Med,2nd Floor, 38/62 Rahman Plaza, Bank Road,Saddar,Rawalpindi | Prelude® Sheath Introducers | **Manufacturer/Manufacturing Site:** M/s MERIT MEDICAL SYSTEMS, INC. 1600 WEST MERIT PKWY, South Jordan, UT 84095, USA. |
|  | 00069-PR-MD | 16-03-2018 | -do- | InQwireTM Guide Wirescodes chcked against DEC0075 | -do- |
|  | 00070-PR-MD | 16-03-2018 | -do- | BasixTouchTM Inflation Device | -do- |
|  | 00071-PR-MD | 16-03-2018 | -do- | Concierge Judkins Right/Left Guiding Catheters | **Manufacturer/Manufacturing Site:** M/s Merit Medical Systems, Inc. 14646 Kirby Drive Houston, TX 77047, USA.**Name of Distributor/legal Manufacturer:** M/s Merit Medical Systems, Inc. 1600 West Merit PKWY, South Jordan, UT 84095, USA. |
|  | 00072-PR-MD | 16-03-2018 | -do- | Reslove TM Locking (RLC) Drainage Catheters | -do- |
|  | 00073-PR-MD | 16-03-2018 | -do- | Reslove TM Billary Locking Drainage Catheters | -do- |
|  | 00074-PR-MD | 16-03-2018 | -do- | Performa Judkins Left/Right Catheters (Angiography Catheters) | -do- |
|  | 00075-PR-MD | 16-03-2018 | M/s B. Braun Pakistan (Pvt) Ltd, The Forum, Suite 216, Kh-e-Jami, Block 9, Clifton, Karachi. | Angiodyn Manifold Kit Pakistan | **Legal Manufacturer:** M/s B. Braun Melsungen AG, Carl-Braun-StraBe-1, 34212, Melsungen, Germany.**Manufactured By:** M/s AESCULAP CHIFA Sp. z.o.o. ul. Tysiaclecia 14, 64-300 Nowy Tomysl, Poland. |
|  | 00076-PR-MD | 16-03-2018 | -do- | Intradyn PTCA F8 | -do- |
|  | 00077-PR-MD | 16-03-2018 | -do- | Intradyn Arterial with J3 Guide Wire | -do- |
|  | 00078-PR-MD | 16-03-2018 | -do- | Intradyn Arterial Puncture Needle (Seldinger) | -do- |
|  | 00079-PR-MD | 16-03-2018 | -do- | Angiodyn Guide Wire | -do- |
|  | 00080-PR-MD | 16-03-2018 | -do- | Angiodyn Contrast Saver Tubing | -do- |
|  | 00081-PR-MD | 16-03-2018 | -do- | Angiodyn High Pressure Tubing | -do- |
|  | 00082-PR-MD | 16-03-2018 | -do- | Angiodyn Contrast Saver Spike | -do- |
|  | 00083-PR-MD | 16-03-2018 | -do- | Angiodyn Manifold | -do- |
|  | 00084-PR-MD | 03-04-2018 | M/s Digital Imaging Systems, 121-Habitat Apartments, Shadman II, Ghaus-ul-Azam Road,Lahore. | PrimeWire Prestige Plus Pressure Guide Wire | **Name and complete address of Manufacturers:** 1. M/s Volcano Corporation 2870 Kilgore Rd. Rancho Cordova, CA 95670 USA
2. M/s Volcano Corporation by Volcarica S.R.L.Coyol Free Zone and Business Park Building B37 Coyol, Alajuela Costa Rica None.
 |
|  | 00085-PR-MD | 03-04-2018 | -do- | Verrata Pressure Guide Wire | -do- |
|  | 00086-PR-MD | 03-04-2018 | -do- | Verrata Plus Pressure Guide Wire | -do- |
|  | 00087-PR-MD | 03-04-2018 | M/s Maxims Medical,534-H-Block, Phase-5, Street No.13, Defense DHA,Lahore. | E Magic Plus Drug Eluting Stent | **Manufactured By:** M/s Eurocor GmbH Ln Den Dauen 6a, 53117 Bonn, Germany. |
|  | 00088-PR-MD | 03-04-2018 | -do- | Dior Drug Eluting Balloon Dilatation Catheter | -do- |
|  | 00089-PR-MD | 03-04-2018 | -do- | Be Graft Coronary Stent Graft System | **Manufactured By:**M/s Bentley InnoMed GmbH Lotzenacker 25, 72379 Hechingen, Germany |
|  | 00090-PR-MD | 03-04-2018 | -do- | Amazonia Sir Drug Eluting Stent | **Manufactured By:** M/s Minvasys 7, rue du Fosse Blanc, 92230 Gennevilliers, France. |
|  | 00091-PR-MD | 03-04-2018 | -do- | Stemi Cath Thrombus Aspiration Catheter | -do- |
|  | 00092-PR-MD | 03-04-2018 | -do- | Yangtze u PTCA Balloon Dilatation Catheter | -do- |
|  | 00093-PR-MD | 03-04-2018 | -do- | Yangtze NC Non-Complaint PTCA Balloon Dilatation Catheter | -do- |
|  | 00094-PR-MD | 03-04-2018 | M/s Alliance Medical,12-B, 1st Floor, Agro Flats, Shadman,Lahore. | Aries Three Stop IV Administration System | **Manufactured By:** M/s Aries Srl, Via XXV Luglio 43-41037 Mirandola (MO), Italy. |
|  | 00095-PR-MD | 03-04-2018 | -do- | Temporary External Pacemaker Pace 203H | **Manufactured By:** M/s Osypka AG, Earl-H, Wood Strasse 1, 79618 Rheinfelden, Germany. |
|  | 00096-PR-MD | 03-04-2018 | -do- | Temporary External Pacemaker Pace 101H with Accessories | -do- |
|  | 00097-PR-MD | 03-04-2018 | -do- | Osypka Electrode Connection Cable | -do- |
|  | 00098-PR-MD | 03-04-2018 | -do- | Osypka Temporary Myocardial Stimulation Electrode (Pacing Wire) | -do- |
|  | 00099-PR-MD | 03-04-2018 | -do- | VACS Percutaneous Valvuloplasty Balloon Catheter | -do- |
|  | 00100-PR-MD | 03-04-2018 | -do- | Lassos Snare Catheter and Cathcher Forcep | -do- |
|  | 00101-PR-MD | 03-04-2018 | M/s Global Marketing Services,111, Hali Road Westridge 1,Rawalpindi. | ADROIT Guiding Catheters | **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. Catle Circuito Interior Norte# 1820 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua Mexico CP 32574 |
|  | 00102-PR-MD | 03-04-2018 | -do- | INFINTI Diagnostic Catheter | -do- |
|  | 00103-PR-MD | 03-04-2018 | -do- | SUPER TORQUE® Angiographic Catheter | -do- |
|  | 00104-PR-MD | 03-04-2018 | -do- | TEMP® AQUA® Angiographic Catheter | -do- |
|  | 00105-PR-MD | 03-04-2018 | -do- | VistaBriteTip/® Guiding Catheter | -do- |
|  | 00106-PR-MD | 03-04-2018 | -do- | AVANTI® + Introducers | -do- |
|  | 00107-PR-MD | 03-04-2018 | -do- | BRITE TIP ® Sheath Introducer | -do- |
|  | 00108-PR-MD | 03-04-2018 | -do- | Poweflex ® Pro PTA Dilatation Catheter | -do- |
|  | 00109-PR-MD | 03-04-2018 | -do- | TEMPO ® Angiographic Catheter | -do- |
|  | 00110-PR-MD | 03-04-2018 | -do- | SUPER TORQUE® Plus Angiographic Catheter | -do- |
|  | 00111-PR-MD | 03-04-2018 | -do- | HIGH FLOW Angiographic Catheter | -do- |
|  | 00112-PR-MD | 03-04-2018 | -do- | TrapEase Permanent Vena Cava Filter | **Legal Manufacturer:** M/s Cordis Cashel, Cahir Road, Cashel, Co. Tipperary, Ireland.**Manufacturing Site:**M/s Cordis De Mexico S.A. DE C.V. Calle Circuito Interior Norte# 1820 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua Mexico CP 32574 |
|  | 00113-PR-MD | 03-04-2018 | -do- | SMART Flex Vascular Stent | -do- |
|  | 00114-PR-MD | 03-04-2018 | -do- | SABER TM PTA Balloon Dilatation Catheter | -do- |
|  | 00115-PR-MD | 03-04-2018 | -do- | MAXI LD PTA Dilatation Catheter | -do- |
|  | 00116-PR-MD | 03-04-2018 | -do- | OPTEASE Retrievable Vena Cava Filter and Introduction Kit | -do- |
|  | 00117-PR-MD | 03-04-2018 | -do- | S.M.A.R.T. ® Control® Nitinol Stent System | -do- |
|  | 00118-PR-MD | 03-04-2018 | -do- | SHINOBI® Plus Steerable Guidewires | **Legal Manufacturer:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA.**Manufacturing Site:**1. M/s Lake Region Medical 340 Lake Hazeltine Dr Chaska, MN 55318 USA
2. M/s Lake Region Medical Limited Butlersland New Ross, Wexford Ireland
 |
|  | 00119-PR-MD | 03-04-2018 | -do- | ATW Marker Intermediate Guidewires | -do- |
|  | 00120-PR-MD | 03-04-2018 | -do- | Emerald Diagnostic Guidewires | -do- |
|  | 00121-PR-MD | 03-04-2018 | -do- | EMPIRA RX PTCA Dilatation Catheter | **Name of Distributor:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014,USA.**Manufacturing Site:**M/s Creganna Medical, 1353 Dell Avenue, Campbell, CA 95008, USA |
|  | 00122-PR-MD | 03-04-2018 | -do- | EMPIRA NC RX PTCA Dilatation Catheter | -do- |
|  | 00123-PR-MD | 03-04-2018 | -do- | CARTO 3 Mapping and Navigation System (Electrophysiology Mapping and Navigation System) | **Manufactured By:** M/s Biosense Webster, Inc., 33 Technology Drive, Irvine, CA 92618 USA. |
|  | 00124-PR-MD | 03-04-2018 | -do- | ACUNAV Diagnostic Ultrasound Catheters (Electrophysiology Catheters) | **Manufactured By:** M/s Siemens Medical Solutions USA, Inc. 685 East Middlefield Road Mountain View, CA 94043, USA.**Manufacturing Site:**M/s Siemens Healthcare Ltd., 2nd & 3rd Venture Building Pohang Technopark, 394, Jigok-ro, Nam-gu Pohang-si, Gyeongsangbugdo KOREA, REPUBLIC OF 790-834.**Name of Distributor:** M/s Biosense Webster, Inc. 15715 Arrow Hwy. Irwindale, CA 91706, USA |
|  | 00125-PR-MD | 03-04-2018 | -do- | Thermocool Navigational Therapeutic Catheters-Irrigated (Uni & Bidirectional) | **Owner Operator:** M/s Biosense Webster, Inc. 33 Technology Drive Irvine, CA 92618 USA.**Manufacturer(s):**1. M/s Biosense Webster, Inc. 15715 Arrow Hwy. Irwindale, CA 91706 USA
2. M/s Biosense Webster, Inc. Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua 32574 Mexico
 |
|  | 00126-PR-MD | 03-04-2018 | -do- | Thermocool Non-Navigational Therapeutic Catheters-Irrigated (Uni & Bidirectional) | -do- |
|  | 00127-PR-MD | 03-04-2018 | -do- | NAVISTAR Navigational Therapeutic RMT Catheters | -do- |
|  | 00128-PR-MD | 03-04-2018 | -do- | NAVISTAR Navigational Therapeutic Catheters- Irrigated (Unidirectional) | -do- |
|  | 00129-PR-MD | 03-04-2018 | -do- | NAVISTAR Navigational Therapeutic Catheters-Non-Irrigated (Uni & Bidirectional) | -do- |
|  | 00130-PR-MD | 03-04-2018 | -do- | CELSIUS Non-Navigational Therapeutic RMT Catheters | -do- |
|  | 00131-PR-MD | 03-04-2018 | -do- | CELSIUS Non-Navigational Therapeutic Catheters Irrigated | -do- |
|  | 00132-PR-MD | 03-04-2018 | -do- | CELSIUS Non-Navigational Therapeutic Catheters Non-Irrigated (Uni & Bidirectional) | -do- |
|  | 00133-PR-MD | 03-04-2018 | M/s Advance Cardiology System,12, Al-Sehat Centre, Rafique HJ Shaheed Road, Hotel Regent Plaza,Karachi. | Apollo Balloon Dilatation Catheter | **Legal Manufacturer:**M/s BrosMed Medical B.V. Hogerbrinkerweg 31 3871KM Hoevelaken, The Netherlands.**Manufactured By:**M/s BrosMed Medical Co., Ltd., 15th Building, SMES Venture Park, Songshan Lake Hi Tech Industrial Dev. Zone Dongguan, Guangdong 523808 China. |
|  | 00134-PR-MD | 03-04-2018 | -do- | Artimes Balloon Dilatation Catheter | -do- |
|  | 00135-PR-MD | 03-04-2018 | M/s Anwar &Sons,Apartment No.10, Safari Villas-2, Commercial Complex, Phase-7, Bahria Town,Rawalpindi. | Emosist® | **Manufactured By:** M/s Mascia Brunell SpA, Viale Monza 272-20128 Milano, Italy. |
|  | 00136-PR-MD | 03-04-2018 | -do- | Bone Wax (Sterile Surgical Haemostatic) | **Manufactured By:** M/s SMI-AG, Steinerberg 8, 4780 St. Vith, Belgium. |
|  | 00138-PR-MD | 04-04-2018 | M/s A.H Distributors,House No. CB-708, Lane No.5, Peshawar Road,Rawalpindi. | MSM PTCA Balloon Catheter (Semi-Compliant PTCA Balloon Catheter) | **Manufactured By:**M/s Micro Science Medical AG Meisenweg 5, D-75443 Oetishiem, Germany. |
|  | 00139-PR-MD | 04-04-2018 | -do- | MSM CIS CoCr (Balloon Expandable Coronary Cobalt Chromium Stent System) | -do- |
|  | 00140-PR-MD | 04-04-2018 | -do- | MSM DES Sirolimus (Balloon Expandable Coronary Drug Eluting Stent System) | -do- |
|  | 00141-PR-MD | 04-04-2018 | M/s Genus,220, Block: 3, DMCHS, S. Abdul Tawwab Road,Karachi. | INMEDFLATOR PTCA Inflation Device | **Manufactured By:**M/s Umbra Medical Products, Inc. 8930 Roan Lane East Inverness, Florida 34450, USA |
|  | 00142-PR-MD | 04-04-2018 | -do- | RadialstatTM Transradial Sheath Kit | -do- |
|  | 00143-PR-MD | 04-04-2018 | -do- | CL-EliteTM Hemostatis Valve Introducer | -do- |
|  | 00144-PR-MD | 04-04-2018 | -do- | C-LineTM (Central Venous Catheter Kit) | -do- |
|  | 00145-PR-MD | 04-04-2018 | -do- | HAWKTM CTO PTCA Balloon Catheter | -do- |
|  | 00146-PR-MD | 04-04-2018 | M/s Cardiac Care,848-C, Shadman-I,Lahore. | Multicath-3 | **Manufactured By:**M/s Vygon, 5 rue de Adeline 95440 Ecouen, France. |
|  | 00147-PR-MD | 04-04-2018 | -do- | Prolongateuru Lectrocath Extension Line | -do- |
|  | 00148-PR-MD | 04-04-2018 | -do- | Arterial Leadercath | -do- |
|  | 00149-PR-MD | 04-04-2018 | -do- | Multicath-6204 17 | -do- |
|  | 00150-PR-MD | 04-04-2018 | -do- | Multicath 4 | **Manufactured By:**M/s Vygon GmbH & Co. KG Prager Ring 100 52070 Aachen Germany**Imported from:** M/s Vygon, 5 rue de Adeline 95440 Ecouen, France. |
|  | 00151-PR-MD | 04-04-2018 | -do- | Multistar 4+ | -do- |
|  | 00152-PR-MD | 04-04-2018 | M/s Sakuf Trading,2nd Floor, G-34 Phase - I, Commercial Area, DHA,Lahore. | Leo+ (Self Expandable Stent) | **Manufactured By:**M/s BALT Extrusion SAS, 10 rue de la Croix Vigneron- Montmorency (95160) – France |
|  | 00153-PR-MD | 04-04-2018 | -do- | Cirrus (Flow Coils) | -do- |
|  | 00154-PR-MD | 04-04-2018 | -do- | SPI (Intravascular Spirales) | -do- |
|  | 00155-PR-MD | 04-04-2018 | -do- | Baltacci Selective and Hyperselective Catheter | -do- |
|  | 00156-PR-MD | 04-04-2018 | -do- | Magic Selective and Hyperselective Catheter | -do- |
|  | 00157-PR-MD | 04-04-2018 | -do- | Vasco+ Selective and Hyperselective Catheter  | -do- |
|  | 00158-PR-MD | 04-04-2018 | -do- | Fargo Selective and Hyperselective Catheter | -do- |
|  | 00159-PR-MD | 04-04-2018 | -do- | Eclipse Selective and Hyperselective Catheter | -do- |
|  | 00160-PR-MD | 04-04-2018 | -do- | Mechanical Detachment System (MDS Embolization Devices) | -do- |
|  | 00161-PR-MD | 04-04-2018 | -do- | Sonic Selective and Hyperselective Catheter | -do- |
|  | 00162-PR-MD | 04-04-2018 | -do- | Gold Embolization Latex Detachable Balloon | -do- |
|  | 00163-PR-MD | 04-04-2018 | -do- | Silk+mono Diameter (Intracranial Self-Expandable Stent) | -do- |
|  | 00164-PR-MD | 04-04-2018 | -do- | Copernic/ Eclipse (Temporary Occlusion Catheters) | -do- |
|  | 00165-PR-MD | 04-04-2018 | -do- | Cristal Balloon (Angioplasty Catheters) | -do- |
|  | 00166-PR-MD | 04-04-2018 | M/s Cor-Med,2nd Floor, 38/62 Rahman Plaza, Bank Road, Saddar,Rawalpindi. | One Step TM Centesis Catheter | **Legal Manufacturer:** M/s Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan UT 84095 USA.**Manufacturing Site:**  M/s Merit Maquiladora Mexico, S. DE R. L. DE C.V. Avenida Sor Juana Ines de la Cruz 19970 Interior B, Edificio 2, Parque Industrial Frontera Tijuana, Baja California MEXICO 22630 |
|  | 00167-PR-MD | 04-04-2018 | -do- | MAK/Mini Access Kits (Micro Puncture Set) | -do- |
|  | 00168-PR-MD | 04-04-2018 | -do- | Impress Angiographic Catheters | **Legal Manufacturer:**  M/s Merit Medical Systems, Inc 1600 West Merit Parkway South JordanUT 84095 USA.**Manufacturing Sites:** M/s Merit Medical Systems, Inc. 14646 Kirby Drive Houston, TX USA 77047. |
|  | 00169-PR-MD | 04-04-2018 | -do- | EN Snare® Endovascular Snare System | **Legal Manufacturer**:M/s Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan UT 84095 USA.**Manufacturing Site:**  M/s MERIT MEDICAL IRELAND, LTD, Parkmore Business Park West Glaway, Galway IRELAND 0000 |
|  | 00170-PR-MD | 04-04-2018 | -do- | Merit Hydrophilic Guide Wire (Laureate) TM | -do- |
|  | 00171-PR-MD | 04-04-2018 | -do- | Merit Maestro TM Micro Catheters | **Manufactured By** : M/s Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan UT 84095 USA. |
|  | 00172-PR-MD | 04-04-2018 | -do- | ASAP Aspiration Catheter Kit | -do- |
|  | 00173-PR-MD | 04-04-2018 | -do- | Bearing TM nsPVA Embolization Particles | **Legal Manufacturer:**  M/s Merit Medical Systems, Inc 1600 West Merit Parkway South Jordan UT 84095 USA.**Manufacturing Site:** M/s BIOSPHERE MEDICAL SA, Parc des Nations – Paris Nord 2, 383 rue de la Belle Etoile 95700 ROISSY EN FRANCE FRA Roissy, Val- dOise FRANCE 95700. |
|  | 00174-PR-MD | 04-04-2018 | -do- | iht DEStiny BD Abluminal/Sirolimus Eluting Coronary Stent System | **Manufactured By:** M/s IHT (Iberhospitex, S.A.) Avda Catalunya 4- 08185 LLica de vall – Barcelona Spain |
|  | 00175-PR-MD | 04-04-2018 | -do- | Crossway® PTCA Semicompliant Balloon | -do- |
|  | 00176-PR-MD | 04-04-2018 | -do- | Crossway NC® PTCA Dilatation Catheter | -do- |
|  | 00177-PR-MD | 04-04-2018 | -do- | Manifold | **Name of Owner Operator:**  M/s Deroyal Industries, Inc. 200 Debusk LN. Powell, TN 37849, USA**Manufactured by: (i)** M/s Deroyal Industries, Inc. 200 Debusk LN. Powell, TN 37849, USA**(ii)** M/s Deroyal Industries, Inc. 1703 Highway 33 S New Tazewell, TN 37825 USA |
|  | 00178-PR-MD | 04-04-2018 | M/s Imtiaz Brothers,Suite No. 7B, 2nd Floor Abrar Business Center,25 Main Wahdat Road, Lahore. | Actalyke (Act Cartridge all Type) | **Name of Manufacturer/Distributor(s):**1. M/s Helena Laboratories, Corp. 1530 Lindbergh Dr Beaumont, TX 77707 USA
2. M/s Helena Laboratories, Corp, 3795 Washington Blvd, Beaumont, TC 77705 USA
 |
|  | 00179-PR-MD | 04-04-2018 | -do- | XEMEX (IABP Balloon Plus/Intra-Aortic Balloon Catheter all type) | **Manufacturing Site:** M/s ZEON Medical Inc. Takaoka Plant 422-1 Futagamishin, Takaoka-shi, Toyama 933-0981, Japan**Marketed By:** M/s ZEON MEDICAL Inc., 2-4-1 Shiba-Koen, Minato-ku, Tokyo 105-0011 Japan |
|  | 00180-PR-MD | 04-04-2018 | -do- | MEDICA (Hemoconcentrator Set / Haemofilter All Sizes) | **Legal Manufacturer / Manufacturing Site:** M/s MEDICA S.p.A., Via degli Artigiani 7- 41036 Medolla (MO) Italy |
|  | 00181-PR-MD | 06-04-2018 | M/s Cardiovascular Medical Systems,Office No. 210, Block J-2, Johar Town, Iqbal Town, Lahore. | ISTAR PTCA Balloon Catheter  | **Manufactured By:** M/s AMG International GmbH, BoschstraBe 16, 21423 Winsen-Luhi, Germany |
|  | 00182-PR-MD | 06-04-2018 | -do- | ISOLV Aspiration Catheter  | -do- |
|  | 00183-PR-MD | 06-04-2018 | -do- | Allunga PTA Balloon Catheter | **Manufactured By:**M/s QualiMed Innovative Medizinprodukte GmbH BoschstraBe 16 21423, Winsen, Germany |
|  | 00184-PR-MD | 09-04-2018 | M/s ACP Systems, 13 & 23 Navel Fleet Club, Iqbal (SJ) Shaheed Road, Karachi. | Medtronic Aortic Punch | **Owner Operator:**M/s Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432, USA**Manufactured By:** 1. M/s Medtronic Heart Valves Division 1851 EAST DEERE Ave. Santa Ana, CA 92705 USA
2. M/s Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210 MEXICO
 |
|  | 00185-PR-MD | 09-04-2018 | -do- | Duran AnCoreTM Annuloplasty Ring 620R | -do- |
|  | 00186-PR-MD | 09-04-2018 | -do- | CG FutureTM Annuloplasty Ring, 638R | -do- |
|  | 00187-PR-MD | 09-04-2018 | -do- | Profile 3DTM Annuloplasty Ring, 680R | -do- |
|  | 00188-PR-MD | 09-04-2018 | -do- | Simiplici-T TM Annuloplasty System, 670-670100 | -do- |
|  | 00189-PR-MD | 09-04-2018 | -do- | Contour 3D TM Annuloplasty Ring, 690R | -do- |
|  | 00190-PR-MD | 09-04-2018 | -do- | Duran AnCoreTM Annuloplasty Handle, 7620H | -do- |
|  | 00191-PR-MD | 09-04-2018 | -do- | BBP241- Affinity Pixie TM Hollow Fiber Oxygenator and Cardiotomy/Venous Resevoir with Balance TM Biosurface | **Owner Operator**: M/s Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN 55432, USA**Manufactured By**:M/s Medtronic Perfusion Systems 7611, Northland Dr Minneapolis, MN 55428 USA**Manufacturing Facility:**1. M/s Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210 Mexico
2. M/s Medtronic Perfusion Systems 18501 E Plaza Dr Parker, Co 80134 USA
 |
|  | 00192-PR-MD | 09-04-2018 | -do- | BB841-Affinity Fusion® Oxygenator with Integrated Arterial Filter | -do- |
|  | 00193-PR-MD | 09-04-2018 | -do- | 541T-Affinity® NT Integrated CVR Oxygenator with Trillium® Biosurface | -do- |
|  |  00194-PR-MD | 09-04-2018 | -do- | MYOtherm XP® 4:1T Cardioplegia Delivery System with Trillium® Biopassive Surface | -do- |
|  | 00195-PR-MD | 12-04-2018 | M/s Ferozsons Laboratories Limited,P.O Ferozsons Amangarh,Nowshera, KPK. | Wallgraft TM Over the Wire Endoprosthesis with UnistepTM Plus Delivery System | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:**M/s Boston Scientific Limited Ballybrit Business Park, Galway, Ireland |
|  | 00196-PR-MD | 12-04-2018 | -do- | XXL Esophageal Balloon Dilatation Catheter | -do- |
|  | 00197-PR-MD | 12-04-2018 | -do- | Wallstent-Uni TM Endoprosthesis Self Expanding Stent | -do- |
|  | 00198-PR-MD | 12-04-2018 | -do- | Express TM LD Vascular Over the Wire Premounted Stent System | -do- |
|  | 00199-PR-MD | 12-04-2018 | -do- | XXL Vascular Balloon Dilatation Catheter | -do- |
|  | 00200-PR-MD | 12-04-2018 | -do- | Epic TM Over the Wire Self-Expanding Nitinol Stent with Delivery System | -do- |
|  | 00201-PR-MD | 12-04-2018 | -do- | Wanda TM Balloon Dilatation Catheter | -do- |
|  | 00202-PR-MD | 12-04-2018 | -do- | Rubicon TM 18 Support Catheter | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way.**Manufacturer:**M/s Boston Scientific Corporation, Two Scimed Place Maple Grove, MN 55311, USA |
|  | 00203-PR-MD | 12-04-2018 | -do- | Express TM Vascular SD Premounted Stent System | -do- |
|  | 00204-PR-MD | 12-04-2018 | -do- | Threader TM Monorail TM Micro-dilatation Catheter | -do- |
|  | 00205-PR-MD | 12-04-2018 | -do- | Rubicon TM 35 Support Catheter | -do- |
|  | 00206-PR-MD | 12-04-2018 | -do- | Stingray TM Catheter | -do- |
|  | 00207-PR-MD | 12-04-2018 | -do- | CrossBoss TM Catheter | -do- |
|  | 00208-PR-MD | 12-04-2018 | -do- | Rubicon TM 14 Support Catheter | -do- |
|  | 00209-PR-MD | 12-04-2018 | -do- | NC Emerge Monorail PTCA Dilatation Catheter | -do- |
|  | 00210-PR-MD | 12-04-2018 | -do- | FilterWire EZ TM Embolic Protection System | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:**M/s Boston Scientific Corporation, 2546 First Street, Propark, El Coyol, Alajuela, Costa Rica |
|  | 00211-PR-MD | 12-04-2018 | -do- | ChoICE TM PT Guidewire with ICE TM Hydrophilic Coating | **Legal Manufacturer/ Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer/ Manufacturing Site:** M/s Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, La Aurora, Costa Rica |
|  | 00212-PR-MD | 12-04-2018 | -do- | PT Graphix TM Guidewire with ICE TM Hydrophilic Coating | -do- |
|  | 00213-PR-MD | 12-04-2018 | -do- | ChoICE TM Magnet Guidewire with ICE TM Hydrophilic Coating | -do- |
|  | 00214-PR-MD | 12-04-2018 | -do- | RotaWire TM and wireClip Torquer TM | -do- |
|  | 00215-PR-MD | 12-04-2018 | -do- | PT2 TM Guidewire | -do- |
|  | 00216-PR-MD | 12-04-2018 | -do- | ChoICE TM Guidewire with ICE TM Hydrophilic Coating | -do- |
|  | 00217-PR-MD | 12-04-2018 | -do- | V-14TM Control Wire TM Guidewire with ICE TM Hydrophilic Coating | -do- |
|  | 00218-PR-MD | 12-04-2018 | -do- | Blazer II XP Temperature Ablation Catheter | -do- |
|  | 00219-PR-MD | 12-04-2018 | -do- | Blazer II HTD Temperature Ablation Catheter | -do- |
|  | 00220-PR-MD | 12-04-2018 | -do- | Blazer Prime XP Temperature Ablation Catheters | -do- |
|  | 00221`-PR-MD | 12-04-2018 | -do- | Intella Tip MiFi XP Ablation Catheters | -do- |
|  | 00222-PR-MD | 12-04-2018 | -do- | Blazer Prime HTD Temperature Ablation Catheters | -do- |
|  | 00223-PR-MD | 12-04-2018 | -do- | IntellaNav Open-Irrigated Ablation Catheters | -do- |
|  | 00224-PR-MD | 12-04-2018 | -do- | Orbiter ST Bidirectional Steerable Diagnostic Catheter | -do- |
|  | 00225-PR-MD | 12-04-2018 | -do- | Dynamic Unidirectional Steerable Diagnostic Catheter | -do- |
|  | 00226-PR-MD | 12-04-2018 | -do- | Orbiter PV Diagnostic Mapping Catheter | -do- |
|  | 00227-PR-MD | 12-04-2018 | -do- | Blazer II Temperature Ablation Catheter | -do- |
|  | 00228-PR-MD | 12-04-2018 | -do- | Viking Fixed Curve Diagnostic Catheter | -do- |
|  | 00229-PR-MD | 12-04-2018 | -do- | EP XT Unidirectional Steerable Diagnostic Catheter | -do- |
|  | 00230-PR-MD | 12-04-2018 | -do- | Pericardiocentesis Kit | -do- |
|  | 00231-PR-MD | 12-04-2018 | -do- | Dynamic XT Unidirectional Steerable Diagnostic Catheter | -do- |
|  | 00232-PR-MD | 12-04-2018 | -do- | Radia Bidirectional Steerable Diagnostic Catheter | -do- |
|  | 00233-PR-MD | 12-04-2018 | -do- | Blazer Open-Irrigated Ablation Catheter | -do- |
|  | 00234-PR-MD | 12-04-2018 | -do- | V-18 TM Control Wire TM Guidewire with ICE TM Hydrophilic Coating | -do- |
|  | 00235-PR-MD | 12-04-2018 | -do- | Choice TM PT Magnet Guidewire with ICE TM Hydrophilic Coating | -do- |
|  | 00236-PR-MD | 12-04-2018 | -do- | Polaris X Steerable Decapolar Mapping Catheters | -do- |
|  | 00237-PR-MD | 12-04-2018 | -do- | Blazer DX-20 Diagnostic Catheters | -do- |
|  | 00238-PR-MD | 12-04-2018 | -do- | IntellaMap Orion TM High Resolution Mapping Catheter | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturing Site:** M/s Boston Scientific Corporation,150 Baytech Drive San Jose, CA 95134, USA |
|  | 00239-PR-MD | 12-04-2018 | -do- | Contour TM Embolization Particles | **Owner Operator:** 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 |
|  | 00240-PR-MD | 12-04-2018 | -do- | Renegade Fiber Braided Microcatheter | -do- |
|  | 00241-PR-MD | 12-04-2018 | -do- | Rotalink TM Plus Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device | -do- |
|  | 00242-PR-MD | 12-04-2018 | -do- | Rotalink TM Burr Exchangeable Burr Catheter | -do- |
|  | 00243-PR-MD | 12-04-2018 | -do- | Encore TM 26 Advantage Kit Inflation Device Kit | -do- |
|  | 00244-PR-MD | 12-04-2018 | -do- | Encore TM 26 Inflation Device | -do- |
|  | 00245-PR-MD | 12-04-2018 | -do- | Rotalink TM Advancer Catheter Advancing Device | -do- |
|  | 00246-PR-MD | 12-04-2018 | -do- | AngioJet TM Spiroflex TM MONORAIL TM VG Thrombectomy Set | **Owner Operator:** 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 |
|  | 00247-PR-MD | 12-04-2018 | -do- | AngioJet TM Distaflex TM Over the Wire Thrombectomy Set | -do- |
|  | 00248-PR-MD | 12-04-2018 | -do- | AngioJet TM Spiroflex TM MONORAIL TM Thrombectomy Set | -do- |
|  | 00249-PR-MD | 12-04-2018 | -do- | Guidezilla TM Guide Extension Catheter | -do- |
|  | 00250-PR-MD | 12-04-2018 | -do- | Imager II Angiographic Catheters | **Legal Manufacturer:** M/s Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760-1537, USA.**Manufactured By:** M/s Teleflex Medical, Unit 7 8 & 9, Annacotty Business Park, Annacotty, Co., Limerick, Ireland |
|  | 00251-PR-MD | 12-04-2018 | -do- | RunWay TM Guide Catheter | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturing Site:** 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. |
|  | 00252-PR-MD | 13-04-2018 | M/s 4S International,Suite No. 205, 2nd Floor Al-Fiza Glass Tower,Rashid Minhas Road Block 10-A, Gulshan e Iqbal Road,Karachi. | Coronary Angioplasty Catheter Fryderyk | **Manufactured By:** M/s Balton Sp. z.o.o., 00-496 Warszawa, ul. Nowy Swiat 7/14, Poland**Manufacturing Site:** 03-152 Warszawa, ul. Modlinska 294, Poland |
|  | 00253-PR-MD | 13-04-2018 | -do- | Cobalt-Chromium Coronary Stent Coflexus | -do- |
|  | 00254-PR-MD | 13-04-2018 | -do- | ALEX Cobalt Chromium Sirolimus Eluting Coronary Stent with Delivery System, Rapid Exchange | **Manufactured By:** M/s Balton Sp. z.o.o., 00-496 Warszawa, ul. Nowy Swiat 7/14, Poland |
|  | 00255-PR-MD | 13-04-2018 | -do- | Introducer Version braided or non-braided kits to introduce and exchange catheters and endocavitary electrodes, with hemostasis valve | -do- |
|  | 00256-PR-MD | 13-04-2018 | M/s Sadqain Health Care Pvt Ltd, Safari Villas II, Commercial Complex, 3rd Floor, Bahria Town; Phase-7,Rawalpindi. | TrachSeal adult endotracheal closed suction system | **Manufactured by:** M/s Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. |
|  | 00257-PR-MD | 13-04-2018 | -do- | InterTherm Micro HMEF with Leur Port-sterile | -do- |
|  | 00258-PR-MD | 18-04-2018 | M/s Pak Punjab Cardex Medical System, 202, 2nd Floor, Eden Heights, Jail Road,Lahore. | BIOTEQ Sheath Introducer Kit | **Manufactured By:** M/s Bioteque Corporation, 5F-6, No.23, Sec1, Chang-An E. Road, Taipei 104, Taiwan, R.O.C. |
|  | 00259-PR-MD | 18-04-2018 | M/s Global Marketing Services, 111, Hali Road Westridge 1,Rawalpindi. | Kaneka PTCA Catheter CO-R7, IKAZUCHI Zero | **Marketed By:**M/s Kaneka Corporation, 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288, Japan**Manufacturing Site:**M/s Kaneka Corporation Osaka Plant 5-1-1,Torikai-Nishi, Settsu-City, Osaka, 566-0072, Japan |
|  | 00260-PR-MD | 18-04-2018 | -do- | Kaneka PTCA Catheter CO-R6, Raiden 3 | -do- |
|  | 00261-PR-MD | 18-04-2018 | -do- | Webster Deflectable Catheters with Auto ID | **Owner Operator:** M/s Biosense Webster, Inc. 33 Technology Drive Irvine, CA 92618 USA.**Manufacturer(s):** 1. M/s Biosense Webster, Inc. 15715 Arrow Hwy. Irwindale, CA 91706 USA.
2. M/s Biosense Webster, Inc. Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua 32574 Mexico.
 |
|  | 00262-PR-MD | 18-04-2018 | -do- | Webster Deflectable Catheters | -do- |
|  | 00263-PR-MD | 18-04-2018 | -do- | Webster Fixed Diagnostic Catheters | -do- |
|  | 00264-PR-MD | 18-04-2018 | -do- | Webster Quadrapoles Fixed Catheters with Auto ID | -do- |
|  | 00265-PR-MD | 18-04-2018 | -do- | EZ Steer Thermocool Non-Nav Catheter | -do- |
|  | 00266-PR-MD | 18-04-2018 | -do- | EZ Steer Bi-Directional Catheters | -do- |
|  | 00267-PR-MD | 18-04-2018 | -do- | LASSO Mapping Catheters | -do- |
|  | 00268-PR-MD | 18-04-2018 | -do- | LASSO 2515 NAV Variable Catheters | -do- |
|  | 00269-PR-MD | 18-04-2018 | -do- | AVAIL Fixed Curve Catheters | -do- |
|  | 00270-PR-MD | 18-04-2018 | -do- | EZ Steer Thermocool Non-Nav Catheter | -do- |
|  | 00271-PR-MD | 18-04-2018 | -do- | DECANAV Catheters | -do- |
|  | 00272-PR-MD | 18-04-2018 | -do- | Pentaray ® Catheters | -do- |
|  | 00273-PR-MD | 18-04-2018 | -do- | LASSO 2515 Variable Circular Mapping Catheter | -do- |
|  | 00274-PR-MD | 18-04-2018 | -do- | LASSO NAV Duo Loop eco Catheters | -do- |
|  | 00275-PR-MD | 18-04-2018 | -do- | LASSO Electrophysiology Catheters with Auto ID | -do- |
|  | 00276-PR-MD | 18-04-2018 | -do- | LASSO NAV Catheters | -do- |
|  | 00277-PR-MD | 18-04-2018 | -do- | Webster CS Catheters with auto ID | -do- |
|  | 00278-PR-MD | 18-04-2018 | M/s Healthline Pharmaceutical Pvt. Ltd.Office No. 402, 4th Floor Al Hafeez Heights Gulberg III,Lahore. | Celox Granules | **Manufactured By:** M/s Medtrade Products Ltd., Electra House CreweBusiness Park Crewe Cheshire CW1 6GL, UK |
|  | 00279-PR-MD | 18-04-2018 | -do- | Celox RAPID Gauze | -do- |
|  | 00280-PR-MD | 18-04-2018 | M/s Universal Enterprises,29/3, Co-Operative Housing Society, Stadium Road, Karachi. | Capiox RX Oxygenator | **Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture, Japan**Marketed By:** M/s Terumo Corporation, 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan. |
|  | 00281-PR-MD | 18-04-2018 | -do- | Capiox FX Oxygenator | -do- |
|  | 00282-PR-MD | 18-04-2018 | -do- | Tubing Set with X-Coating (Optional) pre-connected to Hemoconcentrator | **Manufactured By:**M/s Terumo Europe N.V. Interleuvenlaan 40, 3001 Leuven, Belgium |
|  | 00283-PR-MD | 18-04-2018 | -do- | Blood Cardioplegia System with Pre-Connected CAPIOX® Cardioplegia (CP50) | -do- |
|  | 00284-PR-MD | 18-04-2018 | M/s Interex Company,195 Block 7/8, KMCHS, Justice Inamullah Road,Karachi. | Tyshak Catheter | **Owner Operator / Manufacturer:** M/s NUMED, Inc. 2880 Main St. Hopkinton, NY 12965,USA. |
|  | 00285-PR-MD | 18-04-2018 | -do- | Z-MED Catheters | -do- |
|  | 00286-PR-MD | 18-04-2018 | -do- | Tyshak II Catheter | -do- |
|  | 00287-PR-MD | 18-04-2018 | -do- | CP Stent | -do- |
|  | 00288-PR-MD | 18-04-2018 | -do- | Covered Mounted CP Stent | -do- |
|  | 00289-PR-MD | 18-04-2018 | -do- | Z-5 Atrioseptostomy Catheter | -do- |
|  | 00290-PR-MD | 18-04-2018 | -do- | Multi Track Catheter | -do- |
|  | 00291-PR-MD | 18-04-2018 | -do- | BIB Catheter | -do- |
|  | 00292-PR-MD | 26-04-2018 | M/s Muller & Phipps Pakistan (Pvt) Ltd.,Plot No. 208, 208/1, Sector No. 23, Korangi Industrial Area, Karachi. | Ligaclip® MCA Multiple Clip Appliers | **Legal Manufacturer:** M/s Ehticon, Endo Surgery, LLC 475 Calle C Guaynabo, PR 00969 USA.**Manufactured By:** 1. M/s Ethicon Endo Surgery S.A. De C.V. Planta II, Calle Durango No.2751 Colonia Lote Bravo Ciudad Juarez, Chihuahua Mexico 32575
2. M/s Ethicon Endo Surgery, Inc. 3801 University Blvd SE Albuquerque, NM 87106 USA
3. M/s Ethicon Endo Surgery S.A. De C.V. Avenida De Las Torres No.7125 Colonia Salvarcar 118, Cuidad Juarez, Chihuahua 32580 Mexico
4. M/s Ethicon Endo Surgery, Inc. 4545 Creek Rd. Cincinnati, OH 45242 USA
 |
|  | 00293-PR-MD | 26-04-2018 | -do- | Ligaclip® Endoscopic Clip Appliers | -do- |
|  | 00294-PR-MD | 26-04-2018 | -do- | Ligamax TM 5mm Endoscopic Multiple Clip Applier | -do- |
|  | 00295-PR-MD | 26-04-2018 | -do- | Ligaclip® Endoscopic Rotating Multiple Clip Appliers | -do- |
|  | 00296-PR-MD | 26-04-2018 | -do- | Ligaclip® Clip Appliers | -do- |
|  | 00297-PR-MD | 26-04-2018 | -do- | Ligaclip® Extra Ligation Clips | -do- |
|  | 00298-PR-MD | 26-04-2018 | -do- | Surgicel TM Nu-Knit Absorbable Hemostats | **Legal Manufacturer / Manufacturing Site:** M/s Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR 00754 USA. |
|  | 00299-PR-MD | 26-04-2018 | -do- | Surgicel TM Absorbable Hemostats | -do- |
|  | 00300-PR-MD | 26-04-2018 | -do- | Surgicel TM Snow TM Absorbable Hemostats | -do- |
|  | 00301-PR-MD | 26-04-2018 | -do- | Surgicel TM Fibrillar Absorbable Hemostats | -do- |
|  | 00302-PR-MD | 26-04-2018 | -do- | Temporary Cardiac Pacing Wire (w/Wave) | -do- |
|  | 00303-PR-MD | 26-04-2018 | -do- | TFE Polymer Pledgets | **Legal Manufacturer :**M/s Ethicon, LLC. 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR 00969 USA.**Manufacturing Site:** M/s Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez, Chihuahua C.P. 32575 Mexico |
|  | 00304-PR-MD | 26-04-2018 | -do- | Bone Wax | **Legal Manufacturer :**M/s Ethicon, LLC. 475 C Street Los Frailes Industrial Park, Suite 401 Guaynabo, PR 00969 USA.**Manufacturing Site:** M/s Johnson & Johnson do Brasil Ind. Com. De Prod. p/Saude Ltda, Rodovia Presidente Dutra KM 154 Sao Jose Dos Campos, Sao Paulo 12240-908 Brazil |
|  | 00305-PR-MD | 26-04-2018 | -do- | Surgicel® | **Manufactured By:** M/s Ehticon, SARL, Puits-Godet 20, CH-2000 Neuchatel, Switzerland. |
|  | 00306-PR-MD | 26-04-2018 | M/s SES Associates,61 Bank Square Model Town,Lahore. | SUNA - Stent Delivery System Cobalt Chromium Coronary Stent Delivery System | **Manufactured By:** M/s QualiMed Innovative Medizinprodukte GmbH BoschstraBe 16 21423, Winsen, Germany. |
|  | 00307-PR-MD | 26-04-2018 | -do- | Magma Rapamycin Eluting Coronary Stent System | -do- |
|  | 00308-PR-MD | 26-04-2018 | -do- | Nit-Occlud ASD (Artrial Septal Defect) | **Manufactured By:** M/s pfm Medical mepro GmbH Am Soterberg 4 66620 Nonnweiler-Otzenhausen, Germany. |
|  | 00309-PR-MD | 26-04-2018 | -do- | Multi Snare | -do- |
|  | 00310-PR-MD | 26-04-2018 | -do- | Nit-Occlud PFO (Persistent Foramen Ovale) | -do- |
|  | 00311-PR-MD | 26-04-2018 | -do- | Nit-Occlud VSD (Ventricular Septal Defects) | -do- |
|  | 00312-PR-MD | 26-04-2018 | -do- | Nit-Occlud® PDA: spiral system for interventional closure of PDA (Patent Ductus Arteriosus) | -do- |
|  | 00313-PR-MD | 26-04-2018 | M/s Quality Health Care Services, 148-Ejaz Park, Model Town Link Road, Lahore. | ASD Occluder (Arterial Septal Defect) | **Manufactured By:** M/s Lifetech Scientific (Shenzhen) Co., Ltd. 3rd Floor 1-5, Cybio Electronic Building, Langshan 2nd Street, North Area of High Tech Park, Nanshan District, Shenzhen 518057, P.R. China. |
|  | 00314-PR-MD | 26-04-2018 | -do- | PDA Occluder (Patent Ductus Arteriosus) | -do- |
|  | 00315-PR-MD | 26-04-2018 | -do- | SteerEase Introducer | -do- |
|  | 00316-PR-MD | 26-04-2018 | -do- | VSD Occluder (Ventricular Septal Defect) | -do- |
|  | 00317-PR-MD | 26-04-2018 | M/s A.H Distributors,House No. CB-708, Lane No.5, Peshawar Road,Rawalpindi. | Champion TM PTCA Guide Wires | **Manufactured By:** M/s SP Medical A/S Mollevej 1, DK-4653 Karise, Denmark |
|  | 00318-PR-MD | 26-04-2018 | -do- | Accoat Guide Wires | -do- |
|  | 00319-PR-MD | 26-04-2018 | M/s Genus,220 Block: 3, DMCHS, S. Abdul Tawwab Road,Karachi. | Osprey TM Diagnostic Angiographic Catheter | **Manufactured By:** M/s Umbra Medical Products, Inc. 8930 Roan Lane East Inverness, Florida 34450, USA |
|  | 00320-PR-MD | 26-04-2018 | M/s A&E Medical, 323-Ata Turk Block New Garden Town,Lahore. | Namic Angiographic Manifold | **Legal Manufacturer:** M/sAngio Dyamics, Inc, also DBA Navilyst Medical, Inc, 26 Forest St. Marlborough, MA 01752, USA**Manufacturer:** Angio Dyamics, Inc, also DBA Navilyst Medical, inc., 10 Glens Falls Technical Park Glens Falls, NY 12801, USA |
|  | 00321-PR-MD | 26-04-2018 | -do- | Namic Angiography Control Syringe | -do- |
|  | 00322-PR-MD | 26-04-2018 | -do- | Angiographic Guide wire | **Legal Manufacturer:** M/sAngio Dyamics, Inc, also DBA Navilyst Medical, Inc, 26 Forest St. Marlborough, MA 01752, USA**Manufactured By:** M/s C.R. BARD Inc., 289 Bay Rd., Queensbury, NY 12804, USA |
|  | 00323-PR-MD | 26-04-2018 | -do- | Catheters Percutaneous (Accu Sheath Introducer) | **Manufactured By:** M/s Sungwon Medical Co., Ltd. 199, Taeseongtabyeon-ro, Gangnae-myeon, Heungdeok-gu, Cheongju-si, Chungbuk, Korea |
|  | 00324-PR-MD | 26-04-2018 | M/s ACP Systems, 13 & 23 Navel Fleet Club, Iqbal (SJ) Shaheed Road, Karachi | DLP® Silicone Single Stage Venous Cannulae with Inflatable Cuff | **Name of Owner Operator:** M/s MEDTRONIC INC. 710 Medtronic Parkway, Minneapolis, MN 55432, USA**Name of 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 C.P. 22210 Mexico |
|  | 00325-PR-MD | 26-04-2018 | -do- | DLP® Single Stage Venous Cannulae with Right Anlged Tip | -do- |
|  | 00326-PR-MD | 26-04-2018 | -do- | DLP® Right Angle Single Stage Venous Cannulae | -do- |
|  | 00327-PR-MD | 26-04-2018 | -do- | DLP® Malleable Single Stage Venous Cannulae | -do- |
|  | 00328-PR-MD | 26-04-2018 | -do- | DLP® Single Stage Venous Cannulae with Basket Tip | -do- |
|  | 00329-PR-MD | 26-04-2018 | -do- | VC2® Atrial Caval Venous Cannulae | -do- |
|  | 00330-PR-MD | 26-04-2018 | -do- | MiARTM Cannulae | -do- |
|  | 00331-PR-MD | 26-04-2018 | -do- | DLP® Dual Lumen Aortic Root Cannulae with Vent Line | -do- |
|  | 00332-PR-MD | 26-04-2018 | -do- | DLP® Aoritc Root Cannulae | -do- |
|  | 00333-PR-MD | 26-04-2018 | -do- | DLP® Aortic Root Cannulae with Vent Line | -do- |
|  | 00334-PR-MD | 26-04-2018 | -do- | DLP® Silicone Coronary Artery Ostila Cannulae | -do- |
|  | 00335-PR-MD | 26-04-2018 | -do- | DLP® Flexible Arch Cannulae | -do- |
|  | 00336-PR-MD | 26-04-2018 | -do- | DLP® Metal Tip Arterial Cannulae | -do- |
|  | 00337-PR-MD | 26-04-2018 | -do- | DLP® Curved Tip Arterial Cannulae with One Piece Wirewood Body | -do- |
|  | 00338-PR-MD | 26-04-2018 | -do- | DLP® Curved Tip Cannulae | -do- |
|  | 00339-PR-MD | 26-04-2018 | -do- | Select 3D® II Arterial Cannulae | -do- |
|  | 00340-PR-MD | 26-04-2018 | -do- | Select Series® Angled Tip Arterial Cannulae | -do- |
|  | 00341-PR-MD | 26-04-2018 | -do- | DLP® Straight Tip Arterial Cannulae | -do- |
|  | 00342-PR-MD | 26-04-2018 | -do- | DLP® Pediatric One Piece Arterial Cannulae | -do- |
|  | 00343-PR-MD | 26-04-2018 | -do- | Select Series® Straight Tip Arterial Cannulae | -do- |
|  | 00344-PR-MD | 26-04-2018 | -do- | DLP® PVC RCSP Cannulae with Auto-Inflate Cuff | -do- |
|  | 00345-PR-MD | 26-04-2018 | -do- | DLP® Silicone RCSP Cannulae with Auto-Inflate Cuff | -do- |
|  | 00346-PR-MD | 26-04-2018 | -do- | DLP® Coronary Artery Ostila Cannulae | -do- |
|  | 00347-PR-MD | 26-04-2018 | -do- | DLP® Silicone RCSP Cannulae with Manual Inflate Cuff | -do- |
|  | 00348-PR-MD | 26-04-2018 | -do- | MiRCSP Cannulae (Minimally Invasive Retrograde Cannula) | -do- |
|  | 00349-PR-MD | 26-04-2018 | -do- | Gundry® Silicone RCSP Cannulae with Manual Inflate Cuff | -do- |
|  | 00350-PR-MD | 26-04-2018 | -do- | DLP® High Flow Coronary Artery Ostial Cannulae | -do- |
|  | 00351-PR-MD | 26-04-2018 | -do- | Sensia SR (Model SESR01) | **Legal Manufacturer:** M/s MEDTRONIC INC. 710 Medtronic Parkway, Minneapolis, MN 55432, USA**Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. |
|  | 00352-PR-MD | 26-04-2018 | -do- | Sensia SR (Model SES01) | -do- |
|  | 00353-PR-MD | 26-04-2018 | -do- | Sensia (Model SEDR01) | -do- |
|  | 00354-PR-MD | 26-04-2018 | -do- | Ensura SR MRI SureScan (Model EN1SR01) | -do- |
|  | 00355-PR-MD | 26-04-2018 | -do- | Ensura DR MRI SureScan (Model EN1DR01) | -do- |
|  | 00356-PR-MD | 26-04-2018 | -do- | Adapta SR (Model ADSR01) | -do- |
|  | 00357-PR-MD | 26-04-2018 | -do- | Adapta DR (Model ADDR01) | -do- |
|  | 00358-PR-MD | 26-04-2018 | -do- | Reveal Linq (Model LNQ11) | -do- |
|  | 00359-PR-MD | 26-04-2018 | -do- | Protecta XT VR (Model D354VRG) | -do- |
|  | 00360-PR-MD | 26-04-2018 | -do- | Protecta XT VR (Model D354VRM) | -do- |
|  | 00361-PR-MD | 26-04-2018 | -do- | Protecta XT DR (Model D354DRG) | -do- |
|  | 00362-PR-MD | 26-04-2018 | -do- | Protecta XT DR (Model D354DRM) | -do- |
|  | 00363-PR-MD | 26-04-2018 | -do- | Evera XT VR (Model DVBB2D4) | -do- |
|  | 00364-PR-MD | 26-04-2018 | -do- | Protecta XT CRT-D (Model D354TRG) | -do- |
|  | 00365-PR-MD | 26-04-2018 | -do- | Protecta XT CRT-D (Model D354TRM) | -do- |
|  | 00366-PR-MD | 26-04-2018 | -do- | Viva XT CRT-D (Model DTBA2D1) | -do- |
|  | 00367-PR-MD | 26-04-2018 | -do- | Brava Quad CRT-D (Model DTBC2Q1) | -do- |
|  | 00368-PR-MD | 26-04-2018 | -do- | Evera XT DR (Model DDBB2D4) | -do- |
|  | 00369-PR-MD | 26-04-2018 | -do- | Syncra CRT-P (Model C2TR01) | -do- |
|  | 00370-PR-MD | 27-04-2018 | M/s Ferozsons Laboratories Limited,P.O Ferozsons Amangarh,Nowshera, KPK | LeVeenTM Standard Needle Electrode System | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:** M/s Boston Scientific Coporation 780 Brookside Drive Spencer, IN 47460 USA |
|  | 00371-PR-MD | 27-04-2018 | -do- | Vascular Dilator Set | -do- |
|  | 00372-PR-MD | 27-04-2018 | -do- | SoloistTM Single Needle Electrode | -do- |
|  | 00373-PR-MD | 27-04-2018 | -do- | LeVeenTM CoAccessTM Needle Electrode System | -do- |
|  | 00374-PR-MD | 27-04-2018 | -do- | LeVeenTM SuperSlimTM Needle Electrode System | -do- |
|  | 00375-PR-MD | 27-04-2018 | -do- | FlowswitchTM HP High Pressure Flow Control Device | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:** M/s Boston Scientific Limited Bussiness and Technology Park Model Farm Road, Cork, Ireland |
|  | 00376-PR-MD | 27-04-2018 | -do- | Equalizer Occlusion Balloon Catheter | -do- |
|  | 00377-PR-MD | 27-04-2018 | -do- | GatewayTM Plus Y Adaptor | -do- |
|  | 00378-PR-MD | 27-04-2018 | -do- | 2cm Peripheral Cutting BalloonTM Over the Wire Microsurgical Dilatation Device | **Legal Manufacturer:** M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MN 01752 USA.**Manufacturer:**M/s Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland |
|  | 00379-PR-MD | 27-04-2018 | -do- | InnovaTM Self-Expanding Stent System | **Legal Manufacturer:** M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MN 01752 USA.**Manufacturer:**M/s Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311 USA |
|  | 00380-PR-MD | 27-04-2018 | -do- | SterlingTM Over-the-Wire PTA Balloon Dilatation Catheter | -do- |
|  | 00381-PR-MD | 27-04-2018 | -do- | Constellation Advanced Mapping Catheters | **Owner Operator:** M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MN 01752 USA.**Manufacturer:** M/s Boston Scientific de Costa Rica, S.R.L. |
|  | 00382-PR-MD | 27-04-2018 | -do- | Amplatz Super StiffTM Guidewires | **Owner Operator:** M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MN 01752 USA.**Manufacturer:** M/s Boston Scientific Corporation 302 Parkway, Global Park La Aurora, Heredia Costa Rica. |
|  | 00383-PR-MD | 27-04-2018 | -do- | RF 3000TM Radiofrequency Generator | **Owner Operator:** M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MN 01752 USA.**Manufacturer:** M/s Stellartech Research Corp. 560 Cottonwood Dr Milpitas, CA 95035 USA |
|  | 00384-PR-MD | 08-05-2018 | M/s Ferozsons Laboratories Limited,P.O Ferozsons Amangarh, Nowshera, KPK | 2D Helical-35 Fibered Platinum Coil | **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 |
|  | 00385-PR-MD | 08-05-2018 | -do- | VortX-35 Fibered Platinum Coil | -do- |
|  | 00386-PR-MD | 08-05-2018 | -do- | Coil Pusher-16 | -do- |
|  | 00387-PR-MD | 08-05-2018 | -do- | Occlusion Balloon Catheter | -do- |
|  | 00388-PR-MD | 08-05-2018 | -do- | Multi-Loop-18 Fibered Platinum Coil | -do- |
|  | 00389-PR-MD | 08-05-2018 | -do- | JETSTREAMTM XC OVER-THE-WIRE Atherectomy Catheter | -do- |
|  | 00390-PR-MD | 08-05-2018 | -do- | DirexionTM FathomTM-16 System Pre-Loaded Torqueable Microcatheter | -do- |
|  | 00391-PR-MD | 08-05-2018 | -do- | JETSTREAMTM SC OVER-THE-WIRE Atherectomy Catheter | -do- |
|  | 00392-PR-MD | 08-05-2018 | -do- | DirexionTM HI-FLOTM Torqueable Microcatheter | -do- |
|  | 00393-PR-MD | 08-05-2018 | -do- | DirexionTM Torqueable Microcatheter | -do- |
|  | 00394-PR-MD | 08-05-2018 | -do- | DirexionTM HI-FLOTM FathomTM-16 System Pre-Loaded Torqueable Microcatheter | -do- |
|  | 00395-PR-MD | 08-05-2018 | -do- | JETSTREAMTM PVCN 100 Console | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer/Manufacturing Site:** M/s Boston Scientific Corporation, 150 Baytech Drive, San Jose, CA 95134 USA |
|  | 00396-PR-MD | 08-05-2018 | -do- | AngioJetTM Ultra 5000A Console | -do- |
|  | 00397-PR-MD | 08-05-2018 | -do- | AngioJetTM SolentTM Omni OVER-THE-WIRE Thrombectomy Set | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer/Manufacturing Site:** M/s Boston Scientific Corporation, Two Scimed Place MAPLE GROVE, MN 01752 USA |
|  | 00398-PR-MD | 08-05-2018 | -do- | Carotid WALLSTENTTM MONORAILTM Closed Cell Self-Expanding Stent | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:**M/s Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland |
|  | 00399-PR-MD | 08-05-2018 | -do- | Accustick Needle Introducer Needle | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:** M/s Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela 20904 COSTA RICA |
|  | 00400-PR-MD | 08-05-2018 | M/s Health Tec,10-B, Street 24, Valley Road, Westridge I,Rawalpindi. | Xlimus Sirolimus Eluting Coronary Stent System | **Manufactured By:** M/s CARDIONOVUM Sp. z o.o. 00-834 Warszawa, ul. Panska 73, Poland. |
|  | 00401-PR-MD | 15-05-2018 | M/s Safeway Systems Pakistan,Flat No. 4, 2nd Floor Amna Shopping Centre Misrial Road,Rawalpindi. | Aortic Perfusion Cannulae | **Manufacturer:** M/s Cardiomed Supplies Inc. 199 Saint David Street Lindsay, Ontario K9V 5K7, Canada. |
|  | 00402-PR-MD | 15-05-2018 | -do- | Venous Cannulae | -do- |
|  | 00403-PR-MD | 15-05-2018 | -do- | Arterial Perfusion Cannulae | -do- |
|  | 00404-PR-MD | 24-05-2018 | M/s Cor-Med,2nd Floor, 38/62 Rahman Plaza, Bank Road, Saddar,Rawalpindi. | AegisyTM Vena Cava Filter | **Legal Manufacturer:** M/s LifeTech Scientific (Europe) Cooperatief UA, Kruisdonk 64-A, 6222PH Maastricht, The Netherlands.**Manufacturer:** M/s LifeTech Scientific (Shenzhen) Co., Ltd Floor 1-5, Cybio Electronic Building, Langshan 2nd Str., North Area of High-tech Park, Nanshan District 518057 Shenzhen China. |
|  | 00405-PR-MD | 24-05-2018 | -do- | CeraTM PDA Occluder | -do- |
|  | 00406-PR-MD | 24-05-2018 | -do- | CeraFlexTM ASD Occluder | -do- |
|  | 00407-PR-MD | 24-05-2018 | -do- | SteerEaseTM Introducer | -do- |
|  | 00408-PR-MD | 24-05-2018 | -do- | AcuMarkTM Sizing Balloon | -do- |
|  | 00409-PR-MD | 24-05-2018 | -do- | FuStarTM Steerable Introducer | -do- |
|  | 00410-PR-MD | 24-05-2018 | -do- | SeQureTM Snare System | -do- |
|  | 00411-PR-MD | 24-05-2018 | -do- | AnkuraTM TAA Stent Graft System | -do- |
|  | 00137-PR-MD | 24-05-2018 | M/s A.H Distributors,House No. CB-708, Lane No.5, Peshawar Road,Rawalpindi. | URSA Angiography Catheters | **Manufactured By:**M/s Curatia Medical Ltd., 198 Xiangjiang Road New District Suzhou, Jiangsu, 215011 China**Name of Distributor:** M/s Curatia Medical Co., 3227 Kifer Rd Santa Clara, CA 95051 USA |
|  | 00412-PR-MD | 24-05-2018 | M/s Digital Imaging Systems,121-Habitat Apartments, Shadman II, Ghaus-ul-Azam Road,Lahore. | Xience Sierra Everolimus Eluting Coronary Stent System | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA**Manufacturer:** M/s Abbott Vascular, Cashel Road,Clonmel, Co. Tipperary, Ireland. |
|  | 00413-PR-MD | 24-05-2018 | M/s Life Cares,M-20, Mezzanine Floor, Falaknaz Plaza,Natha Khan Bridge, Shahra e Faisal,Karachi. | Leader Plus TM (Cobalt Chromium Coronary Stent System) | **Manufacturer:**M/s Rontis Corporation S.A., Bahnhofstrasse 7, CH-6301 Zug, Switzerland |
|  | 00414-PR-MD | 24-05-2018 | -do- | Abrax TM (Sirolimus-Eluting Biodegradable Polymer Coronary Stent System) | -do- |
|  | 00415-PR-MD | 24-05-2018 | M/s Ham International,Mezzanine Floor Plot No. LS2, St No. 9, Block No. 15,KDA Scheme 36, Gulistan e Johar,Karachi. | Guide Wires | **Manufactured By:** M/s Shunmei Medical Co., Ltd., R401 of Building B, No.8 of 1st Jinglong Road, Baolong Industrial Zone, LongGang District, 518116 Shenzhen, Guangdong China. |
|  | 00416-PR-MD | 24-05-2018 | -do- | Manifolds | -do- |
|  | 00417-PR-MD | 24-05-2018 | -do- | Balloon Inflation Devices | -do- |
|  | 00418-PR-MD | 24-05-2018 | -do- | Introducer Set | -do- |
|  | 00419-PR-MD | 24-05-2018 | -do- | Hemostasis Valve Set | -do- |
|  | 00420-PR-MD | 24-05-2018 | -do- | Connecting Tubing | -do- |
|  | 00421-PR-MD | 24-05-2018 | M/s Genus,220, Block: 3, DMCHS, S. Abdul Tawwab Road,Karachi. | AdvanceTM Diagnostic Guide Wire | **Manufactured By:** M/s UMBRA Medical Products, Inc., 8930 E Roan Ln Inverness, FL 34450, USA. |
|  | 00422-PR-MD | 24-05-2018 | M/s Sakuf Trading,2nd Floor, G-34 Phase - I, Commercial Area, DHA,Lahore. | Optima Coil System | **Manufacturer/Owner Operator:** M/s Balt USA, LLC 29 Parker Irvine, CA 92618 USA |
|  | 00423-PR-MD | 24-05-2018 | -do- | Barricade Coil System | -do- |
|  | 00424-PR-MD | 24-05-2018 | M/s Intek Corporation,Office No. 30, First Floor Al Amin Plaza, The Mall,Rawalpindi. | MicroPlex® Coil System (MCS) | **Manufacturer/Manufacturing Site:**1. M/s MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA.
2. M/s MicroVention Costa Rica, S.R.L. Zona Franca Coyol, Alajuela, Costa Rica.
 |
|  | 00425-PR-MD | 24-05-2018 | -do- | Headway 17 Advanced Micro Catheter | -do- |
|  | 00426-PR-MD | 24-05-2018 | -do- | Scepter C Occlusion Balloon Catheter | -do- |
|  | 00427-PR-MD | 24-05-2018 | -do- | Chaperon Guiding Catheter System | **Manufacturer/Manufacturing Site:**1. M/s MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA.
2. M/s Ashitaka Factory of Terumo Corp. 150 Maimaigi-Cho Fujinomiya, Sizuoka 418-0015, Japan.
 |
|  | 00428-PR-MD | 24-05-2018 | -do- | Traxcess Guidewire | -do- |
|  | 00429-PR-MD | 24-05-2018 | -do- | SOFIA TM Distal Access Catheter / Guiding Catheter | **Manufacturer:** M/s MicroVention Europe, 30 bis rue du Vieil Abreuvoir, 78100 Saint - Germain-en-Laye, France. |
|  | 00430-PR-MD | 24-05-2018 | -do- | LVIS Intraluminal Support Device | -do- |
|  | 00431-PR-MD | 24-05-2018 | -do- | CASPERTM Carotid Artery Stent System | -do- |
|  | 00432-PR-MD | 24-05-2018 | -do- | Radifocus Glidewire Advantage | **Marketed by:** M/s Terumo Corporation, 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan.**Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation 150, Maimaigi-cho, Fujinomiya City, Shizouka Prefecture, Japan. |
|  | 00433-PR-MD | 24-05-2018 | -do- | Runthrough NS PTCA Guide Wire | -do- |
|  | 00434-PR-MD | 24-05-2018 | -do- | Radifocus Guide Wire M | -do- |
|  | 00435-PR-MD | 24-05-2018 | -do- | Finecross MG (Coronary Micro-Guide Catheter) | -do- |
|  | 00436-PR-MD | 24-05-2018 | -do- | Tsunami (Gold Coronary Stent System) | **Legal Manufacturer/ Manufacturing Site:** M/s Terumo Corporation, 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan. |
|  | 00437-PR-MD | 24-05-2018 | -do- | Radifocus Introducer II | **Marketed by:** M/s Terumo Corporation, 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan.**Manufacturing Site:** 1. M/s Ashitaka Factory of Terumo Corporation 150, Maimaigi-cho, Fujinomiya City, Shizouka Prefecture, Japan.
2. M/s Terumo Vietnam Co., Ltd., Lot 44 A-B-C, Quang Minh Industrial Zone, Me Linh District, Hanoi City, Vietnam.
 |
|  | 00438-PR-MD | 05-06-2018 | M/s Ferozsons Laboratories Limited,P.O Ferozsons Amangarh,Nowshera, KPK. | Starter Guidewire | **Legal Manufacturer:** M/s Lake Region Medical, 340 Lake Hazeltine Drive, Chaska, MN 55318, USA.**Manufacturer:**M/s Lake Region Medical Limited, Butlerslan, New Ross, Co. Wexford, Ireland |
|  | 00439-PR-MD | 05-06-2018 | -do- | ZIPwireTM Hydrophilic Guide Wire | **Legal Manufacturer:** M/s Lake Region Medical, 340 Lake Hazeltine Drive, Chaska, MN 55318, USA.**Manufacturer:**M/s Boston Scientific Corporation, 300 Boston Scientifc Way Marlborough, MN 01752 USA |
|  | 00440-PR-MD | 05-06-2018 | -do- | ThruwayTM Guidewires | -do- |
|  | 00441-PR-MD | 05-06-2018 | -do- | VictoryTM 14 Polymer Tip Guidewire with Hydrophilic Coating | **Legal Manufacturer/ Manufacturer:** M/s Lake Region Medical Limited, Butlerslan, New Ross, Co. Wexford, Ireland. |
|  | 00442-PR-MD | 05-06-2018 | -do- | VictoryTM 18 Polymer Tip Guidewire with Hydrophilic Coating | -do- |
|  | 00443-PR-MD | 05-06-2018 | -do- | RangerTM SL Over the Wire Paclitaxel Coated PTA Balloon Catheter | **Manufacturer:** M/s Hemoteq AG, Adenauerstabe 15 52146 Wurselen Germany. |
|  | 00444-PR-MD | 05-06-2018 | -do- | AgentTM MonorailTM Paclitaxel Coated PTCA Balloon Catheter | -do- |
|  | 00445-PR-MD | 05-06-2018 | -do- | Acurate TF TM Transfemoral Delivery System | **Manufacturer:** M/s Symetis SA, Chemin de la Venoge 11, 1024 Ecublens, Switzerland. |
|  | 00446-PR-MD | 05-06-2018 | -do- | Acurate neo TM TA Transapical Delivery System | -do- |
|  | 00447-PR-MD | 05-06-2018 | -do- | Acurate neo TM Aortic Bioprosthesis | -do- |
|  | 00448-PR-MD | 05-06-2018 | -do- | Safari TM Guidewires | **Legal Manufacturer:** M/s Lake Region Medical 340 Lake Hazeltine Dr Chaska, MN 55318 USA.**Manufactured For:**M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA |
|  | 00449-PR-MD | 05-06-2018 | -do- | Safari 2 TM Guidewires | -do- |
|  | 00450-PR-MD | 05-06-2018 | -do- | Trapper TM Exchange Device | **Legal Manufacturer:** M/s Creganna Medical, Parkmore West, Galway, Ireland.**Manufactured By:** M/s Creganna Medical, 8 Admiralty Street, #07-10 Admirax Building, 757438 Singapore. |
|  | 00451-PR-MD | 05-06-2018 | -do- | Lotus TM Introducer Set | **Manufactured By:** M/s Creganna Medical, Parkmore West, Galway, Ireland. |
|  | 00452-PR-MD | 05-06-2018 | -do- | Zurpaz TM Steerable Sheath | -do- |
|  | 00453-PR-MD | 05-06-2018 | -do- | Diagnostic Fixed Crv-Woven Catheters | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufactured By:** M/s C.R. BARD, Inc., 289 Bay Rd Queensbury, NY 12804, USA |
|  | 00454-PR-MD | 05-06-2018 | -do- | Stingray TM Guidewire with Hydrophilic Coating | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufactured By:** M/s Lake Region Medical, 340 Lake Hazeltine Dr Chaska, MN 55318, USA |
|  | 00455-PR-MD | 05-06-2018 | -do- | RenegadeTM Hi-FloTM Microcatheter kit | **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 |
|  | 00456-PR-MD | 05-06-2018 | -do- | RenegadeTM Hi-FloTM Microcatheter | -do- |
|  | 00457-PR-MD | 05-06-2018 | -do- | VortX-18 Fibered Platinum Coil | -do- |
|  | 00458-PR-MD | 05-06-2018 | -do- | VortXTM Diamond-18 Fibered Platinum Coil | -do- |
|  | 00459-PR-MD | 05-06-2018 | -do- | Straight-18 Fibered Platinum Coil | -do- |
|  | 00460-PR-MD | 05-06-2018 | -do- | InterlockTM-35 Fibered IDCTM Occlusion System | -do- |
|  | 00461-PR-MD | 05-06-2018 | -do- | IDCTM Interlocking Detachable Coil | -do- |
|  | 00462-PR-MD | 05-06-2018 | -do- | Complex Helical-18 Fibered Platinum Coil | -do- |
|  | 00463-PR-MD | 05-06-2018 | -do- | InterlockTM Fibered IDCTM Occlusion System | -do- |
|  | 00464-PR-MD | 05-06-2018 | -do- | DYNAGENTM MINI ICD | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:** M/s Boston Scientific Corporation, 4100 Hamline Ave N Saint Paul, MN 55112 USA. |
|  | 00465-PR-MD | 05-06-2018 | -do- | ORIEN CRT-D | -do- |
|  | 00466-PR-MD | 05-06-2018 | -do- | VALITUDE X4 | -do- |
|  | 00467-PR-MD | 05-06-2018 | -do- | Super Sheath | **Marketed By:** M/s Togo Medikit Co., Ltd., 13-2, Yushima, 1 Chome, Bunkyo-ku, Tokyo, 113-0034, Japan.**Manufacturing Site:** M/s Togo Medikit Co., Ltd., Hyuga Factory 17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City, Miyazaki Prefecture 883-0062, Japan. |
|  | 00468-PR-MD | 05-06-2018 | -do- | Super Sheath XL | -do- |
|  | 00469-PR-MD | 05-06-2018 | -do- | FathomTM-14 Steerable Guidewires | **Legal Manufacturer:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752 USA.**Manufacturer:** M/s Boston Scientific Corporation, 302 Parkway, Global Park, Heredia, La Aurora, Costa Rica. |
|  | 00470-PR-MD | 05-06-2018 | M/s Flowtronix Systems,Flat No. 02, 1st Floor Al-Ashraf Plaza Range Road,Rawalpindi. | Vent Catheter (Andocor) | **Manufactured By:** M/s Andocor NV Kwikaard 104 2980 Zoersel Belgium. |
|  | 00471-PR-MD  | 05-06-2018 | -do- | Aortic Catheter (Andocor) | -do- |
|  | 00472-PR-MD  | 05-06-2018 | -do- | Flex Line Venous Catheter (Andocor) | -do- |
|  | 00473-PR-MD | 05-06-2018 | -do- | Ostial Perfusion Cannula (Andocor) | -do- |
|  | 00475-PR-MD | 05-06-2018 | -do- | Pericardial Sump (Andocor) | -do- |
|  | 00476-PR-MD | 05-06-2018 | -do- | Cardiopelgia Set | -do- |
|  | 00477-PR-MD | 05-06-2018 | -do- | Two Stage Venous Catheter, Proximal Reinforced, Rigid tip, with luer | -do- |
|  | 00478-PR-MD | 05-06-2018 | -do- | Retrograde Cardioplegia Cannula | -do- |
|  | 00479-PR-MD | 05-06-2018 | -do- | Aortic Root Cannulae | -do- |
|  | 00480-PR-MD | 05-06-2018 | -do- | Arterial Cannulae Reinforced | -do- |
|  | 00481-PR-MD  | 05-06-2018 | -do- | Antegrade Cardioplegia Cannula | **Manufactured By:** M/s Surge Cardiovascular 2680 Walker Ave NW Ste C Walker, MI 49544, USA/M/s Alliant Enterprises LLC (Alliant Healthcare) 333 Bridge Street NW Ste. 1125 Grand Rapids, 49504 MI |
|  | 00482-PR-MD | 05-06-2018 | -do- | Suction Safety Device | -do- |
|  | 00483-PR-MD | 05-06-2018 | -do- | Retrograde Cardioplegia Cannula (Manual Inflate) | -do- |
|  | 00484-PR-MD | 05-06-2018 | -do- | Central Venous Catheter Kit | **Legal Manufacturer:**M/s Well Kang Limited, The Black Chruch, St. Mary's Place, Dublin 7, Ireland.**Manufacturer:**M/s Guangdong Baihe Medical Technology Co., Ltd, No.89, Taoyuan East Road, Nanhai, Foshan, Guangdong 528225, China PR |
|  | 00485-PR-MD | 05-06-2018 | -do- | Aortic Punch | **Manufacturer/Owner Operator:**M/s International Biophysics Corp. 2101-2 E. St. ELMO uite 275 Austin, TX 78744 USA. |
|  | 00486-PR-MD | 05-06-2018 | M/s Health Tec,10-B, Street 24, Valley Road, Westridge I,Rawalpindi. | Pointer Angiographic Catheter | **Manufactured By:** M/s Pendracare International B.V. Van der Waalspark 22 9351 VC Leek, The Netherlands. |
|  | 00487-PR-MD | 05-06-2018 | M/s Hakimsons (Pvt) Ltd,Hakimsons House A-58/B, S.I.T.E, Manghopir Road,Karachi. | Pennine Suction Catheter | **Manufacturer:** M/s Pennine Healthcare, City Gate, London Road, Derby, DE24 8WY, UK. |
|  | 00488-PR-MD | 05-06-2018 | -do- | Pennine Link Yankauers | -do- |
|  | 00489-PR-MD | 05-06-2018 | M/s Iqbal & Company,Alfalah Manzil Opp. National Police Foundation,Street # 26, Sector E-11/4,Islamabad. | Hemochron® HRF TCA 510 Celite Act Tubes (55994) | **Manufacturer:**M/s Accriva Diagnostics, Inc. 6260 Sequence Dr. 92121 San Diego, CA USA.**Distributor:**M/s Instrumentation Laboratory SpA (A Werfen Company), Viale Monza 338-2018 Milan, Italy. |
|  | 00490-PR-MD | 12-06-2018 | M/s Fresenius Medical Care (Pvt) Ltd,TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore. | Hemoflow HF (High - Flux Dialysers) HF 60S, HF 80S | **Manufacturer:** M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany.**Manufacturing Site:**1. M/s Fresenius Medical Care Deutschland GmbH, St. Wendel Plant Frankfurter, Strabe 6 - 8, 66606 St. Wendel, Germany.
2. M/s Fresenius Medical Care Srbijia d.o.o. Beogradski put bb, 26300 Vrsac, Serbia
 |
|  | 00491-PR-MD | 12-06-2018 | -do- | Hemoflow HPS (Low - Flux Dialysers) F4 HPS,F5 HPS,F6 HPS,F7 HPS,F8 HPS | -do- |
|  | 00492-PR-MD | 12-06-2018 | -do- | FX CorDiax (High - Flux Dialysers) FX CorDiax 40, FX CorDiax 50, FX CorDiax 60, FX CorDiax 80, FX CorDiax 100, FX CorDiax 120, | **Manufacturer:** M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany.**Manufacturing Sites:**1. M/s Fresenius Medical Care Deutschland GmbH, St. Wendel Plant Frankfurter, Strabe 6 - 8, 66606 St. Wendel, Germany.
2. M/s Fresenius Medical Care - SMAD, Z.I. de la Pontchonniere, Route de la Chanade / Savigny, 69591 L' Arbresle Cedex, France.
3. M/s Fresenius Medical Care (Jiangsu) Co., Ltd. Guli Industrial Park, Guli Zhen Changshu City, Jiangsu Province, China.
 |
|  | 00493-PR-MD | 12-06-2018 | -do- | FX (Low - Flux Dialysers) FX 5, FX 8, FX 10 | -do- |
|  | 00494-PR-MD | 12-06-2018 | -do- | FX Classix (High - Flux Dialysers) FX 60 Classix, FX 80 Classix, FX 100 Classix | -do- |
|  | 00495-PR-MD | 12-06-2018 | -do- | Ultraflux AV (Haemofilter) Ultraflux AV 400 S, Ultraflux AV 600 S, Ultraflux AV 1000 S, Ultraflux AV paed | **Manufacturer:** M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany.**Manufacturing Site:** M/s Fresenius Medical Care Deutschland GmbH, St. Wendel Plant Frankfurter, Strabe 6 - 8, 66606 St. Wendel, Germany. |
|  | 00496-PR-MD | 12-06-2018 | -do- | PlasmaFlux (Plasmafilter) PlasmaFlux P1dry, PlasmaFlux P2dry | -do- |
|  | 00497-PR-MD | 12-06-2018 | -do- | Cascade Hemodialysis Catheter | **Legal Manufacturer:** M/s Health Line International Corporation (HLIC), 5675 West 300 South Salt Lake City, UT 84104, USA.**Manufacturer:** M/s Health Line International Corporation--Foshan Xing Yuan 2nd Road Jili Industry Park Nanzhuan, Foshan, Guangdong 528061 China. |
|  | 00498-PR-MD | 12-06-2018 | M/s Al-Waali Care Concepts,Office No. 86, Allama Iqbal Road,Chahbaba Shadiwal Street,Near Meraj Masjid, Ghari Shahu,Lahore. | Linkset (Extension Lines) | **Manufacturer:** M/s Multimedia S.r.l. Via G. Rossa, 71-Zona Ind. Gerbolina-46019 Viadana (MN) Italy. |
|  | 00499-PR-MD | 12-06-2018 | -do- | Rampa D1 Rubinetti (Manifolds)  | **-**do- |
|  | 00500-PR-MD | 12-06-2018 | M/s Arfi International,Suite No 904, Al Rahim Tower, I.I. Chundrigar Road,Karachi. | Haemodialysis Catheter Set | **Distributor:** M/s Well Kang Limited, The Black Church St. Mary's Place Dublin 7, Ireland**Manufacturer:** M/s Guangdong Baihe Medical Technology Co., Ltd., No.89 Taoyuan East Road, Nanhai, Foshan, Guangdong, 528225, China PR. |
|  | 00501-PR-MD | 12-06-2018 | -do- | High Pressure Syringe | **Authorized Representative:** M/s Shanghai International Holding Corp. GmbH (Europe) Eiffestrabe 80 20537 Hamburg Germany.**Manufacturer:**M/s Shenzhen Ant Medical Devices Co., Ltd., 18 Jinhui Ave., Pingshan New District, 518122 Shenzhen, P.R China. |
|  | 00502-PR-MD | 12-06-2018 | M/s Global Marketing Services,111, Hali Road Westridge 1,Rawalpindi. | Defectable Braided Tip Temperature Catheter | **Owner Operator:** M/s Biosense Webster, Inc., 33 Technology Drive Irvine, CA 92618 USA.**Manufacturers:** (i)M/s Biosense Webster, Inc., 15715 Arrow Hwy. Irwindale, CA 91706 USA.(ii) M/s Biosense Webster, Inc., Circuito Interior Norte, No 1820 Parque Industrial Salvarcar Juarez, Chihuahua 32574 Mexico. |
|  | 00503-PR-MD | 12-06-2018 | -do- | Defectable Tip Electrode Catheters | -do- |
|  | 00504-PR-MD | 12-06-2018 | -do- | Halo Tricuspid Deflectable Catheter | -do- |
|  | 00505-PR-MD | 12-06-2018 | -do- | Defectable Tip Temperature Catheter | -do- |
|  | 00506-PR-MD | 22-06-2018 | M/s Cardiac Care, 848-C, Shadman-I,Lahore. | Dualyse-Cath | **Manufactured By:**M/s Vygon GmbH & Co. KG Prager Ring 100 52070 Aachen Germany**Import From:**M/s Vygon, 8 rue de Paris 95440 Ecouen France. |
|  | 00507-PR-MD | 22-06-2018 | -do- | Titanium Ligating Clips | **Manufactured By:** M/s MDD Medical Device Development GmbH Steigacker 20 (Industrial Area) D-78582 Balgheim/ Germany |
|  | 00508-PR-MD | 22-06-2018 | -do- | MYO PUNCH | **Manufactured By:** M/s A&E Medical Corporation 5206 Asbury Rd., P.O. Box 758, Farmingdale, NJ 07727 U.S.A |
|  | 00509-PR-MD | 22-06-2018 | -do- | BioGlue® Surgical Adhesive | **Manufacturer:** M/s CryoLife, Inc. Bramley House, The Guildway, Old Portsmouth Road,Guilford Surrey GU3 1LR, UK |
|  | 00510-PR-MD | 22-06-2018 | -do- | Ultra IABP 7Fr Catheter Kit | **Legal Manufacturer:** M/s INSIGHTRA Medical, Inc. 141 Hatcher Lane Clarksville, TN 37043 USA**Contract Manufacturer:**M/s Life Science Outsourcing, Inc. 830 Challenger Street Brea, CA 92821 USA. |
|  | 00511-PR-MD | 22-06-2018 | M/s Ferozsons Laboratories Limited,P.O Ferozsons Amangarh,Nowshera, KPK. | ExpelTM Uretel Stent System Ureteral Stent System | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA 01752 USA.**Manufacturer:** M/s Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela 20904 COSTA RICA. |
|  | 00512-PR-MD | 22-06-2018 | -do- | FleximaTM Ureteral Stent System Kit | **-do-** |
|  | 00513-PR-MD | 22-06-2018 | -do- | Platinum PlusTM Guidewires | **Owner Operator:** M/s Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA 01752 USA.**Manufacturer:** M/s Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela 20904 COSTA RICA. |
|  | 00514-PR-MD | 22-06-2018 | -do- | PlacehitTM Biliary WallstentTM | **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. |
|  | 00515-PR-MD | 22-06-2018 | -do- | WallstentTM RP Endoprosthesis Self-Expanding Stent | -do- |
|  | 00516-PR-MD | 22-06-2018 | -do- | TruePathTM CTO Device | **Owner Operator:** M/s Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA.**Manufacturer:** M/s Boston Scientific Limited Business and Technology Park, Model Farm Road, Cork, Ireland. |
|  | 00517-PR-MD | 22-06-2018 | -do- | Figure 8-18 Fibered Platinum Coil | -do- |
|  | 00518-PR-MD | 22-06-2018 | -do- | JourneyTM Guidewire | **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. |
|  | 00519-PR-MD | 27-06-2018 | M/s Saving Life Technologies (SLT), 427-K Block, Model Town,Lahore. | Eucalimus (Sirolimus Eluting Stent System) | **Name of Manufacturer:** M/s Eucatech AG, Rebgartenweg 27, 79576 Weil am Rhein, Germany. |
|  | 00520-PR-MD | 27-06-2018 | -do- | CC Flex (Coronary Cobalt Chromium Stent System) | -do- |
|  | 00521-PR-MD | 27-06-2018 | -do- | Euca VI (PTCA Balloon Catheter) | -do- |
|  | 00522-PR-MD | 27-06-2018 | M/s Physiomed, 268/3, Kamal Road, Saddar,Rawalpindi. | BRK TM Transseptal Needle | **Name of Manufacturer (s):**1. M/s St. Jude Medical Costa Rica Ltda., Edificio # 44, Calle 0, Ave. 2, Zona Franca Coyol El Coyol, Alajuela 1897-4050 Costa Rica
2. M/s St. Jude Medical, 14901 Deveau Pl. Minnetonka, MN 55345 USA
3. M/s St. Jude Medical, 5050 Nathan Lane North Plymouth, MN 55442 USA
 |
|  | 00523-PR-MD | 27-06-2018 | -do- | Supreme TM Electrophysiology Catheter | -do- |
|  | 00524-PR-MD | 27-06-2018 | -do- | Response TM Electrophysiology Catheter with Lumen | -do- |
|  | 00525-PR-MD | 27-06-2018 | -do- | Livewire TM Steerable Electrophysiology Catheter | -do- |
|  | 00526-PR-MD | 27-06-2018 | -do- | Fast Cath Transseptal Guiding Introducer | **Name of Manufacturer (s):**1. M/s St. Jude Medical, 14901 Deveau Pl. Minnetonka, MN 55345 USA
2. M/s St. Jude Medical, 5050 Nathan Lane North Plymouth, MN 55442 USA
 |
|  | 00527-PR-MD | 27-06-2018 | -do- | Fast Cath Hemostasis Introducer | -do- |
|  | 00528-PR-MD | 27-06-2018 | -do- | Swartz Braided Transseptal Guiding Introducer | -do- |
|  | 00529-PR-MD | 27-06-2018 | -do- | Sensor Enabled TM Ablation Connection Cable | **Name of Manufacturer (s):**1. M/s St. Jude Medical Costa Rica Ltda., Edificio # 44, Calle 0, Ave. 2, Zona Franca Coyol El Coyol, Alajuela 1897-4050 Costa Rica
2. M/s St. Jude Medical, 5050 Nathan Lane North Plymouth, MN 55442 USA
 |
|  | 00530-PR-MD | 27-06-2018 | -do- | Advisor TM FL Circular Mapping Catheter, Sensor Enabled TM | -do- |
|  | 00531-PR-MD | 27-06-2018 | -do- | Therapy TM Ablation Catheters | **Name of Manufacturer (s):** M/s Irvine Biomedical Inc, St. Jude Medical Company, 2375 Morse Avenue, Irvine, CA 92614, USA |
|  | 00532-PR-MD | 27-06-2018 | -do- | Pacel TM Bipolar Pacing Catheter | **Name of Manufacturer (s):**1. M/s St. Jude Medical 14901 Deveau PL. Minnetonka, MN 55345 USA
2. M/s St. Jude Medical 5050 Nathan Lane North Plymouth, MN 55442 USA
 |
|  | 00533-PR-MD | 27-06-2018 | M/s Interex Company, 195 Block 7/8, KMCHS, Justice Inamullah Road, Karachi. | Navien TM Intracranial Support Catheter | **Name of Manufacturer:**M/s Micro Therapeutics, Inc. dba ev3 Neurovascular 9775, Toledo Way Irvine, CA 92618 USA |
|  | 00534-PR-MD | 27-06-2018 | -do- | Apollo TM Onyx TM Delivery Micro Catheter | -do- |
|  | 00535-PR-MD | 27-06-2018 | -do- | Axium TM Detachable Coil System | -do- |
|  | 00536-PR-MD | 27-06-2018 | -do- | Axium TM Prime Detachable Coil System | -do- |
|  | 00537-PR-MD | 27-06-2018 | -do- | Echelon TM -10 Micro Catheter | -do- |
|  | 00538-PR-MD | 27-06-2018 | -do- | Arc TM Intracranial Support Catheter | -do- |
|  | 00539-PR-MD | 27-06-2018 | -do- | Marksmann TM Catheter | -do- |
|  | 00540-PR-MD | 27-06-2018 | -do- | Rebar TM Micro Catheter | -do- |
|  | 00541-PR-MD | 27-06-2018 | -do- | Concerto TM Detachable Coil System - Nylon Fiber | -do- |
|  | 00542-PR-MD | 27-06-2018 | M/s ACP Systems, 13 & 23 Navel Fleet Club, Iqbal (SJ) Shaheed Road, Karachi. | Medtronic Open Pivot TM Heart Valve, Model 500FA (Standard, Aortic) | **Name of Owner Operator:** M/s MEDTRONIC INC. 710 Medtronic Parkway, Minneapolis, MN 55432, USA**Name of Manufacturer:** M/s Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis Lane Minneapolis, MN 55447 USA |
|  | 00543-PR-MD | 27-06-2018 | -do- | Medtronic Open Pivot TM Heart Valve, Model 500DM (Standard, Mitral) | -do- |
|  | 00544-PR-MD | 27-06-2018 | -do- | Medtronic Open Pivot TM Heart Valve, Model 505DA (AP360, Aortic) | -do- |
|  | 00545-PR-MD | 27-06-2018 | -do- | Medtronic Open Pivot TM Aortic Valve Graft, Model 502AG | -do- |
|  | 00546-PR-MD | 27-06-2018 | -do- | Medtronic Open Pivot TM Heart Valve Sizer Set, Model 576 | -do- |
|  | 00547-PR-MD | 27-06-2018 | -do- | Medtronic Open Pivot TM Standard Heart Valve Sizers, Model 577 | -do- |
|  | 00548-PR-MD | 27-06-2018 | -do- | Simulus TM Flexible Annuloplasty Ring, Model 700FF | **Name of Owner Operator:** M/s MEDTRONIC INC. 710 Medtronic Parkway, Minneapolis, MN 55432, USA**Name of Manufacturer(s):** 1. M/s Medtronic Heart Valves Division 1851 EAST DEERE AVE. Santa Ana, CA 92705 USA
2. M/s Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California C.P. 22210 MEXICO
 |
|  | 00549-PR-MD | 27-06-2018 | -do- | Simulus TM Adjustable Annuloplasty Ring, Model 735AF | -do- |
|  | 00550-PR-MD | 27-06-2018 | -do- | Simulus TM Semi-Rigid Annuloplasty Ring, Model 800SR | -do- |
|  | 00551-PR-MD | 27-06-2018 | -do- | Tri-AdTM Adams Tricuspid Ring, Model 900SFC | -do- |

**Annexure-III**

**CHECK LIST FOR GOOD DISTRIBUTION PRACTICES FOR MEDICAL DEVICES**

**Name of the importer/ distributor**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Address** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**List of Medical Devices intended to be imported \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Sr.No.** | **Description** | **Compliance** |
| **Yes** | **No** |
| **PREMISES DETAILS** |
|  | Are surfaces free of flaking paint, corrosion, rust and other materials (eg., tape, Woods etc? |  |  |
|  | Checklist for personal safety |  |  |
|  | Are openings to doorways, vents, and drains covered to prevent the ingress of pests, etc. |  |  |
|  | Is there a smoke alarm and firefighting equipment available. |  |  |
|  | Is it clear from any rubbish. |  |  |
|  | Is floor clean from water. |  |  |
|  | Is there a cleaning schedule in place for store and surrounding? |  |  |
|  | Is there a procedure for pest control monitoring and treatment |  |  |
|  | Is there any signs of vermin such as cockroaches, mice, rats, and bats. |  |  |
|  | Check temperature record. |  |  |
|  | Has all recording and monitoring equipment been calibrated in the last year |  |  |
|  | Is standby generator/UPS available  |  |  |
|  | Is there any routine and emergency maintenance plan? |  |  |
| **INVENTORY AND RECORD MANAGEMENT** |
|  | Whether there is proper inventory control system |  |  |
|  | Are all the products are properly placed or arrangements are made for systematic storage. |  |  |
|  | Is their warranty system established |  |  |
| **OUTSOURCE ACTIVITIES** |
|  | Check if there is any maintenance agreement with an outside agency. |  |  |
|  | Is routine maintenance being performed correctly at the intervals stated in the agreement |  |  |
| **TECHNICAL STAFF AND DRUG SALE LICENCE DETAILS** |
|  | Does the importer have hired qualified Technical Staff (Pharmacist, Bio-medical engineer, Software engineer, Biotechnologist, Medical Lab Technologist, microbiologist, veterinary sciences, biochemist, medical physicist or bio physicist, or software technologists) to manage the proper storage |  |  |
|  | If the answer of above question is yes then what is the name and registration number of the qualified technical staff (also attach copy of the DSL)Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Registration No.\_\_\_\_\_\_\_\_\_\_\_\_\_DSL Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Validity:-\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| **POST MARKET SURVEILLANCE SYSTEM** |
|  | Does the importer have established the Re-Call system of Medical Devices ? |  |  |
|  | Does the importer have established a Complaint Handing system? |  |  |
| 1. D
 | Does the importer have established a Corrective and Preventive action (CAPA) mechanism? |  |  |
|  | Does the importer have established a Field Corrective and Field safety mechanism?  |  |  |
| **FOR SPECIALIZED TEMPERATURE SENSITIVE MEDICAL DEVICES (IF APPLICABLE)** |
| **Sr.No.** | **Description** | **Compliance** |
| **Yes** | **No** |
|  | Check weather the cold chain is established from manufacturer to the importer (For specialized products). |  |  |
|  | Is there a mechanism for the cold chain from manufacturer to the importer? |  |  |
|  | Is there any cold storage system at the Air Port/Sea-port/Dry Port. |  |  |
|  | Does the firm have special vehicle for distribution of temperature sensitive Medical Devices. |  |  |
|  | Does importer ensured the cold chain establishment from their distributor to the retailer/ consumers |  |  |
|  | Does the importer have documentation and list and list of authorized distributor who ensure the cold storage and cold chain onward to retailer and consumer? |  |  |
|  | Does the importer developed guidelines to ensure the cold storage and cold chain facility till the end consumer |  |  |

Any Comments \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Final remarks: - Please Fill the relevant Box.

**Recommended Not Recommended**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Name of Inspector** | **Designation** | **Signature** | **Date** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Reference:- Good Distribution practices for Medical Devices MDB/GD No.2 dated September, 2016**

**List of Documents required:-**

1. Site Master File ( Establishment details, Owners detail, product portfolio, etc) .
2. Job descriptions of all workers.
3. SOP for Import or Purchase of Medical Devices.
4. SOP for Complaint Handling, Corrective and Preventive Action.
5. SOP for Medical Device Re-call.
6. SOP for Incident and Accident Investigation.
7. SOP for Field Corrective and Safety Action, where applicable.
8. SOP for Return and disposal of Medical Devices.
9. SOP for handling of Expired, Spurious, Mis-Branded, Counterfeit etc, Medical Devices.
10. SOP for Internal Audit (i.e inventory, expiry, premises etc).
11. SOP for Personnel Hygiene.
12. SOP for Training ( i.e SOP and product related).
13. SOP for Receiving, Storage and Handling of Medical Devices.
14. SOP for Issuance of Medical Devices.
15. SOP for Rejected and Damaged Medical Devices.
16. SOP for Environmental Control.
17. SOP for Handling of medical devices with Special Storage Condition i.e. Temperature Sensitive (if any).
18. SOP for Labeling/ Relabeling of Medical Devices (for printing of Licence Details, etc).
19. SOP for Installation and Service Providing for Maintenance of Medical Devices, where applicable.
20. Work instructions for Handling of Medical Devices during Installation and Servicing, where applicable.
21. SOP for Calibration and Validation.
22. SOP for Management of Spare Parts of Medical Devices.
23. SOP for Outsource Activities.
24. SOP for Cleaning of Area.

