**Government of Pakistan**

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

**Drug Regulatory Authority of Pakistan**

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**MINUTES OF THE 10TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 09-10-2018**

 10th 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 9th October, 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:-

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| **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 |
|  | Mr. Imranullah, Senior Drug Inspector, Abbottabad, KPK(Nominee of Director General Health, Khyber Pakhtunkhwa )  | Member |
|  | Mr. Syed Abdul Saleem Shah,Chief Drug Inspector, Health Department, Balochistan(Nominee of Director General Health, Balochistan)  | Member |
|  | Brig.(R) Dr. Waqar Azim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hospital, Golra Mor, Islamabad.  | Member |
|  | Dr. Sajid Bashir, Prof. of Pharmaceutics, University of Sargodha, Sargodha. | Member |
|  | Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar.   | Member |
|  | Mrs. Tazeen S. Bukhari,Biomedical Equipment Planner, Saleem Memorial Trust Hospital, 31-Q, Gulberg-II, Lahore. | Member |
|  | Mr. Muhammad Asghar,CEO, Cyber Soft Technologies,Lahore. | Member |
|  | Prof. Dr. Saqib Shafi Sheikh,Interventional Cardiologist/Cardiovascular Surgeon, Mayo Hospital, Lahore. | Member |
|  | Dr. Ghazanfar Ali Khan, 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 9TH MEDICAL DEVICS BOARD MEETING**.

**Decision:** The Board confirmed the minutes of the 9th meeting of MDB.

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

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

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

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| **S.No.** | **Name of Establishment** | **Director/Proprietor/****partners** | **Name of panel Inspector (s)** | **Cold Chain****(Yes/No)** | **Decision** |
|  | M/s Medicamp International, First Floor Raja Naseer Plaza, Mohalla Raja Yousaf, New Abadi Morgah Rawalpindi. | 1.Muhammad Hussain2.Chaudhry Arif Hussain. | Mrs Unum Zia Shamsi, Assistant Director-IV (MDMC),DRAP, Islamabad.Miss Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility  |
|  | M/s Diagnostic Medical Associates, 205-Muhammadia Plaza Gordon College Road, Rawalpindi. | Naveel Farooq | -do- | No | **Approved** for room temperature medical devices without cold chain facility  |
|  | M/s Seico Medical Traders, 104 Mohammadia Plaza, Gordon College Road, Rawalpindi. | Muhammad Farooq Malik. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Hi-Tech Scientific International, F- 833/11-B, F-Block, Satellit Town, Rawalpindi. | Muhammmad Rehan | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Global Clinical Cura Pvt Ltd., House No 334, Lane 6, Peshawer Road Rawalpindi. | 1.Mr Hamza Ali.2.Ms. Sonia Anum  | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Blazon Diagnostic, Office No 45, Rawalpinhi Cricket Stadium, Double Road Rawalpindi. | Mr Ahmar Zaman Khan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility  |
|  | M/s Future Scientific, FS House, Opposite Street No 4, Main Road Shaheen Town, Gangal West, Rawalpindi | Malik Najam Farooq | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Elite Traders Rawalpindi, House No B-342 B Block St Town, Rawalpindi. | Muhammad Imran. | -do- | No | **Approved** for room temperature medical devices without cold chain facility  |
|  | M/s Pakistan Marketing Services, House No 4, 1st Floor, Street Haider Karar, Allah Abad School Road, Westridge 3, Rawalpindi. | Khawaja Semab Akhtar | -do- | No | **Approved** for room temperature medical devices without cold chain facility  |
|  | M/s Mediland Pakistan (Pvt) Ltd, Office B-09, 2nd Floor, Masood Arcade, IJP road, Near Saidpur Road, Rawalpindi.**Godown:**PD-452-B, Kareem Plaza, ISP Road, Near Pindora Chungi, Rawalpindi. | 1. Mr Ghulam Murtaza Tariq (CEO)2.Mr. Abdul Shakoor3.Mr. Arfat Javeed4.Mr. Naveed Akhter 5.Mr Shahid Mehmood. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s S.M. Diagnostics, 42C, Asghar Mall Scheme Rawalpindi. | Rehan Musarrat. | -do- | No | **Approved** for room temperature medical devices without cold chain facility.  |
|  | M/s Hasnain Scientific, Flat No 16, Shalimar Floor Aries Tower Shamsabad Murree Road Rawalpindi. | Hassan Nawaz Lalee. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Meritorious Business Solutions (Pvt) Ltd, Office 202, 2nd Floor 153, D, Civic Center, Phase-4, Bahria Town, Rawalpindi. | 1.Muhammad Raza Jaffary2.Zainab Raza. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Physiomed (Pvt) Ltd., 268/3, Kamal Road Saddar, Rawalpindi. | 1. Muhammad Ramzan.2.Sher Zaman.3.Nusrat. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Freesia Enterprises, First Floor 104, Dawn Plaza, Bank Road Saddar, Rawalpindi. | Muhammad Ibrar | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Gulf Marketing International, 11-B/2 Mohallah Satellite Town, Abdullah Jan Masjid Street, Near Kali Tanki, Said Pur Road, Rawalpindi. | 1. Rana Muhammad Shafiq.2.Muhammad Shabir. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility subject to provision of DSL. |
|  | M/s Sanwa Trading Corporation, Office No 85, Rawalpindhi Cricket Stadium Double Road Rawalpindi. | Mr Ajmal Masih | Mr.Muhammad Ayub Naveed, Assistant Director-II (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 Surgi World, Office No 303, Muhammdia Plaza College Road Rawalpindi. | Muhammad Saeed Iqbal | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Perfect Vision, Ali Plaza Near Rahat Bakers, Chur Chowk, Main Peshawar Road, Rawalpindi. | Muhammad Imran Khalid | -do- | No. | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Uni brand International, Flat No 104, 1st Floor Muhammadia Plaza, collage Road, Rawalpindi. | 1. Mr Abdul Rahim Shahid2. Mr . Nadeem Shahid. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s A.H Distributors, House No CB-708 Lane No 5 Peshawar Road Rawalpindi. | Mr Muhammad Javed. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Cor-Med, 2nd Floor 38/62 Rehman Plaza Bank Road Saddar Rawalpindi. | Israr Ul Haq. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Kiswa Cares, Office No.07, Gulf Plaza Chandni Chowk, Rawalpindi. | Waqas Ahmed Malik. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Hospital Appliances, Office No 1, G-274, Chishti Plaza, Gordon Collage Road, Rawalpindi. | Muhammad Irfan Ali Chishti. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Zuis Pharmaland, H CB974/8, St NO 3, Shabbir Ln, Rawalpindi. | 1.Muhammad Ibrahim2.Saeeda Ibrahim. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Zaidi Traders, 1.417, Satellite Town Distt Rawalpindi. | Syed Masood Akhtar Zaidi | -do- | No | **Rejected** due to inadequate storage area. |
|  | M/s Princess Scientific Services, Plot No. 67/62, Adam-Jee Road 1st Floor Deen Plaza Saddar Cantonment, Rawalpindi. | Abdul Hafeez. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Biocare Enterprises, 64/2, St/17,FESCH (NPF) 0-9 PWD Road, Islamabad. | Mr Muhammad Asif. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility subject to provision of DSL. |
|  | M/s Alpha Evolution Enterprises Pvt Ltd., Suit 2 First Floor Sultan Plaza Gulshane Khudadad Colony, E-11/1, Islamabad. | 1.Usman Rasheed butt.2.Khaqan Babar. 3.Muhammad Ehtisham. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Vantage Technologies, 251, Street 11-B, Phase-1, Ghouri Town, Islamabad. | Muhammad Saeed Zia.  | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility subject to provision of DSL. |
|  | M/s Sveda Health Care, Office No, 4 3rd Floor MB City Plaza 1/8 Markaz Islamabad. | Naveed Aslam. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Bio Life, Office No 4, 2nd Floor, Ahmed Center, 1-8 Markaz, Islamabad. | Sohail Akram | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Reaction Scientific, 337, street No 17, Sector B-17, Block B, Islamabad.(PVT. lTD) CHANGE TO BE ADDED. | Kashif Rehman Siddiqui.Muhammad AltafMuhammad ImranMuhammad NawazNadeem Akhter | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Rehab Initiative, Sadaat Plaza, Thanda Pani, main Lehtrar Road, Islamabad. | Ihtisham Ahmad . | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Irteqa Biotek, Office 7& 8, Basement floor Chaudhary Akhmat Plaza Gulberg Green, Islamabad. | Muhammad Azm Saeed Dar | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Safemed Technologies, Apartment No.3, 2nd Floor, Retoon Plaza, Sector G-15/1, Islamabad. | Mrs. Humara Rasool | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Allied Surgicals, Ist floor A, Unit No.1, Justice Inamullah Road, Block 7/8 KCHS Karachi**Godown:**Plot NO.37/1, Unit No.01, Sector 15, Korangi Industrial Area, Karachi. | Muhammad Salman Muddasir | 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 Medica, House No 188-1-B first Floor Near Nursery Area, Block -2 PECHS, Karachi. | 1. Mr salman Qureshi.2.Mr Asif Dosslani | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Best - Med Traders,Lower Ground suit No 27 & 28 resham Bazar, Main University Road, Gulshan Town, Karachi | Adnan Hayat Nizami | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s A.T Associates,2. Flat No. F1, 1st ,51-C, Block-6, PECHS, Karachi | Mr Tahir Ali Ghaghro. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Timax Life Sciences (Pvt) Ltd., 2 Mezzaine -1 Fl-37, Block-B, Gulshan - e Jamal, Karachi. | 1. Nadeem Rana2.Muhammad Kaleem Rana. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s A.M Sales & Services, A. M House, 82-L, Block-02, PECHS Karachi. | 1.Mr Anwar Habib2.Karima. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Meditec Instruments Co., Suit No 202, Tahir Plaza, A-20, KCSHU, Near Duty Free Shop, Karachi | 1.Mrs. Tanseem Hozaifa.2.Ms. Ismat Hatim Gabaji.3.Mrs. Arwa Idris.4.Mr. Hozaifa Hashim . | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/ Otsuka Pakistan Limited, 30-B, SMCHS, Karachi. | Hanif SattarMr. Saddiq Rafee. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Scientific Supplies Pvt Ltd, 57-A, Block 2, PECHS, Karachi  | 1.Mr Maqsood Khan2. Mr Masroor Khan3.Mansoor Ahmad Khan4.Mudassir Maqsood. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Medworks, 327 Haider Ali Road, Block -3 DMCHS Karachi. | Faisal Masood Younus. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Medisurg InnovativesHealth Care, 1/6-N Block-6,PECHS, Shahrah - e- Faisal Karachi**Godown:**F-1102, Saima Square One, Gulshan-e-Iqbal, Block-10-A, Karachi. | Dr Muhammad Rizwan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Rafi Sultan Enterprises,Plot No -19-1-A, Office No. M-5, Mezzanine floor Business Centre, Block-6,PECHS, Main Shahrah-E-Faisal, Karachi. | 1.Mr Khalil Ahmed Allahwala2.Mr Sabih Mohsin3.Mr Ahsan Mehmood4.Mr Raza Mahmood. | -do- | No | **Approved** for room temperature medical devices without cold chain facility.. |
|  | M/s Meher Enterprises,1st Floor Azzainab Court Campbell Street, Karachi.**Godown:**A-IV, 1st Floor Azzainab Court Campbell Street, Karachi. | Muhammad Anwar Idress. | -do- | No | **Approved** for room temperature medical devices without cold chain facility.Name Alert. |
|  | M/s Ghazali Brothers, 1st Floor Azzainab Court Campbell Street Karachi.**Godown:**1. Ground Floor, Karimgi & others, Shop No.14,Plot No.W.07/15, North Napier Road, Karachi.2. 2nd Floor, Karimgi & others, Off-2/D, Plot No.W.07/15, North Napier Road, Karachi. | Ahmed Ghazali. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Musaji Adam & Sons.Office No. C-285,Block- 10, Federal B Area, Karachi.**Godown:**F-14, Phase-II, S.I.T.E Super Highway, Ahsanabad, Karachi. | 1.Muhammad Ilyas Vohra2.Muhammad Irfan Vohra3.Muhammad Ismail Vohra4.Muhammad Sufyan Vohra. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility subject to provision of DSL. |
|  | M/s GD Traders, Plot No 110-C, Mezzanine Floor in Between 9th & 10th Commercial Street Phase -IV DHA, Karachi. | 1.Syed Sami uddin2.Syed Salah uddin. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Novo Nordisk Pharma (pvt) Ltd., 113, Shahrah -e- Iran , Clifton Karachi | 1.Jahanzeb Kamal Khan.2.Wasi Uddin Syed. 3.syed Abdul Azeem.4.Anila Sikandar.5.Saqib Zia.5.Mohammad Adil. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Amanco, 402, Marine Point, Bl.9, Clifton Karachi.**Godown:** Plot No.36, Ware House No.3& 4, Sector 28, KIA, Karachi. | Amna Ashraf. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s JF International, 4th Floor 10-C, 6th Phase-II, EXT, DHA, Karachi. | Saima Azeem. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Tri Tech International, 10- C, Sunset Commercial Lane, Phase-II EXT, DHA, Karachi. | 1. Sheikh Muhammmad Azeem2.Shakeel Ahmad. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s A.M Distributors,4th Floor Plot No. 37-C, Bukhari Commercial Lane-8, Phase-VI, DHA. Karachi. | Mr. Muhammad Rafiq. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Interex Company, House No.195, 2nd Floor, KMCHS, Near Hill Park, Karachi. | Mr Inam Ullah Arain. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Trans Angio System, Suite 507, Progressive Square Block -6, P.E.C.H.S Shahrah -e- Faisal Karachi.**Godown:**35-B/1, Portion-C, Block-6, PECHS, Shahra-e-Faisal, Karachi. | Zahid Ahmed. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Rech International, Office No.247-B, P.E.C.H.S., Block-6, Near Hotel Faran, Yaseen Suleman Street, Karachi. | 1.Alia Shafiq.42201-1956737-62.M. Muneeb. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Shirazi Trading Company (Private) Limited, Plot N0.114-C, Al-Murtaza Commercial Lane-3, Khayaban-e-Iqbal, Phase-8, DHA, Karachi.**Godown:**1st Floor, Nadir House, I.I.Chundrigarh Road, Karachi. | Mr. Yusuf Hussain Shirazi2.Mr Amir Hussain Shirazi.3.Mr Saqib Hussain Shirazi.4.Ali Hussain Shirazi.5.Mr Frahim Ali Khan.6.Mr Khaleeq -ur- Rehman7.Mr.Farooq Saleem | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Hospital Solutions,174-E, Block -2, P.E.C.H.S Karachi. | 1. Masood Shams Ul Haq.2.Muhammad Nadeem. Anwer. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Business Medical International, Suit. 203, 2nd Floor, Hafeez Center, Shahra-e-Faisal, Karachi.**Godown:**Plot No.C-16, Block-7/8, K.A.E.C.H.S., Karachi. | Muhammad Nadeem. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Scilife Pharma Pvt Ltd., 16 K.O.C.H.S. Amir Khusro Road, Karachi.**Godown:**Plot No.FD-57/58-A/2, Korangi Creek Industrial Park, Karachi. | 1.Mr Shahid Ghoury.2.Mr Inam Ur Rehman3.Mr waqar Hassn siddiqui4.Mr Asim Hussain Siddiqui. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Medichem Enterprises,331/C, Block No 3, DMCH Society, Alamgir Road Karachi. | Khalid Sultan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Greenstar Social Marketing (Guarantee) Limited, Ocean Tower, 8th Floor, G-3, Block-9, K.D.A. Scheme No.5, Main Clifton Road, Karachi.**Godown:**Ground floor, Plot No.F-A/A-2, Hub River Road, Sher Shah Site, Karachi. | 1.Dr. Syed Aziz Ur Rab.2.Javid Sadiq.3.Karl Hofmann.4.Mahtab Akbar Rashdi5.Marcie Anne Cook.6.Douglas Call.7.Dr Mushtaq Ali Khan.8.Muzzafar Mahmood Qurashi.9.Dr Rehana Ahmed.10.Dr. Aliya Iqbal Naqvi.11.Faisal Farooq. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Grace Pharmaceutical, 102, 1st Floor, Block-9, Clifton, Karachi.**Godown:**F-112, S.I.T.E, Karachi. | Shahdev Vankwani. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Batla Impex,SH. NO 40, Namco Centre Cambell Street Karachi.**Godown:**Rehman Chamber, Medicine Street No.2, Marriot Road, Karachi. | Iqbal Batla. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Fabnos International,Bulding No 26-C, 1st Floor, Tauheed Commercial Area Street No 26, Phase- V, DHA, Karachi. | Burhanuddin Banday. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Flying Distribution Network,M- 57, Mezzaine Floor Glass Tower Main Clifton Road Karachi.**Godown:**Plot No.2, FT/3, M-62, Frere Town, Main Clifton Road, Karachi. | Hussain Muhammad Akbar | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ophthalmo-Tec, Haji Fazal Ellahi Building, Opp. Women Collage Shahrah -E- Liaquat, Karachi.  | Farha Masoom. | Ms. Hira Bhutto, Assistant Director-I (MDMC),DRAP, Islamabad.Muhammad Ayub Naveed, Assistant Director-II (MDMC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s United International,GNB-F 18/A Ground Floor F- Block Meher Sons Estate Karachi. | Mr Sohail Kadvavi. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Medtronic Pakistan Pvt Ltd., Office No. 1301, 13th Floor Dilkusha Forum Tariq Road, Karachi.**Godown:**Plot No. S1, Survey 231, Sector 2, Road No. 4000, Korangi Industrial Area, Karachi. | 1. Mr Shahid Manzoor.2. Mr Fabiano Favretto.3. Mr. Moussa Srour. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Hospicare Systems,Mazzanini Floor, Rabbiya Garden, Plot No, 3, MCHS Society, Shaheed-e-Millat Road, Karachi. | Masood Ahmad. | -do- | Yes | **Approved** for room temperature medical devices alongwith freeze and cold chain facility. |
|  | M/s Safe Health PakistanBizcon, Office No.25, 2nd Floor, Dilkusha Chamber Marston Road, Karachi. | Naveed Ur Rizwan Azizi. | -do- | No. | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Angel Medical Services,House No 7/4 Drigh Road Cantt Bazar Korangi Shah Faisal Town Karachi. | Kaleem Sharoon. | -do- | No | **Approved** for room temperature medical devices with limited storage capacity without cold chain facility. |
|  | M/s N Z Trader, 9/16 AR KAY Squire extension Shahra -e- Liaquit New Challi Karachi.**Godown:**Room No.112-113, New Charli Trade Center, Shahra-e-Liaqut, Karachi. | Muhammad Imran Khan Sherwani. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Vida Laboratories, Plot No 225, Sector 23, Korangi Industrial Area, Karachi. | Mr Atif Iqbal. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Hamza Trading Co., 302, 3rd Floor, Makkah Market, KatchiGali 2. No1, Marriot Road, Densohall, Karachi.**Godown:**Puri House, 4/22, West Wharf Road, Karachi. | Daniyal Iqbal. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Battla Associates, No. 4, Allawala Building Kutchi Gali No 1, Marriot Road Karachi. | Ikhlas Ahmed Battla | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Maqsood Brothers, Office No 503, B, 5th Floor, Saima Trade Tower, I.I Chandrigar Road, Karachi.**Godown:**Shop No.1-2, 66/2 SB/2, Al-Noor Arcade, Opp. CIA Residency, Near Lucky Star Market, Saddar, Karachi. | Maqsood Ahmad | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Alere Medical Pakistan (Pvt) Ltd, 21 Buhadarabad Block - 3 Shaheed- e- Millat Road Karachi. | 1.Mr. Arthur Mark Hengerer.2.Mr. Foo Suan Chin. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility with limited capacity. |
|  | M/s Uniferoz Pvt Ltd., Plot No. 32/8 and 33/2, Sector-15, Korangi Industrial Area, Karachi.**Godown:**Plot No.108 & 109, Sector 23, KIA, Karachi. | 1.Tariq Mehtab Feroz.2.Sadiq Mehtab Feroz,3.Muneer Mehtab Feroz4. Mehtab - uddin Feroz. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Al Hamd Enterprises, FL-111/1, Block-6, Gulshan-e- Iqbal, Karachi | Aslam ullah Khan | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Uniprom Healthcare,L-151, 2nd Floor SehbaAkhter Road, Block 13-G Gulshan-e-Iqbal Karachi**Godown:**A-33, Bukhari Town, Block 10-A,Gulshan-e-Iqbal, Karachi. | Syed Hameed Ahmed. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Nismedical,Mashriq Center, Suite No315, 3rd Floor, Gulshan-e-Iqbal Block 14, Karachi | Syed Hameed Ahmed. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s A J International Company, Suit No 313, 3rd Floor Mashriq Center, Gulshan- e- Iqbal Block-14, Karachi | Rehan Mohsin Khan. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ontech Corporation, 154 Block 13-D/2, Gulshan-e- Iqbal, Karachi | Zareen Mujeeb | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s 4S International,Suit No 205, 2nd Floor Al - Fiza Glass Tower Rashid Minhas Road , Blok 10-A Gulshan-e-Iqbal, Karachi. | Foquia Liaquat. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Eastern Optical Co., Lakshmi Building M.A. Jinnah Road Karachi. | 1.Muhammad Sarwar 2.Muhammad Kamran3.Sajida Sharif | -do- | No. | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Life Scan Enterprises, R-274, 1st Floor Railway Society Block-13-D2 Sehba Akhtar Road Gulshan -e- Iqbal, Karachi. | 1.Yasir Baig.2.Shaikh Muhammad Zubair.3.Moiz Shahid. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Multi Med Healthcare. Plot No 17, Street No 1, Sector 19, Korangi Industrial Area, Karachi. | Kanwal Rehman. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s DIAG. M (Private) Limited, B-270 Sector 6-F EBM causeway, Mehran Town Korangi, Karachi. | 1.Arshad Aleem2.Muhammad Zia Ullah3.Muhammad Shahabuddin4.Muhammad Nadeem Biswas5.Manzar Aleem6.Faisal Warsi. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s New Pakistan Traders, Office No. 306/1 Trade Tower Altaf Hussain Road New Challi, Karachi.**Godown:**1st Floor, Puri House, West Wharf Road, Karachi. | Muhammad Rafiq. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ruella Medical, Suit No. 1002, 10th Floor, Kawish Crown Plaza, Karachi | Mr. Kamran Muhammad Khan. | -do- | No. | **Rejected** due to poor inventory management system and limited storage capacity and absence of qualified person.No documents available as per GDPMD.  |
|  | M/s Wasim Co, Kutchi Gali No.1, Marriot Road, Karachi.**Godown:**Sadaf Center, SR-3, Serial Road, 2nd Floor No.15 & 26, Karachi. | Khalil Ahmed. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Curelink Pharmaceuticals,Office No 6, 3rd Floor B.B. Shoping Mall, Opp, Ned University, Block 1, Gulistan-e- Jauhar, Karachi | Syed Najam Abbas. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Medilution Healthcare, A- 322, First Floor, Gulshan- e-Iqbal Block 2, KDA Scheme 24, Karachi | Adnan Ahmed Saddiqui. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Martin Dow Marker Specialities (Pvt) Ltd., D-7 Shaheed-e-Millat Road, Karachi.**Godown:**1. Plot No.130, Sector 15, KIA, Karachi. | 1.Mr Amjad2.Ali Amir3.Anis Ahmad Shah. | -do- | Yes | **Approved** only for cold chain facility. |
|  | M/s AB Enterprises, Plot No.C-155-156, Sector-6, F, Mehran Town, Karachi. | Farhan Javeed. | -do- | No. | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s United Healthcare, 435, BYJ Society, Bahadurabad, Karachi. | Mr. Asad Feroz. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Elate CC Pvt Ltd., Suite No 1,2, 3, St-3 Block 3, Gulshan e Iqbal, Karachi. | Syed Ashar Alam. | -do- | No. | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Eastern Medical Care (Pvt) Ltd, 7-A, Block- N, Model Town Extension, Lahore | 1.Muhammad Sarwar 2.Muhammad Kamran3.Sajida Sharif | Miss Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad.Hafiz Muhammad Tayyab, Assistant Director, DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Total Technologies (Pvt) Ltd., House No 696, J-2 M.A. Johar Town, Lahore  | 1.Mr. Shoukat Ali2.Mr Tallat Mahmood Qureshi. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Mukhtar Enterprises, 55 Block B, Faisal Town Lahore. | Farooq Ahmad. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Sial Traders, 156-A, Abubaker Block, New Garden Town Lahore | Muhammad Ashiq. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Med Impex, 101-A Faisal Town, Lahore | Muhammad Jamil. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Premier Health Care, 31, Block A- 1, Johar Town Lahore | 1.Wasib Hanif2.Asad Chughtai. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Human Health Care, 61-A, Revenue Employee Coorperative Housing Society, M.A Johar Town, Lahore | Muhammad Arslan Latif. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Meditron Medical Systems, 369-E, Johar Town Lahore | Muhammad Arshad | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s M. Yousaf & Co, Office No 131, Tippu Block, Garden Town, Lahore. | Muhammad Yousaf | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s 3A Nutra, 12-F-1 Mohamod Chowk Johar Town, Lahore | Mushtaq Ahmed | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Jam's Heart International, Office No 602 6th Floor Al-Qadir Heights New Garden Town Lahore | 1. Jamshaid Alam2.Kashif Hussain. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Radiant Medical (Pvt) Ltd., 6th Sher Shah, New Garden Town, Lahore | 1. Sabir Ali Ch.2. Ali Ahmad Ch. | -do- | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Health Care International, Office No. 210 1st Floor, Block J/2 Johar Town Lahore. | Omer Jan Shaukat | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s M.S. Associates,Shop No 5, Plot No. 8 Al - Meraj Arcade Chauburgy, Lahore.**Godown:**Ground & 1stFloor, Shop No.12, Property No.S-94-R-1/E, Super Market, Chowk Chouburgy, Lahore. | Shahzad Wazir | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility subject to compliance of GDPMD. |
|  | M/s Cardiovascular Medical System, Office No.210-Block, J/2 Johar Town, Iqbal Town, Lahore | Asim Toqeer. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Optic Classic Distribution Network, Office No.2, 1st Floor, Shan Arcade, Barkat Market, New Garden Town, Lahore. | 1.Fareed Akhtar.2.Dr Nadeem Ashraf | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Bio Care Medical System, 415 Gulshan Block Allama Iqbal Town Lahore. | 1.Khurram Bukhari.2.Mohsin Nisar | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s ICU Pharmaceuticals, House No.515, Karim Block Allama Iqbal Town, Lahore | Inam Ullah Khosa. | -do- | No | **Rejected** due to poor storage conditions. |
|  | M/s Uniplan Trade International (Pvt) Ltd., 2-132 Industrial Estate, KotLakhpat Lahore | 1.Muhammad Khalid Javaid2.Nasir Javid.3.Tahir Javeed.4.Naveed Khalid. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Glow Pak International, 129/5-M Quaid- E- Azam Industrial Estate, Kot Lakhpat, Lahore | 1. Idress Qadri.2.Shoaib Afzal Qureshi. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Optisurg, 17- C1, Valancia Town, Lahore | 1.Mahfooz Ahmad Qureshi.2.Fayyaz Ahmad Qureshi. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Metro Commercial Enterprises, Suit No 1, LGF, Abrar Business centre, Wahdat Road, Lahore | Muhammad Jalil Tahir. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Imtiaz Brothers, Suit No 7 B,2nd Floor Abrar Bussiess Center 25 Main Wahdat Road Lahore.**Godown:**22 Lower Ground Floor, Abrar Business Center, 25 main Wahdat Road, Lahore. | Saqib Ameen. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Algene Medical (Pvt) Limited , 139-B 2nd Floor, Commercial zone Jasmine block Bahria Town Lahore.  | 1. Muhammad Ramzan2. Tanveer Akhtar | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Dental Supply (Pvt) Ltd., UD 42, Land Mark Plaza, Jail Road, Lahore | 1. Idress Qadri.2.Shoaib Afzl Qureshi. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ever-X, 1-E, Samanbergm, Johar Town, Lahore. | 1.Muhammad Farooq2.Imran Latif | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Horizon Group of Company, 603-Kamran Block, Allama Iqbal Town, Lahore.- | 1.Ahmad Farhan Aslam2.Sana Farhan | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Safmed, 124- A Shadman-1, Lahore | 1.Naheed Shafiq 2.Safia Ahmad. | Hafiz Muhammad Asif Iqbal, Assistant Director-V (MD&MC), DRAP, Islamabad.Hafiz Muhammad Jawad Ali, Assistant Director (EC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Chemical House, 6-C SikandarMalhi Road Canal Park, Gulberg-II, Lahore  | Shoaib Rana. | -do- | Yes | Recommended for cold chain and room temperature medical devices. |
|  | M/s Renacon Pharma Ltd. House No,3 Street No 1, 18 Km, Ferozepur Road, Mujahid Colony Lahore. | 1.Dr Salman Shakoh.2.Syed Shahid Ali Shah.3.Syed Shehryar Ali.4.. Abdul Majeed Ch.5.Mr. Jamal Mustafa Saddiqui.6.Dr. Salman Faridi7.Mrs. Lubna Shakoh | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Sterijekt Medical Devices, 22 Km Ferozpur Road Lahore. | 1.Mr Omer Manzoor.2.Manzoor Elahi Taj. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Tek Enterprises, Office No MZ-9 Mezzanine Floor Al Hafeez Heights 65 -D Sir Syed Road Gulberg-III, Lahore.  | Tariq Rasheed Qureshi. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s M & M Pharma, 1st Floor, Javid Plaza, Opposite Gate No 2, Pepsi Factory, Gurumangat Road, Gulberg-II, Lahore. | 1. Munawar Akhtar Islam2.Adeel Munawar3.Raheel Munawar. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Treu-Dynamic International (Pvt) Limited, C-206, 2nd Floor, City Tower, Main Boulevard Gulberg, Lahore.  | 1.Mr. Rizwan zahid Khan2.Mr. Salman zahid Khan.3.Mr. M. Zaman Khan.4.Mr. M. Irfan Khan.5.Mr. M. Tahir Khan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Novum Life Solutions, 328/16 W-Block, DHA, Lahore. | Salam Ahmed. | -do- | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Denovo Pharma, D-7, 90-C, Canal Park, Gulberg-II, Lahore. | 1.Anwar Ul Haq Ghafoor.2.Shahid Rafique.3.Waqas Zaib Mughal. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ortholink, 55-4, Shadman Market, Lahore | 1.Imtiaz Ahmad2.Ismat Mahmood. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ghrasa Laboratory Supplies, 174- Ferozpur Road, Pearl Plaza, 2nd Floor, Shahjamal Stop, Lahore | Mr Ghulam Hussain. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s Vertex Medical (Pvt) Ltd., 70-B-1, Gulberg-III, Lahore.**Godown:**108- Tipu Block, New Garden Town, Lahore. | 1.Qasim Ali2. Umair Qasim3.Shouqat Ali4.Ramzan Arif | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Alfa Scientific Store, 24-Maclogen Road, Lahore**Godown:**LG-1, LG-2, LG-3, Lower Ground, Sourth Counter, 10-Adward Road, Lahore. | Muhammad Sajjad. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s The Holy Green International, Office No 8 & 9, First Floor Fatima Center Queens Road, Lahore. | Waqar Ahmed Butt. | -do- | No | **Approved** for room temperature medical devices without cold chain facility.. |
|  | M/s Siemens Heathcare (Pvt) Ltd., 4th Floor, State Life Building 15-A, Sir Agha Khan Road, Lahore. | 1. Khurram Jameel 2.Syed Imran Raza. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Electro Med Corporation, 53 Mall, Near Panorama Shopping Centre, Lahore | 1.Saif Ur Rehman2.Razi Ur Rehman3.Zaki Ur Rehman4.Shoaib Rizwan Usmani. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s SHAHCO Medical (Pvt ) Limited, Office No. 934, Shahdman-01, Lahore | 1.Mr Shahid Mahmood.2. Mrs. Salamat Bibi. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility subjecdt to provision of DSL**.** |
|  | M/s Pak Punjab Cardex Medical Systems, Office No.202, 2nd Floor, Eden Heights Jail Road, Lahore**Godown:**Plot No.257, Ground Floor, K-Block, DHA, Lahore. | Waqas Liaqat. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Ahmad Care International, 2nd Floor, 7-Shahra-e-Tajbagh, Main Market, Phase-I, Tajbagh Housing Scheme, Lahore. | Amir Ijaz Butt. | -do- | No | **Rejected** due to not having storage facility. |
|  | M/s Crystal Health Care, Naseem Manzil, 10-A, Main Market, Samanabad, Lahore. | 1. M. Moien Uddin 2. Imtiaz Haq | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Endoaid Biomedica, 185 C, DHA EME Sector, Lahore**Godown:**2nd Floor, 85-D, Commercial Area, DHA EME, Lahore. | 1. Muhammad Rashid Khan.2. Mohammad Naeem. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Nwill Healthcare, Office No. B-9, Royal Garden Hotel Building, 19- Birdwood Road, Lahore | Naveed Sarwar. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Reliance (Pvt) Ltd., 17/3, Mulana Zafar Ali Khan Road, Lahore | 1.Adrees Waqar Hayee.2. Adrees Saleem Hayee.3.Address Kamran Hayee. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore | Wasim Ijaz. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Pharma Consultant Pakistan (Pvt) Ltd. Suit No 207, 207 A Khan Tower DHA Square Walton Road Lahore Cantt. | Muhammad Kashif Saleem | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Medi Health Services, 1st Floor , 16-E Mehta Street Temple road, Lahore. | Mr. Faisal Ikram | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Kaumedex, E-144/2, New Super Town, Defence Road, Lahore Cantt. | Ali Raza Khan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Hope Pharma, 1-B, Guldasht Town, Zarar Shaheed Road, Lahore. | Kashif Amin | -do- | No | **Approved** with limited storage area for room temperature medical devices without cold chain facility. |
|  | M/s Genome Pharma, House No.166-A, Street No.9, Chaklala Scheme-III, Rawalpindi.**Godown:**Basement C-19, main Commercial Access Road, RCCI Industrial Estate, Rawalpindi. | 1.Abuzar Faizy Rattu 2.Faisal Zafar. | Muhammad Ayub Naveed, AD-II(MDMC), DRAP, Islamabad.Mr. Arsalan Tariq, AD (QC-I), QA&LT, DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility subject to provision of DSL. |
|  | M/s Fresenius Kabi Pakistan (Pvt) Ltd., Tanwir Ahmad Medical Center (TAMC), First Floor MM Alam Road, 27-C/3, Gulberg-III, Lahore**Godown:**Agility Logistrics Private Limite, RLC-2, 26 KM, Multan Road, Opp.Hussani Darbar, Near Shamshad Farm House, Lahore. | Noman Zia | Ms. Hira Bhutto, Assistant Director-I (MDMC),DRAP, Islamabad.Muhammad Ayub Naveed, Assistant Director-II (MDMC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s A.S Enterprises, 3, Mozang Road, Lahore. | Shafi ud Din. | -do- | Yes | **Approved** for room temperature medical devices alongwith cold chain facility. |
|  | M/s 3M Pakistan Pvt Ltd., 3M Pakistan Pvt Ltd.Islamic Chamber Of Commerce Building, St No 2/A Block 9, KDA Scheme 5, Clifton Karachi.**Godown:**Plot No.A-6, A-7, Qasim Logistics Center, North West Industrial Zone, Port Qasim, Karachi. | 1. Jarrri Masood Zaidi.2. Andrei Liviu Holban. | 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 Krestacorp, M/s Krestacorp.76-C, 3rd Floor, Office No.2 Khayaban-e-Jami Street No.9, DHA 7, Karachi. | 1.Mr.Kanwar Nouman Haseeb2. Mr. Kanwar Abdul Haseeb | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Eli Lillly Pakistan Pvt Ltd.5-A 5th floor 10th Buliding Floor , Al Tijarah Center, 32- A, Block 6, PECHS Main Shahrah e Faisal Karachi**Godown** B 23- (EL-1) Gate 5, S.I.T.E, Karachi. | Muhammad Mahmood Hanif | 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 Atlantic Pharmaceuticals. 445, Sodawaterwala Building Dr Ziauddin Ahmad Road, Near Light House, Karachi.**Godown:**C-1/8, Sector 16, Korangi Industrial Area Karachi. | Azmat ullah khan. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Easha Enterprises. Office No 376, Pak Khaleej Center Saidpur Road Rawalpindi. | Tauseef Ahmed Farooqi. | Mrs Unum Zia Shamsi, Assistant Director-IV (MDMC),DRAP, Islamabad.Miss Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Blue Birds Enterprises. Office No 01, Ashraf Plaza, Iqbal Road Rawalpindi.**Godown:**Office No 04, Ashraf Plaza, Iqbal Road Rawalpindi. | Waseem Aslam. | -do- | No | **Approved** for room temperature medical devices without cold chain facility. |
|  | M/s Claris Medical.Unit 27, 3rd Floor, Twin City Plaza I-8 Markaz Islamabad. | Mr. Saqib Altaf Chudhry. | Miss Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad.Hafiz Muhammad Asif Iqbal, AD-V (MDMC), DRAP, Islamabad. | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Safeway Systems Pakistan.Flat No. 4, 2nd Floor Amna Shopping Centre Misrial Road, Rawalpindi. | Mr. Zeeshan Haider. | Mrs Unum Zia Shamsi, Assistant Director-IV (MDMC),DRAP, Islamabad.Miss Hira Bhutto, Assistant Director-I (MD&MC), DRAP, Islamabad. | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Kohsar Distributors.Hill View Block, Lower Basement, Block No 516-523, Pakistan Town, Islamabad**Godown:**Plot No.3-4, Hall No.1, Korang Town, Islamabad. | Mr. Raja Iftikhar Ahmed. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |
|  | M/s Shaheen Medical Services. Opposite Benazir Bhutto International Airport Chaklala Rawalpindi. | Muhammad Sajid Waheed. | -do- | No | **Approved** for warm range (above 30°C) medical devices without cold chain facility. |

The Board also discussed at length the implications of imminent expiry of exemption period i.e 15-10-2018 for Class D medical devices and the resultant negative impact on import and availability of such medical devices. The Board taking into consideration the limitations of the Medical Devices Division in terms of human resource and time requirement for proper evaluation / assessment of enlistment / registration dossiers, decided that import of all such life saving / life sustaining Schedule "D" medical devics shall not be hampered, which have been provisionally registered and shall continue to be effective till decision is made on their submitted registration application by the MDB.

**Item No. III** . **APPLICATIONS FOR RENEWAL OF ESTABLISHMENT LICENSE TO MANUFACTURE MEDICAL DEVICES.**

 The below mentioned firms have applied for renewal of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel were constituted for inspection of their establishments. The information about the firms/companies and recommendations of the panel are submitted for consideration of MDB please:-

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **S.No** | **Name of Establishment** | **Address** | **Name of Production Inchange** | **Name of QC Incharge** | **Inspection panel & date of inspection** | **Recommendations** |
| 1. | M/s Crespak Medical Industries | 8.KM, Manga Raiwind Road, Lahore. | Muhammad Imran(Pharmacist)10 year exp | Nehmatullah, M.Sc. Microbiology10 year exp (not as per requirement) | Prof. Dr.Nadeem Irfan Bu,khari, Principal, Colege of Pharmacy, University of Punjab, Lahore.Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad.Muhammad Ayub Naveed, AD-II (MDMC), DRAP, Islamabad. | Recommended for renewal of Establishment License to manufacture medical devices for Hypodermic Syringe, Infusion Giving Sets, I.V.Catheter/Butterfly Needle Section. |
| **Decision:** Approved the Renewal of Establishment License to Manufacture Medical Devices alongwith following Sections. The firm shall surrender the Drug Manufacturing Licence and a fresh Establishment Licence to Manufcture Medical Devices shall be issued.(i) Hypodermic Syringe Section.(ii) I.V. Catheter/Butterfly Section.(iii) I.V Products Section. |
| 2.  | M/s Amson Vaccines & Pharma (Pvt) Limited | Plot No.113, Industrial Triangle, Kahuta Road, Islamabad. | Ch. Sajid Elahi(Pharmacist)06 year exp  | Fiaz Arshad(Pharmacist)06 year exp  | Prof. Dr.Abdul Halim Khan, Member, MDB.Muhammad Tahir Aziz, Member, MDB.Mrs. Unum Zia Shamsi, AD-IV (MDMC), DRAP, Islamabad | Recommended for renewal of Establishment License to manufacture medical devices in Syringe Section. |
| **Decision:** Approved the Renewal of Establishment License to Manufacture Medical Devices alongwith following Sections. The firm shall surrender the Drug Manufacturing Licence and a fresh Establishment Licence to Manufcture Medical Devices shall be issued.1. Syringe Section.
 |

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

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

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

In the light of above decision, this Division has issued 47 Provisional Registration Certificates (PRCs) to different importers of medical devices uptil 04-10-2018. The list of PRCs is annexed at Annexure-I for information of MDB please.

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

**Item No. V**. **Inspection of Manufacturer Abroad M/s Engineering Technical Plastic Industries (ENTEPLIN) Egypt.**

 The Registration Board in its 246th meeting held on 10th & 11th December, 2014 considered and approved the following medical devices of M/s. A. Feroz & Co, Karachi subject to inspection of manufacturer abroad, local storage facility etc:-

|  |  |  |  |
| --- | --- | --- | --- |
|  | M/s. A. Feroz & Co., Medicine Street No.1, Marriot Road, Karachi.**Manufactured by**M/s. Engineering Technical Plastic Industries (Enteplin-Egypt) 10th of Ramadan City, Industrial Zone, A-1 Part 41/3. Sharqia, Egypt.**Sterilization Site:**M/s EG Med (S.A.E) having their plant at Part 100-Industrial Zone, B-3, 10th of Ramadan City, Egypt. | Star IV. Catheter with Injection Port | (14G, 16G, 18G, 20G, 22G, 24G)100 per box |

 Accordingly the inspection of manufacturer abroad has been carried out by the panel comprising Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore and Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad on 20-03-2018. The recommendation of the panel is as under:-

***"The panel unanimously concluded that the firm has adequate building, machinery and know-how for manufacturing of IV Catheter but they are deficient in an important component of QC and Sterility testing, therefore, is of the opinion that the firm is not recommended for import of IV Catheter under current circumstance. The panel thus proposed that the firm be re-inspected once it is equipped with the QC and microbiology lab."***

**Decision:** The Board rejected the application of M/s A. Feroz & Co., Medicine Street No.1, Marriot Road, Karachi for import of Star IV Catheter with Injection Port from M/s Engineering Technical Plastic Industries (Enteplin-Egypt) 10th of Ramadan City, Industrial Zone, A-1 Part 41/3. Sharqia, Egypt based on the panel inspection report whereby inte-ralia deficiencies of Quality Control and Sterility Testing facilities were pointed out.

**Item No. VI**. **TRANSFER OF REGISTRATION.**

 M/s Premier Agencies, Karachi has requested for transfer of following registered imported drugs (Medical Devices) from the name of M/s Becton Dickinson Pakistan (Private) Limited, Lahore to their name:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| S.# | Regn.No. | Brand Name of Medical Device | Packing | Shelf Life | Name of Manufacturer |
| (i) | 059212 | BD Ultra Fine TM II Insuline Syringe | 1 ml | 5 years | M/s Becton Dickinson and Company, USA |

 The firm has submitted following documents:-

1. Application dossier alongwith Form 7-A for the above product.
2. Fee of Rs.100,000/- for above product.
3. Letter of Authorization regarding above product to M/s Premier Agencies, Karachi from the foreign manufacturer, namely, M/s Becton Dickinson and Company, USA (legalized from High Commission of Pakistan/Embassy).
4. Letter of Termination of Authorization of M/s Becton Dickinson Pakistan (Pvt) limited, Lahore from the foreign manufacturer (legalized from High Commission of Pakistan/Embassy).
5. Original NOC from M/s Becton Dickinson Pakistan (Pvt) Limited, Lahore regarding transfer of registration of above products to M/s Premier Agencies, Karachi (legalized from High Commission of Pakistan/Embassy).
6. Original and valid Free Sale Certificate of US FDA for the above product.
7. Clarification from M/s Asto Life Sciences (Pvt) Limited, Lahore (Authorized Distributor of BD, other than BD Insulin Syringe-II 0.5ml and 1 ml) that they have no concern in this regard.
8. Memorandum of Understanding between M/s Asto Life Sciences (Pvt) Limited and M/s Premier Agencies for transfer of registration of above mentioned medical device.

 It is submitted that M/s Premier Agencies, Karachi has been issued Establishment Licence to Import Medical Devices under MDR, 2017 vide Licence No. ELI-00050, dated 3rd August, 2018.

Decision: TheBoard apporved the new registration of BD Ultra Fine TM II Insuline Syringe, 1 ml in tha name of M/s Premier Agencies, Karachi on the same terms and conditions as was previously registered and cancelled the registration of the same in the name of M/s Becton Dickinson and Company, USA.

**Item No. VII. Applications for 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 Establishment** | **Name of Medical Device** | **Product Details**  | **MD Class** | **Shelf Life** |
|  | M/s Vikor Healthcare (Pvt) Ltd 159/P, Block 3, Kashmir Road P.E.C.H.S., Karachi.Manufacturing Facility, Plot C-126 to C-135 LIEDA, Hub District Lasbela, Baluchistan. | SURGLINE TM POLYCRYL TM PLUS(Polyglactin 910 PGA-PLA with anti-bacterial coating, sterile, braided, absorbable synthetic surgical suture) | A sterile absorbable, synthetic braided surgical suture composed of copolymers made from 90% glycolide and 10% L-lactide | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| LCH201, LT201, LT202,LB301,LCH202,LT203,LT204,LT205,LT206,LC201,LT207,LT208,LT209,LT211,LT210,LT601,LT212,LT213,LT214,LS001,LS002,LT215,LCH203,LC202,LT216,LX301,LT217,LT218,LT219,LR301,LCH204,LN301,LN302,LT220,LT221,LC203,LX302,L0001,LS003. |
|  | -Do- | SURGLINE TM PERMA STEEL TM(Stainless Steel Wire) | SURGLINE TM PERMA STEEL TMis a sterile non absorbable surgical suture composed of high grade Stainless Steel Wire of finest quality (AISI 316LVM, AISI316L) | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| WA201, WR201, WC201, WR202, WC202, WR301, WTS201, WTS202, WT201, WTS203, WTS204, WTS205, WTS206. |
|  | -Do- | SURGLINE TM Mono TM PLUS(Polyglycolide-co-caprolactone) | SURGLINE TM Mono TMPLUS is a sterile monofilament, absorbable, synthetic, surgical suture composed of Poly (glycolide –co-caprolactone) Copolymer (polyglicaprone 25) with antibacterial coating of ChlorhexidineDiacetate. | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| UR301, UR302, UR303, US001, UTH201, UT201 |
|  | -Do- | SURGLINE TM POLYSORB TMQUICK(Fast Absorbable Polyglycolic Acid) | SURGLINE TM POLYSORB TMQUICK is a sterile, braided, absorbable, synthetic surgical suture composed of Polyglycolic Acid. | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| QC201, QR301, QC202, QS001, QC203, QR302, QS002, QC204, QR303, QR304, QX301, QR305, QN301, QX302, QR306, QTH201, QR307, QU301, QU302. |
|  | -Do- | SURGLINE TM NYFLEX TM(Polyamide 6.6) | SURGLINE TM NYFLEX TMis a sterile, monofilament, non-absorbable synthetic surgical suture composed of polymide 6.6. | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
|  |
| FR201, FT201,FX301, FS001, FR301, FR302, FN301, FT301, FT302, FUD201, FUD301, FT303, FT202, FTH201. |
|  | -Do- | SURGLINE TM POLYSTER(Polyester) | SURGILINETM POLYESTER is a sterile, nonabsorbable synthetic surgical sutureComposed of poly (ethylene terephthalate). | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| BT201, BT202, BT203, BT204, BT205, BC201, BTD201, BTD202, BTD203, BCD201, BCD202, BCD203,BUD201, BUD401, BCD301, BX301, BCH201, BCH202, BCD204, BCD205, BCD206, BCD207, BCD208,BRD201, BCH203. |
|  | -Do- | SURGLINE TM POLYSORB TM(Polyglycolic Acid) | SURGILINETM POLYSORBTM is a sterile,braided, absorbable, synthetic surgical suture composed of Polyglycolic Acid | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| GT201, GCH201, GT202, GB301, GCH202, GT203, GT204, GC201, GT205, GT206, GT207, GT208, GT601, GT209, GS001, GT210, GCH203, GC202, GX301, GT211, GT212, GCH204, GN302 GX302 , GN301, GR301, GX303, GC203 ,GX304, G0001, G0002, GS002, GS003, GN303, GX305, GT213, GT214, GN304, GX306, GN305, GR302, GX307, GT301, GR303, GT602, GT215, GN306, GX308, GT216, GX309, G0003, GN307, GX310, GT217, GX311, GN308, GT302, GT218, GT219, GX312, GN309, GX313, GT220, GT303, GR304, GT221, GT222, GX316, GT223, GN310, GX317, GR305, GT304, GUD201, GUD401, GT224, GT225, GX318, GN311, GT305, GR306, GT306, GUD301, GUD302, GT307, GUD402, GUD202, GT226, GUD304, GUD203, GUD303, GT308, GT309, GUD305, GUD306. |
|  | -Do- | SURGLINE TM POLYCRYL TM(Polyglactin 910) | SURGLINE TM POLYCRYL TM is a sterile, absorbable synthetic braided surgical suture composed of copolymer made from 90% glycolide and 10 % L-lactide. | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| YT224, YT225, YX318, YN311, YT305, YR306, YT306, YUD301, YUD302, YT307, YUD402, YUD202, YT226, YUD304, YUD203, YUD303, YT308, YT309, YUD305, YUD306, ZYT702, ZYT701, ZYT001, ZY001.  |
|  | -Do- | SURGLINE TM DIOXOSORB TMPLUS(Polydioxanone) anti-bacterial coated  | SURGILINE TM DIOXOSORBTM Plus is a sterile, absorbable, synthetic monofilament, surgical suture composed of Poly (p -dioxanone). | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| XT201, XT202, XTH203, XT203, XT204, XT205, XTH204, XT206, XT207, XTH205, XT208, XTH206, XT209, XTD201, XN301, XX301, XT210, XT211, XTD301, XTD302, XT301, XTH201, XTH202, XCH201, XTD302, XED301, XTD303, XED302. |
|  | -Do- | SURGLINE TM DIOXOSORB TM(Polydioxanone PDO) | SURGILINE TM DIOXOSORBTM is a sterile, monofilament, absorbable synthetic surgicalsuture composed of poly (p - diaxanone). | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| DT201, DT202, DTH203, DT203, DT204, DT205, DTH204, DT206, DT207, DTH205, DT208 , DTH206, DT209, DTD201, DN301, DX301, DT210, DT211, DTD301, DTD302, DT301, DTH201, DTH202, DCH201, DTD302, DED301, DTD303, DED302, ZD001, ZD002, ZD003. |
|  | -Do- | SURGLINE TM POLYCRYL TMRAPID(Fast AbsorablePolyglactin 910) | SURGILINE TM POLYCRYLTM RAPID is a sterile,absorbable, synthetic braided surgicalNeedle. Surgical suture composed ofcopolymers made from 90% glycolide and10% L-lactide. | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| RC201, RR301, RC202, RS001, RC203, RR302, RS002, RC204, RR303, RR304, RX301, RR305, RN301, RX302, RR306, RTH201, RR307, RU301, RU302 |
|  | -Do- | SURGLINE TM POLYSORB TMPLUS(Polyglycolic Acid) | SURGILINE TM POLYSORBTM Plus is a sterile,braided, absorbable, synthetic surgicalsuture composed of Polyglycolic Acid withantibacterial coating SURGILINETM | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| ACH201, AT202, AT201, AB301, ACH202, AT206, AT207 , AT208 , AC201 , AT205, AT204, AT203, AT601, AT214, AT213, AT212, AT211, AT210, AT209, AT216,, AX301 , AR301, AX302, AT215, AT217, AT218 AT219, AT220, AT221, AC202, AC203, ACH203, ACH204, AS001, AS002, A0001, AN301, AN302, AT222 , AT223, AT303, , AT224,, AT225, AT226, AT227, AT602, AS003, AS004, AR302, AR303, A0002, AN303, AN304, AN305, AN306, , AX303, AT301 , AT228, AT230, AT231, AT232 , A0003, AN307 , AN308, AN309, AX304, AT233, AT229 , AT234, AT302, ,AT235, AUD201, AUD401, AR304, AR305, AX305, AN310. |
|  | -Do- | SURGLINE TM SURGILENE TM(Polyproylene) | SURGLINE TM SURGILENE TM sutures are sterilized by Ethylene oxide,Validation. | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| NT201, NT202, NS001, NT203, NTH201, NT204, NC201, NC201, NR301, NTH202, NS002, NS003, NX301, NT205, NR302, NCD201, NT206, NED201, NC202, NT207, NCD202, NTD201, NT208, NS004, NT209, NTD202. NTD203, NTD204, NN301, NX303, NR304, NX312, NT210, NC203, NT211, NX201, NE301, NE302, NTD205, NX302, NT212, NT213, NX304, NN302, NX307, NTD206, NT214, NED202, NTD207, NX305, NR305, NC204, NTD208, NT215, NX306, NN3O3, NX308, NED203, NN304, NR304, NR307, NX309, NTD209, NN305, NT216, NTD210, NED204, NX310, NTD211, NTD301, NR306, NR308, NED205, NN306, NX311, NTD302, NTD303, NED302, NED303, NW303, NR309, NTD304, NTD212, NED303, NT101, NTD306, NED304, NE304, NW302, NTD213, NCD203, NTD305, NCD301, NE305, NW301, NED305, NTD307, NED306, NE306, NW304, NTD308, NCD302, NE307, NW305, NED307, NWD302, NRD302, NED308, NE308, NW306, NT217, NTD214, NWD301, NCD303, NRD301, NE309, NW307, NED309, NTD309, NSD001, NUD301, NUD302. |
|  | -Do- | SURGLINE TM MONO TM(Polyglycolide-co-caprolactone) | SURGILINE TM MONOTM is a sterile,monofilament, absorbable synthetic surgicalsuture composed of (Polyglycolide-cocaprolactone) | Class D | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| MR301,MR302, MR303, MS001, MTH201, MT201.  |
| **Decision:** The Board after thorough deliberations regarding manufactruing and quality control conditions of the firm and on knowing that the firm has a microbiology section and experienced technical staff, approved the product from serial No. 1-14 subject to recommendations of the follwoing Committee: i) Dr. Saqib Shafi (member MDB)ii) Dr. Abdul Haleem Khan (member MDB)The Committee shall re-evaluate the dossiers and shall give clear recommendations regarding utility and requirement of products in surgery.It was also decided that a GMP inspection shall be conducted of the firm to ascertain the present GMP status during due course of manufacturing.  |
|  | M/s Cotton Craft (Pvt) LtdNo. 407-408, Sunder Industrial Estate, Raiwand, Lahore. | Pro-Max Alcohol Swab(Isopropyl Alcohol.) | For preparation of skin prior to injection. For first aid to decrease germs in minor cuts, scrapes and burns. | Class C | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| Pro-Max Alcohol Swab Sterile (1x100) 3cm x 3cm (2-Ply) Pro-Max Alcohol Swab Sterile (1x200) 3cm x 3cm (2-Ply)   |
|  | -Do- | Farma-Tulle BpFarmycetin Sulphate BP....1 | Treatment of infected or potentially infected burns, wounds, ulcers, graft sites and other lesions that are clinically infected by organisms shown to be sensitive to framycetin. | Class C | 5 Years**DML Holder****Stability study not provided (Undertaking)** |
| 1. -Tulle Bp (Framycetin Sulphate 1 %) Sterile 10cm x 10 cm
2. Frama-Tulle Bp (Framycetin Sulphate 1 %) Sterile 15cm x 20 cm
3. Frama-Tulle Bp (Framycetin Sulphate 1 %) Sterile 15cm x 150 cm
 |
| **Decision:** The Board approved the products at serial No. 15-16 subject to the submission of stability studies.  |
|  | M/s Injection System (Pvt) Ltd,Plot No. 271, Main Road , Industrial Estate GadoonAmazai | BIOSAFE U-100/1ML Insulin Syringe | (U100/1ml Insulin Syringe) | Class B | **5 Years****DML Holder****Stability study not provided (Undertaking)** |
| **Decision :** The Board approved the product at serial No. 17 subject to submission of stability studies and satisfactory GMP inspection report. |
|  | M/s Silver Surgical Complex Pvt Ltd. C-40, S.I.T.E II, Super Highway Industrial Area Karachi. | Orange 1cc, 3cc, 5cc, 10cc, 20cc, Syringe(Auto Disable Syringe) | Auto Disable Syringe with Detachable Needle | Class B | 5 YearsDML HolderStability study not provided (Undertaking) |
|  | -do- | Silver Intravenous Set(I.V Set) | It is used as universal device for the administrator of fluids and drugs with no particulars filtration requirements. | Class B | 5 YearsDML HolderStability study not provided (Undertaking) |
| **Decision :** The Board approved the product at serial No. 18-19 subject to submission of stability studies and satisfactory GMP inspection report. |
|  | M/s Idcot Pharmaceuticals 57, 1st floor Muslim Town# 1 Sargodha Road, Faisalabad. | Gauzocracy Surgical Gauze Swab / Sponge | 100% Cotton fabric with loose wave. It is used in Hospitals. | Class B | 3 Years |
| **Decision :** The Board approved the product at serial No. 20. |

**Item No.VIII. Renewal of registration of Medical Devices for Local Manufacture.**

 Following firms have applied for renewal of their medical devices for local manufacture.:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr.No.** | **Name and Addresses of Establishment** | **Name of Medical Device** | **Product Details**  | **MD Class** | **Shelf Life & Registration No.** |
|  | M/s Rehman Rainbow (Pvt) Ltd 82-M Industrial Estate KotLakhpat Lahore. | Surgee Gauze B.P.C(Swabs & Sponges (Sterile) | Gauze Swabs and sponges are used for packing open wounds and swabbing procedures. They are also used as direct wound dressings. | Class C | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030772 |
| SurgeeGuaze5cm X 5cmSurgeeGuaze7.5 cm X 7.5 cmSurgeeGuaze10 cm X 10 cmSurgeeGuaze15 cm X 15 cmSurgeeGuaze10 cm X 10 cm |
|  | -do- | Surgee Cot B.P.C (Absorbent Cotton Wool) | Nil | Class A | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030779 |
| 1. Surgee Cotton 50 grm
2. Surgee Cotton 100 grm
3. Surgee Cotton 200 grm
4. Surgee Cotton 250 grm
5. Surgee Cotton 400 grm
6. Surgee Cotton 500 grm
 |
|  | -do- | Surgee Wax (Paraffin Gauze Dressing) | Surgee Bandage B.P.C is intended to be used principally with wounds which have breach the dermis. | Class C | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030778  |
| Surgee Wax 10 cm x 10 cm |
|  | -do- | Surgee Bandage B.P.C(Open wove Bandage Type-I) | Surgee Bandage B.P.C is intended to be used principally with wounds which have breach the dermis. | Class B | 3 Years |
| 1. Surgee Bandage 2.5 cm x 1 meter/ Dozen |
|  | -do- | Surgee Bandage B.P(Bandage Type-II) | Surgee Bandage B.P. Type-I is used to protect dressing and hold them in place and to give support. It is also used to secure splints. | Class B | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030775  |
| 1. Surgee Bandage 5 cm x 2 meter /Dozen
2. Surgee Bandage 7.5 cm x 2 meter /Dozen
3. Surgee Bandage 10 cm x 2 meter/ Dozen
4. Surgee Bandage 15 cm x 2 meter/Dozen
5. Surgee Bandage 5 cm x 3 meter/Dozen
6. Surgee Bandage 7.5 cm x 3 meter/Dozen
7. Surgee Bandage10 cm x 3 meter/Dozen
8. Surgee Bandage 15 cm x 3 meter/Dozen
 |
|  | -do- | Surgee Crepe( Cotton Crepe Bandage B.P.C) | Surgee Crepe (Cotton Crepe Bandage) consist of Characteristics fabric of plain weave, in which the warp thread are of cotton and weft threads are of cotton or rayon or of combined cotton and rayon yarn. | Class A | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030776 |
| 1. Surgee Crepe 3” x 4.5 meter
2. Surgee Crepe 4” x 4.5 meter
3. Surgee Crepe 6” x 4.5 meter
 |
|  | -do- | Surgee Optic (Eye Pads B.P.C) | Surgee Optic is a pad of absorbent cotton wool, Face on both sides with absorbent muslin, attached to an open woven bandage. It is used as a protective covering of eye. | Class A | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030782  |
| Surgee-Optic 1 x 50 |
|  | -do- | Surgee Shell B.P.C(Dressing Shell) | Consists of cotton pads in different sizes. Wrapped with highly absorbent acriflavine. Treated gauze stitched with brown roller bandage of size 5 cm x 4 meters. Wrapped in butter papers and sealed in poly coated paper pack. It is used as a first aid during war. | Class B | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030781  |
| Surgee Shell 1’s |
|  | -do- | Surgee Tulle B.P (Wound Dressing (Sterile) | Surgee Tulle consist of fabric of leno weave with two picks in each shed in which the warp and weft threads consists of cotton or viscos or combine. Fabric is evenly impregnated with a paraffin wax with suitable ointment. | Class C | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030783  |
| Surgee Tulle 10 cm x 10 cm |
|  | -do- | Surgee Lint B.P.C (Absorbent Lint) | Surgee Lint B.P.C consist of cotton cloth plain have one side a nap well raised from the warp yarn it is bleached to good white clean and reasonably free from weaving defect. | Class A | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030780 |
| 1. SurgeeLint 25 grams
2. Surge Lint 500 grams
 |
|  | -do- | Surgee Absorbent Gauze Cloth(Absorbent Gauze B.P.C) | Surgee absorbent Gauze cloth is intended to be used principally with wounds which have breached the dermis including devices principally intended to manage the micro environment of a wound. | Class B | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030773 |
| 1. Absorbent Gauze 1 m x 20 m
2. Absorbent Gauze 1 m x 30 m
3. Absorbent Gauze 1 m x 40 m
4. Surgee Gauze 5 cm x 5xm
5. Surge Gauze 7.5 cm x 7.5 cm
6. Surgee Gauze 10 cm x 10 cm
 |
|  | -do- | Orthofast B.P.C(Plaster of Paris Bandagers) | Orthofast consist of cotton cloth impregnated with derived calcium sulphate and suitable adhesive so that the calcium sulphate is adhere to the fabric. | Class A | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 030777 |
| 1. Orthofast plaster of Paris 10 cm x 2.7 cm
2. Orthofast Plaster of Paris 15 cm x 2.7 m
 |
| **Decision :** The Board approved the renewal of products at serial No. 1-12, however the firm will be asked to submit the ongoing stability studies of the products.  The Board further constituted the following Committee to identify all the categories / classes of medical devices for whcih stability study is required: i) Dr. Tahir Aziz (member MDB) ii) Dr. Ghazanfar Ali Khan (Secretary MDB) iii) Mr. Asif Iqbal, AD-V, MDMC Division |
|  | M/s Surgical Textiles (Pvt) Ltd 70 km Multan Road Near Pattoki Distt Kasur. | RayLint Absorbent Cotton Lint (B.P)Sterile Absorbent Cotton Lint Gauze (B.P) (Surgical Dressings) | Absorbent Cotton Lints Gauze (Surgical Dressings), used to stop flow of blood, absorb immobilize an injured part of the body to prevent further injury and to facilitate. Protects cushions the wound. | Class B | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 009950 |
| **RayLint (Absorbent Cotton And Viscose Gauze (B.P)****10cm x 10cm (8-ply)** |
|  | -do- | RayBand Absorbent Cotton Gauze(Sterile Absorbent Cotton Gauze (B.p) (Surgical Dressings) | Absorbent Cotton Gauze (Surgical Dressings) used to stop flow of blood, absorb immobilize and uninjured part of the body to prevent further injury and to facilitate. Protects and cushions the wound. | Class B | 3 YearsDML HolderStability study not provided (Undertaking)Registration No. 009951 |
| Rayband Gauze Swabs/ Sponges Absorbent Cotton Gauze (B.P)10cm x 10cm (8 Ply ) |
| **Decision:** The Board approved the renewal of products at serial No. 13-14 subject to GMP inspection and satisfactory inspection report. |
|  | M/s BSN Medical Pvt Ltd , A/69, S.I.T.E Manghopir Road, Karachi | Cuticelll ® CChlorhexidine Acetate Tulle Gras Dressing | Cuticell C is used as an antiseptic non-adherent dressing for the prevention of infection in wounds and may be used include lacerations, abrasions, minors, burns, leg ulcers and donor and recipient graft sited. | Class C | 2 YearsDML HolderStability study not provided (Undertaking)Registration No. 053282 |
| 1. 5cm x 5cm
2. 10cm x 10 cm
3. 15cm x 20cm
4. 15cm x 1m
5. 15cmx2cm
 |
| **Decision:** The Board approved the renewal of products at serial No. 15 subject to GMP inspection and satisfactory inspection report. |
|  | M/s Amson vaccines & Pharma (Pvt) Ltd. **Head Office :** Plot No.115, Industrial Triangel, Kahuta Road, Islamabad.**Plant:**Plot 113, Industrial Triangle, Kahuta Road, Islamabad.  | Apple K1 5.0 ml | Auto Disable Syringe | Class B | 5 YearsRegistration No.050850 |
|  | -do- | Apple 3.0 ml | Disposable Syringe  | Class B | 5 YearsRegistration No.050851 |
|  | -do- | Destroject AD 1000, 0.5ml | Auto Disable Syringe  | Class B | 5 YearsRegistration No.050852 |
|  | -do- | Apple K1 0.5 ml | Auto Disable Syringe  | Class B | 5 YearsRegistration No.050853 |
|  | -do- | Apple K1 2.0 ml | Auto Disable Syringe  | Class B | 5 YearsRegistration No.050854 |
|  | -do- | Apple 5.0 ml | Disposable Syringe  | Class B | 5 YearsRegistration No.050855 |
|  | -do- | Apple K1 3.0 ml | Auto Disable Syringe  | Class B | 5 YearsRegistration No.052999 |
| **Decision:** The Board approved the renewal of products at serial No. 16-22. |

**Item No. IX. Change of Brand Name of Medical Devices for Local Manufacture.**

 Following firms have applied for change of registration name of their medical devices for local manufacture.:-

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sr.No.** | **Name and Addresses of Establishment** | **Name of Medical Device** | **Product Details**  | **MD Class** | **Shelf Life** | **Fee Deposit** |
|  | M/s Silver Surgical Complex Pvt Ltd. C-40, S.I.T.E II, Super Highway Industrial Area Karachi. | **SILVER IV Cannula****Existing Registered Name:****Silver IV Cannula/ Catheter with wings injection port type.****(Proposed Name/ to be change as” Silver I.V Cannula)** | Cannula is a small plastic tube (E.T.F.E or F.E.P) that is inserted through the skin in to one of the small vein in the hand or arm of patient. They are used to give many different type of medication, e.g., antibiotics or fluids. | Class B | 5 Years | 10,000/= |
| **Decision:** The Board acceeded to the request of the firm for the change in brand name. |

**Item No.X. Application For Enlistment of Medical Devices For Local Manufacture.**

 Following firms have applied for enlistment of their medical devices for local manufacture.:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr.No.** | **Name and Addresses of Establishment** | **Name of Medical Device** | **Product Details**  | **MD Class** | **Shelf Life** |
|  | M/s Cotton Craft (Pvt) LtdNo. 407-408, Sunder Industrial Estate, Raiwand, Lahore. | Pro-Max Combine Dressing (Sterile) | Non woven surgical dressing | Class-A | 3 Years |
| Pro-Max Combine Dressing (Sterile) 10cm x 10cmPro-Max Combine Dressing (Sterile) 10cm x 10cm |
|  | -do- | Tacheal Non-Woven Sponges | Now-woven material/ FabricHighly absorbent | Class-A | 3 Years |
| 1. Tracheal Non-Woven Sponges Sterile (1x5x2)x 10 10cm x 10cm (8-ply)
2. Tracheal Non-Woven Sponges Sterile (1x10x10) 10cm x 10cm (8-ply)
3. Tracheal Non-Woven Sponges Sterile (1x12) 10cm x 10cm (8-ply)
4. Tracheal Non-Woven Sponges Sterile (1x100) 10cm x 10cm (8-ply
 |
| **Decision:** The Board approved the enlsitment of product at serial No. 1-2. |
|  | M/s Idcot Pharmaceuticals 57, 1st floor Muslim Town# 1 Sargodha Road, Faisalabad. | Bandocracy Type IICotton Bandage**Size**5 cms to 15 cms width 3m to 6m length. | Cotton Bandage | Class-A | 3 Years |
|  | -do- | Bandocracy BPCCotton Bandage**Size**5 cms to 15 cms width 3m to 6m length. | Cotton Bandage | Class-A | 3 Years |
|  | -do- | Crepocracy Cotton Crepe Bandage**Size**7.5 cms to 15 cms width 4.5m length. | Cotton Crepe Bandage | Class-A | 3 Years |
|  | -do- | Gauzocracy Surgical Gauze Roll**Size**100 cms width per roll 2.5 meter to 50 meter length per roll.  | Surgical Gauze Roll | Class-A | 3 Years |
|  | -do- | Cottonocracy Absorbent Cotton**Size**Cotton rolls of 25 grams to 1000 grams  | Absorbent Cotton | Class-A | 3 Years |
| **Decision:** The Board approved the enlsitment of products at serial No. 3-7. |

**Item No. XI. Application For Renewal of Enlistment of Medical Devices For Local Manufacture.**

 Following firms have applied for renewal of enlistment of their medical devices for local manufacture.:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sr.No.** | **Name and Addresses of Establishment** | **Name of Medical Device** | **Product Details**  | **MD Class** | **Shelf Life & Registration No.** |
|  | M/s Uniferoz (Pvt) Ltd Karachi.32/8 Sector 15, Korangi Industrial Area, Karachi. | Nichipore | Surgical Tape | Class- A | 4 YearsRegistration No. 016123 |
| 1. Nichipore Surgical Tape 12mm x 4.5 m Nichipore Surgical Tape 20mm x 4.5 m
2. Nichipore Surgical Tape 25mm x 4.5 m Nichipore Surgical Tape 50mm x 4.5 m
3. Nichipore Surgical Tape 75mm x 4.5 m
4. Nichipore Surgical Tape 100mm x 4.5 m
 |
|  | -do- | Uniplast-F Bandage | Fabric Bandage (First Aid Bandage | Class- A | 4 YearsRegistration No. 035328 |
| Uniplast Medium (20mm x 70mm) |
|  | -do- | Saniplast | Fabric Bandage (First Aid Bandage | Class- A | 4 YearsRegistration No. 030650 |
| Uniplast Medium (20mm x 70mm) |
|  | -do- | Saniplast | First Aid Bandage | Class- A | 4 YearsRegistration No. 030651 |
| 1. Saniplast Medium 20mm x 72mm
2. Saniplast Medium 25mm x 25mm
3. Saniplast Medium 25mm x 72mm
4. Saniplast Medium 30mm x 72mm
5. Saniplast Medium 38mm x 38mm
6. Saniplast Junior 20mm x 56mm
7. Saniplast Assorted 4 in 1

Medium+Spot+Large+Square1. Saniplast First Aid Bandage 38mm x 76mm Knuckle
 |
|  | -do- | Dermapore | (Non-woven paper Surgical Tape) | Class- A | 4 YearsRegistration No. 070869 |
| 1. Dermapore Non-woven Paper Surgical Tape 12mm x 4.5m
2. Dermapore Non-woven Paper Surgical Tape 20mm x 4.5m
3. Dermapore Non-woven Paper Surgical Tape 25mm x 4.5m
4. Dermapore Non-woven Paper Surgical Tape 50mm x 4.5m
5. Dermapore Non-woven Paper Surgical Tape 75mm x 4.5m
6. Dermapore Non-woven Paper Surgical Tape 100mm x 4.5m
 |
|  | -do- | Saniplast Xcel  | First Aid Bandages | Class- A | 4 YearsRegistration No. 061557 |
| 1. Saniplast Medium 20mm x 72mm
2. Saniplast Large 385mm x 72mm
3. Saniplast Spot 25mm
4. Saniplast square 38mm x 38mm
5. Saniplast Assorted 20mm x 72mm,30mm x 82mm, 25mm
6. Saniplast Assorted 20mm x 72mm, 38mm x 38mm, 38mm, 72mm
 |
|  | -do- | Uniplast | Fist Aid Bandages | Class- A | 4 YearsRegistration No. 042239 |
| Uniplast Medium 20mm x 72mm  |
|  | -do- | Saniplast Ultra | Fist Aid Bandages | Class- A | 4 YearsRegistration No. 067469 |
| 1. Saniplast Medium 20mm x 72mm
2. Saniplast Large 38mm x 72mm
3. Saniplast Spot 25mm
4. Saniplast Square 38mm x 38mm
5. Saniplast Assorted: 20mm x 72mm, 25mm
6. Saniplast Assorted: 20mm x 72mm, 38mm x 38mm, 38mm x 72mm
 |
| **Decision:** The Board approved the enlistment of products at serial No. 1-8 subject to GMP inspection and satisfactory inspection report. |

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

 Following firms has applied for the grant of registration of medical devices for import on prescribed form 7-A:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S #** | **Name and Addresses of Establishment** | **Manufacture Details** | **Name of Medical Device with sizes/Class/Shelf Life** | **Brief Description** | **Remarks** |
| 1 | M/s Hashir Surgical Services(i) Office No. 16, Street No.1, F-2, Phase 6, Hayatabad, Peshawar(ii) Office No. 5, 2nd Floor, Syed's Tower, University Road, Peshawar(iii) House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar(ELI00075) | **Legal Manufacture:** M/s Meditop Corporation (Malaysia) SDN BHD No.3, Persiaran Usahawan, Taman IKS, Seksyen 9, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia**Manufacturer:** M/s Top Corporation 19-10 Senju Nakai-Cho, Adachi-Ku, Tokyo 120-0035, Japan(FSC Malaysia) | Top IV CatheterGB2856564616Class BShelf Life: 5 Years | IV Catheter |  |
| **Decision:** The Board approved the registration of product for import at serial No. 1 subject to re-evaluation of dossier by the Secretary MDB. |
| 2 | M/s Atco Pharma International (Private) Limited, B-18, S.I.T.E., Karachi | **Manufactured By:**M/s CID S.p.A Strade per Crescentino s/n, 13040 Saluggia (VC), Italy (FSC Italy) | Cre8 Amphilimus Eluting Coronary StentSizes:Stent Length (mm): 8, 12, 16, 20, 25, 31, 38 & 46.Stent Dia (mm): 2.25, 2.50, 2.75, 3.00, 3.50, 4.00 & 4.50.Class DShelf Life: 2Year**Cre8 code:**ICLI22508, ICLI22512, ICLI22516, ICLI22520, ICLI22525, ICLI22531, ICLI2508, ICLI2512, ICLI2516, ICLI2520, ICLI2525, ICLI2531, ICLI2538, ICLI2546, ICLI27508, ICLI27512, ICLI27516, ICLI27520, ICLI27525, ICLI27531, ICLI27538, ICLI27546, ICLI3008, ICLI3012, ICLI3016, ICLI3020, ICLI3025, ICLI3031, ICLI3038, ICLI3046, ICLI3508, ICLI3512, ICLI3516, ICLI3520, ICLI3525, ICLI3531, ICLI3538, ICLI3546, ICLI4008, ICLI4012, ICLI4016, ICLI4020, ICLI4025, ICLI4031, ICLI4038, ICLI4512, ICLI4516, ICLI4520, ICLI4525, ICLI4531 | Polymer-free Amphilimus (Sirolimus + Organic Acid) Eluting Coronary Stent |  |
| **Decision:** The Board approved the registration of product at serial No. 2 for import subject to re-evaluation of dossier by the Secretary MDB. |
| 3 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) Transfer Case | WEGO Disposable Blood Bag Single 250ml and 500mlClass CShelf Life: 2Year | Disposable Blood Bag Single with anticoagulant CPDA | Transfer of Registration case from M/s Genome Pharma to M/s IBL Healthcare |
| 4 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) | WEGO Disposable Infusion Set, with needle; without needle, model of needle (if with needle) 0.45#, 0.5#, 0.55#, 0.6#, 0.7#, 0.8#, 0.9#, 1.1#, 1.2#Class BShelf Life: 3Year | Disposable Infusion Set, with needle; without needle |  |
| 5 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) | WEGO Disposable Syringes for Single Use 1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20mlClass BShelf Life: 5Year | Disposable Syringes for Single Use |  |
| 6 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) Transfer Case | WEGO Disposable Blood Bag Double 250ml and 500mlClass CShelf Life: 2Year | Disposable Blood Bag Double with anticoagulant CPDA | Transfer of Registration case from M/s Genome Pharma to M/s IBL Healthcare |
| 7 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) | WEGO I.V. Cannula for Single Use 14G, 16G, 18G, 20G, 21G, 22G, 23G, 24, 26GClass BShelf Life: 2Year | Cannula for Single Use  |  |
| 8 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) Transfer Case | WEGO Disposable Quadruple Blood Bag250ml and 500mlClass CShelf Life: 2Year | Disposable Quadruple Blood Bag with anticoagulant CPDA | Transfer of Registration case from M/s Genome Pharma to M/s IBL Healthcare |
| 9 | M/s IBL HealthCare Limited, 9th Floor, NICL Building, Abbasi Shaheed Road, Karachi(ELI-00119) | **Manufactured By:**M/s Shandong Weigao Group Medical Polymer Co., Ltd., No. 18 Xingshan Road, Weihai Torch Hi-Tech Science Park, Shandong Province, China(FSC China) Inspection Conducted by Panel Constituted by Drug Registration Board (DRB) Transfer Case | WEGO Disposable Triple Blood Bag250ml and 500mlClass CShelf Life: 2Year | Disposable Triple Blood Bag with anticoagulant CPDA | Transfer of Registration case from M/s Genome Pharma to M/s IBL Healthcare |
| **Decision:** The Board approved the products at serial 3-9 for import in the name of M/s IBL Health Care Limited, Karachi. |
| 10 | M/s Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi(ELI-000046) | **Manufactured By:**M/s CARDIONOVUM Spolka z ograniczona odpowiedzialnoscia ul. Panska 73, 00-834 Warszawa, Poland (FSC Spain) | Xlimus Sirolimus Eluting Coronary Stent SystemClass DShelf Life: 2Year | Sirolimus Eluting Coronary Stent System |  |
| **Decision:** The Board approved the products at serial 10 for import in the name of M/s Health Tec subject to re-evaluation of dossier by Secretary MDB. |
| 11 | M/s KM Enterprises, 605, D-Block, M.A. Johar Town, Lahore(ELI-000054) | **Manufactured By:**M/s Euromed for Medical Industries, Area No.10, Block (i), Free Zone Nasr City, Cairo Egypt(FSC Egypt) | Euro Flow Foley CathetersClass BShelf Life: 5Year | Foley Catheters |  |
| 12 | M/s KM Enterprises, 605, D-Block, M.A. Johar Town, Lahore(ELI-000054) | **Manufactured By:**M/s Euromed for Medical Industries, Area No.10, Block (i), Free Zone Nasr City, Cairo Egypt(FSC Egypt) | Euro Flow I.V CannulaClass BShelf Life: 5Year | I.V Cannula |  |
| 13 | M/s KM Enterprises, 605, D-Block, M.A. Johar Town, Lahore(ELI-000054) | **Manufactured By:**M/s Euromed for Medical Industries, Area No.10, Block (i), Free Zone Nasr City, Cairo Egypt(FSC Egypt) | Euro Flow Silicone FollyClass BShelf Life: 5Year | Folly Catheters |  |
| **Decision:** The Board referred the products at serial 11-13 for constitution of panel for foreign inspection of the manufacturer as per import policy/ Medical Device Rules, 2017.  |
| 14 | M/s Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi(ELI-000109) | **Legal Manufacturer:**M/s Cordis Cashel Cahir Road Cashel Co. Tipperary , Ireland**Manufacturing Site:**M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico(FSC Ireland) | Trapease Permanent Vena Cava FilterClass DShelf Life: 3Year | Permanent Vena Cava Filter  | Manufacuring and Quality Control, EPSP not Provided |
| 15 | -do- | **Legal Manufacturer:**M/s Cordis Corporation 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA**Manufacturing Site:**M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico(FSC USFDA) | INFINITI® Diagnostic CatheterClass DShelf Life: 3Year**Infiniti — 4F**538417, 538418, 538419, 538420, 538421, 538422,538423, 538424, 538425, 538427, 538428, 538429, 538430, 538431, 538440, 538441, 538443, 538444, 538445, 538446, 538447, 538448, 538449, 538450E, 538450S, 538451V, 538453S, 538455S, 538457V, 538459V, 538460, 538470, 538472, 538474, 538476, 538491P, 538492C, 538493, 538493C, 538493P, 538494, 538494C, 538494P, 538498, 538499, 538499C, 538499P, 538442**Infiniti — 5F**5345161, 5345171, 5345181, 534519T, 534520T, 534521T, 534522T, 534523T, 534524T, 534525T, 5345271, 5345281, 5345291, 5345301, 5345311, 5345391, 5345401, 5345411, 5345421, 5345431, 534550E, 5345441, 5345451, 5345461, 5345471, 5345481, 534549T, 534550S, 534552S, 534553S, 534554S, 534555S, 5345601, 5345621, 5345641, 5345701, 5345721, 5345741, 5345761, 5345781, 5345771, **Infiniti — 6F**534614T, 53461ST, 534617T, 534618T, 534619T, 534620T, 534621T, 5346221, 5346231, 5346351, 534670T, 534637T, 534672T, 534641T, 534674T, 534642T, 534676T, 534643T, 534644T, 534645T, 5346461, 5346471, 5346481, 534624T, 534625T, 5346491, 534627T, 534650E, 5346281, 534650S, 5346291, 534652S, 5346301, 534654S, 5346311, 5346601 | Angiography Diagnostic Catheter | Manufacuting and Quality Control, EPSP not Provided |
| 16 | -do- | **Legal Manufacturer:**M/s Cordis Cashel Cahir Road Cashel Co. Tipperary , Ireland**Manufacturing Site:**M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico(FSC Ireland) | Optease Retrievable Vena Cava Filter and Introduction Kit(466F210A, 466F210B, 466F210AF, 466F210AJ, 466F210BJ)Class DShelf Life: 3Year | Vena Cava Filter and Introduction Kit | Manufacuting and Quality Control, EPSP not Provided |
| 17 | -do- | **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

(FSC USFDA) | Emerald Diagnostic GuidewireCordis Emerald GuidewiresClass DShelf Life: 3Year**J Tip Wires**502716, 502524, 502717, 502536, 502537, 502522, 502538, 502521, 502570, 502521F, 502539, 502521E, 502540, 502526, 502550, 502519, 502532, 502531, 502582A, 502534, 502701, 502587, 502585, 502585F, 502585E, 502589, 502535, 502535F, 502535E, 502576, 502533, 502520, 502520F, 502584E, 502584, 502584F, 502588, 502525, 502525E, 502575, 502530, 502569, 502572, 502571**JTip (Tapered)**502572A, 502568A, 502571A, 502574A, 502570A, 502573A**Exchange JTip Wires**502456, 502452, 502453, 502453F, 502453E, 502454, 502455, 502455F, 502455E**Straight Tip Wires**502549, 502548, 502542, 502542E, 502546, 502560, 502541, 502563, 502544, 502545, 502561, 502580, 502581, 502703, 502704**Straight Tip Wires (Tapered)**502581A**Exchange Straight Tip Wires**502442E, 502554, 502558, 502555, 502557, 502553**Diagnostic Guidewire Specials**SMxxxx, SMxxxxx, SLxxxx**Super Stiff JTip Wires**502731, 502733, 502735**Super Stiff StraightTip Wires**502726, 502728 | Steerable Guidewires  | Manufacuting and Quality Control, EPSP not Provided |
| 18 | -do- | **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(FSC Japan) | IKAZUCHI Zero PTCA Balloon Dilatation CatheterClass DShelf Life: 3YearZE-6-100F, ZE-12-350, ZE-6-100P, ZE-12-375, ZE-6-120, ZE-12-400, ZE-6-150, ZE-15-150, ZE-6-175, ZE-15-175, ZE-6-200, ZE-15-200, ZE-6-225, ZE-15-225, ZE-6-250, ZE-15-250, ZE-6-275, ZE-15-275, ZE-6-300, ZE-15-300, ZE-6-325, ZE-15-325, ZE-6-350, ZE-15-350, ZE-6-375, ZE-15-375, ZE-6-400, ZE-15-400, ZE-8-100F, ZE-18-150, ZE-8-100P, ZE-18-175, ZE-8-120, ZE-18-200, ZE-8-150, ZE-18-225, ZE-8-175, ZE-18-250, ZE-8-200, ZE-18-275, ZE-8-225, ZE-18-300, ZE-8-250, ZE-18-325, ZE-8-275, ZE-18-350, ZE-8-300, ZE-18-375, ZE-8-325, ZE-18-400, ZE-8-350, ZE-20-150, ZE-8-375, ZE-20-175, ZE-8-400, ZE-20-200, ZE-10-150, ZE-20-225, ZE-10-175, ZE-20-250, ZE-10-200, ZE-20-275, ZE-10-225, ZE-20-300, ZE-10-250, ZE-20-325, ZE-10-275, ZE-20-350, ZE-10-300, ZE-20-375, ZE-10-325, ZE-20-400, ZE-10-350, ZE-30-150, ZE-10-375, ZE-30-175, ZE-10-400, ZE-30-200, ZE-12-150, ZE-30-225, ZE-12-175, ZE-30-250, ZE-12-200, ZE-30-275, ZE-12-225, ZE-30-300, ZE-12-250, ZE-30-325, ZE-12-275, ZE-30-350, ZE-12-300, ZE-30-375, ZE-12-325, ZE-30-400 | Angioplasty Balloon Catheter  | Manufacuting and Quality Control, EPSP not Provided |
| 19 | -do- | **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

(FSC USFDA) | ATW Steerable GuidewiresClass DShelf Life: 2Year595014595J014595X014595Y014595E014595EJ014595EX014595EY014595-M014595-MJ014595-MX014595-MY014595-ME014595-MEJ014595-MEX014595-MEY014 | Steerable Guidewires  | Manufacuting and Quality Control, EPSP not Provided |
| 20 | -do- | **Legal Manufacturer:**M/s Cordis Corporation 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA**Manufacturing Site:**M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico(FSC USFDA) | VistaBriteTip® Guiding Catheter Class DShelf Life: 2YearVista Brite Tip — 5F5560020L, 5561700L, 77800000, 5560040L, 5561720L, 778001005560080L, 5561740L, 77800200SM7331, 5561900L,7780020E, 5560400L, 55627000,77800300,5560540L, 5562700L, 77800400,5560560L, 5562780L, 7780040E,5560600L, 77800500, 5560620L,7780050E, 5560800L,77800600, 5560820L, 77800700, 5561100L,77800800,5561120L,77800900,5561620L,77801000,5561640L,77801200, 5561660L,77801300,5561680L, 77801400Vista Brite Tip — 7F77801500, 77804500,77806500,77800490,77818200,77822455,77801600,77804800,77808000,77803690,77818300,77825090,77801800,77804900,77808100,77808290,77818800,77827090,77802200,77811400,77808200,77808390,77819000,77827855,77805200,7780820E,77811090, 77819100, 77827890,77803400,77805300,77808300,77818090,77827000,77827990,77803600,77805400,7780830E,77819090,77827100,77828055,7780360E,77805500,77808400,77819190,77827200,77828090,77803700,77805600,77808500,77827090,77827300,77803800,77805700,77808800,77827890,77827055,77803900,77805800,77808900,77827990,77827800,77804000,77805900,77809000,77811000,77827900,77804090,77806000,77809100,77811100,77821055,77804100,77806100,77809200,77811200,77821255,77804200,77806200,77811600,77811300,77821455,77804300,77806300,77811800,77818000,77821690,77804400,77806400,77800290,77818100,77822255.Vista Brite Tip 8F588800, 588854, 5888116 5888102, 588839, 588858 588883, 588809, 588828,588815, 5888103, 588840, 588859, 588884, 588810, 588830, 588818, 5888104, 588842, 588860, 588885, 588812, 588830E, 588816, 5888105, 588840P, 588861, 588886, 588813, 588831, 588819, 588803, 588841, 588862, 588887, 588821, 588831E, 588801, 588804, 588841P, 588863, 588889, 588822, 588833, 588802, 588805, 588850, 588864, 588890, 588823, 588835, 588815T, 588806, 588857P, 588865, 588891, 588823E,588855, 588816T, 588817,588858P, 588866, 588892, 588824, 588856, 588823T, 588820, 588842P, 588867, 588892T, 588825, 588857, 588830T, 588836, 588843P, 588870, 588893, 588825E, 588811, 588831T, 588837, 588844P, 588871, 588894, 588826, 5888106, 588841T, 588845, 588845P, 588872, 588895, 588827, 5888107,588842P, 588846, 588846P, 588873, 588896, 588832, 5888108, 588843T, 588843, 588847P, 588874, 588898, 588834, 5888109, 588844T,588843E, 588848P, 588875, 588899, 588834E, 5888110, 588845T, 588844, 588849P, 588876, 588851, 5888111, 588850T, 588844E, 5888200, 588877, 588851E, 5888112, 5888511, 588847, 5888201, 588878, 588852, 5888113, 588829, 588848, 5888202, 588879, 588853, 5888114, 5888100, 588849, 5888206, 588880, 588853E, 5888115, 5888101, 588838, 5888207, 588882Vista Brite Tip 9F598900, 598915, 598949, 598941P, 598909, 598918, 598978, 598942P, 598910, 598916, 598991, 598943P, 598923, 598919, 598994, 598944P, 598932, 598917, 598996, 598945P, 598934, 598920, 598997, 598946P, 598951, 598941, 598942, 598949P, 598952, 598950, 598986, 598953, 598937, 598987, 598928, 598945, 598992, 598930, 598936, 5989200, 598931, 598943, 5989201, 598933, 598944, 5989202, 598955, 598947, 5989206, 598966, 598948, 5989207Vista Brite Tip 10F511040PVista Brite Tip 5F55600200 5560800055600400 5560820055600800 5561120055604000 5561620055605400 5561680055605600 5561720055606000 55617400 | Guiding Catheter | Manufacuting and Quality Control, EPSP not Provided |
| **Decision:** The Board approved the products at serial 14-20 for import in the name of M/s Global Marketing Services subject to submission of manufacturing, Quality Control and Essential Principal of Safety and Performance data. |
| 21 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany**Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT Anti-HCV KitClass DShelf Life:(i) 1Year(ii) 1Year(iii) 9Month(iv) 9Month(v) 9Month(i) ARCHITECT Anti-HCV Calibrator 6C37-01(ii) ARCHITECT Anti-HCV Controls6C37-10(ii) ARCHITECT Anti-HCV Reagent Kit6C37-27(iv) ARCHITECT Anti-HCV Reagent Kit6C37-32(v) ARCHITECT Anti-HCV Reagent Kit6C37-37 | IN-VITRO DIAGNOSTIC Kit for Anti-HCV Testing  |  |
| 22 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany**Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT Anti-HBc II KitClass D(i) ARCHITECT Anti-HBc II Calibrator8L44-01Shelf Life: 1Year(ii) ARCHITECT Anti-HBc II Controls 8L44-10Shelf Life: 1Year(iii) ARCHITECT Anti-HBc II Reagent Kit 8L44-25Shelf Life: 1Year(iv) ARCHITECT Anti-HBc II Reagent Kit8L44-30,Shelf Life: 1Year(v) ARCHITECT Anti-HBc II Reagent Kit8L44-35Shelf Life: 1Year | IN-VITRO DIAGNOSTIC Kit for Anti-HBc Testing |  |
| 23 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT Anti-HBc IgM KitClass D(i) ARCHITECT Anti-HBc IgM Calibrators6C33-02Shelf Life: 14Month(ii) ARCHITECT Anti-HBc IgM Controls6C33-11Shelf Life: 15Month(iii) ARCHITECT Anti-HBc IgM Reagent Kit6C334-27Shelf Life: 15Month | IN-VITRO DIAGNOSTIC Kit for Anti-HBc IgM Testing |  |
| 24 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT Anti-HBe KitClass D(i) ARCHITECT Anti-HBe Calibrator6C34-01Shelf Life: 15Month(ii) ARCHITECT Anti-HBe Controls6C34-10Shelf Life: 12Month(iii) ARCHITECT Anti-HBe Reagent Kit6C34-25Shelf Life: 11Month(iv) ARCHITECT Anti-HBe Reagent Kit6C34-35Shelf Life: 11Month | IN-VITRO DIAGNOSTIC Kit for Anti-HBe Testing |  |
| 25 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland(FSC Ireland) | ARCHITECT Anti-HBs KitClass D(i) ARCHITECT Anti-HBs Calibrators7C18-03Shelf Life: 12Months(ii) ARCHITECT Anti-HBs Controls7C18-13Shelf Life: 10Months(iii) ARCHITECT Anti-HBs Reagent Kit7C18-29Shelf Life: 15Months(iv) ARCHITECT Anti-HBs Reagent Kit7C18-39Shelf Life: 15Months(v) ARCHITECT Anti-HBs Reagent Kit7C18-33Shelf Life: 15Months(vi) ARCHITECT Anti-HBs Reagent Kit7C18-41Shelf Life: 15Months(vii) ARCHITECT Anti-HBs Reagent Kit7C18-42Shelf Life: 15Months(viii)ARCHITECT Anti-HBs Specimen Diluent 7C18-40Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for Anti-HBs Testing |  |
| 26 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT HBeAg KitClass D(i) ARCHITECT HBeAg Calibrators6C32-01Shelf Life: 12Months(ii) ARCHITECT HBeAg Controls6C32-10Shelf Life: 12Months(iii) ARCHITECT HBeAg Reagent Kit6C32-25Shelf Life: 11Months(iv) ARCHITECT HBeAg Reagent Kit6C32-27Shelf Life: 11Months(v) ARCHITECT HBeAg Reagent Kit6C32-37Shelf Life: 11Months(vi) ARCHITECT HBeAg Quantitative Calibrators7P24-01Shelf Life: 12Months(vii) ARCHITECT HBeAg Quantitative Controls7P24-10Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for HBeAg Testing |  |
| 27 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland(FSC Ireland) | ARCHITECT HBsAg KitClass D(i) ARCHITECT HBsAg Calibrators3M61-02Shelf Life: 14Months(ii) ARCHITECT HBsAg Controls6C36-10Shelf Life: 14Months(iii) ARCHITECT HBsAg Reagent Kit6C36-29Shelf Life: 12Months(iv) ARCHITECT HBsAg Reagent Kit6C36-34Shelf Life: 12Months(v) ARCHITECT HBsAg Reagent Kit6C36-35Shelf Life: 12Months(vi) ARCHITECT HBsAg Reagent Kit6C36-43Shelf Life: 12Months(vii) ARCHITECT HBsAg Manual Diluent6C36-40Shelf Life: 14Months | IN-VITRO diagnostic Kit for HBsAg Testing |  |
| 28 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT rHTLV-I/II KitClass D(i) ARCHITECT rHTLV-I/II Calibrator6L61-01Shelf Life: 12Months(ii) ARCHITECT rHTLV-I/II Controls6L61-10Shelf Life: 12Months(iii) ARCHITECT rHTLV-I/II Reagent Kit6L61-25Shelf Life: 12Months(iv) ARCHITECT rHTLV-I/II Reagent Kit6L61-30Shelf Life: 12Months(v) ARCHITECT rHTLV-I/II Reagent Kit6L61-35Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for rHTLV-I/II Testing |  |
| 29 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT Syphilis TP KitClass D(i) ARCHITECT Syphilis TP Calibrator8D06-04Shelf Life: 12Months(ii) ARCHITECT Syphilis TP Controls8D06-13Shelf Life: 12Months(iii) ARCHITECT Syphilis TP Reagent Kit8D06-29Shelf Life: 12Months(iv) ARCHITECT Syphilis TP Reagent Kit8D06-39Shelf Life: 12Months(v) ARCHITECT Syphilis TP Reagent Kit8D06-32Shelf Life: 12Months(vi) ARCHITECT Syphilis TP Reagent Kit8D06-42Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for Syphilis TP Testing |  |
| 30 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT HCV Ag KitClass D(i) ARCHITECT HCV Ag Calibrators6L47-02Shelf Life: 18Months(ii) ARCHITECT HCV Ag Controls6L47-11Shelf Life: 18Months(iii) ARCHITECT HCV Ag Reagent Kit6L47-27Shelf Life: 12Months(iv) ARCHITECT HCV Ag Reagent Kit6L47-29Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for HCV Ag Testing |  |
| 31 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland(FSC Ireland) | ARCHITECT HBsAg Qualitative II KitClass D(i) ARCHITECT HBsAg Qualitative II Calibrators2G22-01Shelf Life: 12Months(ii) ARCHITECT HBsAg Qualitative II Controls2G22-10Shelf Life: 12Months(iii) ARCHITECT HBsAg Qualitative II Reagent Kit2G22-25Shelf Life: 12Months(iv) ARCHITECT HBsAg Qualitative II Reagent Kit2G22-30Shelf Life: 12Months(v) ARCHITECT HBsAg Qualitative II Reagent Kit2G22-35Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for HBsAg Qualitative II Testing |  |
| 32 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland(FSC Ireland) | ARCHITECT HBsAg Qualitative II KitClass D(i) ARCHITECT HBsAg Qualitative II Calibrators2G22-01Shelf Life: 12Months(ii) ARCHITECT HBsAg Qualitative II Controls2G22-10Shelf Life: 12Months(iii) ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit2G23-25Shelf Life: 12Months(iv) ARCHITECT HBsAg Qualitative II Confirmatory Manual DiluentKit2G23-40Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for HBsAg Qualitative II Testing |  |
| 33 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT HIV Ag/Ab Combo KitClass D(i) ARCHITECT HIV Ag/Ab Combo Calibrator4J27-03Shelf Life: 10Months(ii) ARCHITECT HIV Ag/Ab Combo Controls4J27-12Shelf Life: 10Months(iii) ARCHITECT HIV Ag/Ab Combo Reagent Kit4J27-27Shelf Life: 10Months(iv) ARCHITECT HIV Ag/Ab Combo Reagent Kit4J27-32Shelf Life: 10Months(v) ARCHITECT HIV Ag/Ab Combo Reagent Kit4J27-37Shelf Life: 10Months | IN-VITRO DIAGNOSTIC Kit for HIV Ag/Ab Combo Testing |  |
| 34 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany(FSC Germany) | ARCHITECT Chagas KitClass D(i) ARCHITECT Chagas Calibrator2P25-01Shelf Life: 10Months(ii) ARCHITECT Chagas Controls2P25-10Shelf Life: 10Months(iii) ARCHITECT Chagas Reagent Kit2P25-25Shelf Life: 12Months(iv) ARCHITECT Chagas Reagent Kit2P25-35Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for Chagas Testing |  |
| 35 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland(FSC Ireland) | Alinity i HBsAg KitClass D(i) Alinity i HBsAg Calibrators08P0801Shelf Life: 09Months(ii) Alinity i HBsAg Controls08P0810Shelf Life: 14Months(iii) Alinity i HBsAg Reagent Kit08P0822Shelf Life: 09Months(iv) Alinity i HBsAg Reagent Kit08P0832Shelf Life: 09Months(v) Alinity i HBsAg Reagent Kit08P0852Shelf Life: 09Months(vi) Alinity i HBsAg Reagent Kit08P0857Shelf Life: 09Months(vii) Alinity i HBsAg Manual Diluent08P0843Shelf Life: 14Months | IN-VITRO DIAGNOSTIC Kit for i HBsAg Testing |  |
| 36 | M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi(ELI-00019) | **Legal Manufacturer/ Manufacturing Site:**M/s Abbott Ireland Diagnostic Division, Finisklin Business Park, Sligo, Ireland(FSC Ireland) | Alinity i HBsAg Confirmatory V.1 KitClass D(i) Alinity i HBsAg Confirmatory V.1 Calibrators08P0901Shelf Life: 14Months(ii) Alinity i HBsAg Confirmatory V.1 Controls08P0910Shelf Life: 14Months(iii) Alinity i HBsAg Confirmatory V.1 Reagent Kit08P0922Shelf Life: 12Months | IN-VITRO DIAGNOSTIC Kit for i HBsAg Confirmatory V.1 Testing |  |
| **Decision:** The Board approved the products at serial 21-36 for import in the name of M/s Abbott Laboratories (Pakistan) Ltd., Karachi. |
| 37 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Corporation 780 Brookside Drive, Spencer, IN 47460 USA (FSC USFDA) | Accustick TM II Introducer SystemClass BShelf Life: 37MonthM00120702008714729157588 Accustick II w .038” J Tip and 0.018” SS GuidewireM00120703008714729157601 Accustick II w .038” Str and 0.018” SS GuidewireM00120704008714729194514 Accustick II w 0.018” SS GuidewireM00120705008714729157625 Accustick II woGuidewireM00120710008714729201137 Accustick II w .038” J Tip and 0.018” NitinolGuidewire | The AccuStick II Introducer System with radiopaque marker facilitates introduction and placement of a guidewire. |  |
| **Decision:** The Board approved the product at serial no. 37 in Class B for import as per Rule 6 of Classification Rules of Medical Devices Rules, 2017 which is reproduced as under:

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| **Rule 6**All surgically invasive devics intended for **transient use** are in Class B | A majority of such devices fall in several major groups: those that create conduit through the skin (e.g syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical sdtaplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc. |

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| 38 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Limited Business and Technology Park Model farm Road Cork, Ireland (FSC Ireland) | ContourTM Embolization ParticlesClass CShelf Life: 36MonthM0017600121Contour Embolization Particles 45-150 micronsM0017600221Contour Embolization Particles 150-250 microns M0017600321Contour Embolization Particles 250-355 micronsM0017600421Contour Embolization Particles 355-500 micronsM0017600621Contour Embolization Particles 500-710 micronsM0017600821Contour Embolization Particles 710-1000 micronsM0017601121Contour Embolization Particles 1000-1180 micronsM0017600151Contour Embolization Particles 45-150 micronsM0017600251Contour Embolization Particles 150-250 micronsM0017600351Contour Embolization Particles 250-355 micronsM0017600451Contour Embolization Particles 355-500 micronsM0017600651Contour Embolization Particles 500-710 micronsM0017600851Contour Embolization Particles 710-1000 micronsM0017601151Contour Embolization Particles 1000-1180 microns | Boston Scientific’s Contour Embolization Particles are used for the embolization of peripheral hypervascular tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri. Contour Embolization Particles are artificial embolization devices. These devices are intended to provide vascular occlusion upon selective placement via an angiographic catheter. Contour Embolization Particles are packaged sterile by gamma irradiation. Each vial is intended for single patient use only |  |
| 39 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Limited Ballybrit Business Park Galway Ireland(FSC Ireland) | Wallstent-Uni TM Endoprosthesis Self-Expanding StentClass CShelf Life: 24MonthM001731000WALLSTENT Uni 5 x20mm x 75cmM001731010 WALLSTENTUni5x 20mm x 135cmM001731020 WALLSTENTUni5x40mm x 75cmM001731030 WALLSTENTUni5x40mm x 135cmM001731040 WALLSTENTUni5x55mm x 75cmM001731050 WALLSTENTUni5x 55mm x 135cmM001731060 WALLSTENTUni5x80mm x 75cmM001731070 WALLSTENTUni5x80mm x 135cmM001731080 WALLSTENTUni 6 x20mm x 75cmM001731090 WALLSTENTUni6x20mm x 135cmM001731100 WALLSTENTUni6x45mm x 75cmM001731110 WALLSTENTUni6x45mm x 135cmM001731120 WALLSTENTUni6x60mm x 75cmM001731130 WALLSTENTUni6x60mm x 135cmM001731140 WALLSTENTUni6x90mm x 75cmM001731150 WALLSTENTUni6x90mm x 135cmM001731160 WALLSTENTUni7x20mm x 75cmM001731170 WALLSTENTUni7x20mm x 135cmM001731180 WALLSTENTUni7x40mm x 75cmM001731190 WALLSTENTUni7x40mm x 135cmM001731200WALLSTENTUni7x60mm x 75cmM001731210WALLSTENT Uni 7x60mm x 135cmM001731220WALLSTENT Uni 7x90mm x 75cmM001731230WALLSTENT Uni7x90mm x 135cmM001731240WALLSTENT Uni8x20mm x 75cmM001731250WALLSTENT Uni 8x 20mm x 135cmM001731260WALLSTENT Uni 8x 40mm x 75cmM001731270WALLSTENT Uni 8x 40mm x 135cmM001731280WALLSTENT Uni 8x 60mm x 75cmM001731290WALLSTENT Uni 8x 60mm x 135cmM001731300WALLSTENT Uni 8x 80mm x 75cmM001731310WALLSTENT Uni 8x 80mm x135cmM001731320WALLSTENT Uni 10x 20mmx75cmM001731330WALLSTENT Uni 10 x 20mm x 135cmM001731340WALLSTENT Uni 10 x 42mm x 75cmM001731350WALLSTENT Uni 10x 42mmx 135cmM001731360WALLSTENT Uni 10 x 68mm x 75cmM001731370WALLSTENT Uni 10 x 68mm x 135cmM001731380WALLSTENT Uni 10 x 94mm x 75cmM001731390WALLSTENT Uni 10 x 94mm x 135cmM001731400WALLSTENT Uni 12 x 20mm x 75cmM001731410WALLSTENT Uni 12 x 20mm x 135cmM001731420WALLSTENT Uni 12 x 40mm x 75cmM001731430WALLSTENT Uni 12 x 40mmx135cmM001731440WALLSTENT Uni 12 x 60mm x 75cmM001731450WALLSTENT Uni 12 x 60mm x 135cmM001731460WALLSTENT Uni 12 x 90mm x 75cmM001731470WALLSTENT Uni 12 x 90mm x 135cmM001731480WALLSTENT Uni 14 x 20mm x 75cmM001731490WALLSTENT Uni 14 x 40mm x 75cmM001731500WALLSTENT Uni 14 x 60mm x 75cmM001731510WALLSTENT Uni 14 x 90mm x 75cmM001731520WALLSTENT Uni 16 x 20mm x 75cmM001731530WALLSTENT Uni 16 x 40mm x 75cmM001731540WALLSTENT Uni 16 x 60mm x 75cmM001731550WALLSTENT Uni 16 x 90mm x 75cmM001731560WALLSTENT Uni 18 x 40mm x 75cmM001731570WALLSTENT Uni 18 x 60mm x 75cmM001731580WALLSTENT Uni18 x 90mm x 75cmM001731590 WALLSTENT Uni 20 x 40mm x 75cmM001731600 WALLSTENT Uni 20 x 55mm x 75cmM001731610 WALLSTENT Uni 20 x 80mm x 75cmM001731620 WALLSTENT Uni 22 x 35mm x 75cmM001731630 WALLSTENT Uni 22 x 45mm x 75cmM001731640 WALLSTENT Uni 22x 70mm x 75cmM001731650 WALLSTENT Uni 24 x 35mm x 75cmM001731660 WALLSTENT Uni 24 x 45mmx 75cmM001731670WALLSTENT Uni24 x 70mmx 75cm | Wallstent-Uni Endoprosthesis is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are ≤ 10cm in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavourable lesion morphology such as:• An inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, lesion recoil, or intimal flaps.• Flow limiting dissections post PTA longer than the initial lesion length.• A 5mm Hg or greater mean transtenotic pressure gradient post PTA.Superficial Femoral ArteryWallstent-Uni Endoprosthesis is intended for use in superficial femoral artery (SFA) stenoses or occlusions.Transjugular Intrahepatic Portosystemic Shunt (TIPS)Wallstent-Uni Endoprosthesis is indicated for creation of transjugular intrahepatic shunt connections between the portal venous system and the hepatic vein for prophylaxis of variceal bleeding or intractable ascites in the treatment of portal hypertension and its complications in patients who have previously failed conventional treatment techniques.BiliaryWallstent-Uni Endoprosthesis is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.TracheobronchialWallstent-Uni Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. Central VenousWallstent-Uni Endoprosthesis is indicated for central venous obstruction and for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥30% for a vein ≤10 mm in diameter or ≥50% for a vein >10 mm in diameter, a tear which interrupts the integrity of the intima lumen, abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the Wallstent-Uni Endoprosthesis product range are the innominate and subclavian veins, ranging from 8mm to 15mm in diameter.Iliac VeinThe Wallstent-Uni Endoprosthesis is intended for use in the iliac veins for the treatment of symptomatic venous obstruction.WallstentUniEndoprosthesis is comprised of two components: the implantable metallic stent and the Unistep Plus Delivery System.The stent is composed of biomedical superalloy wire with a radiopaque core, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists of a coaxial tube system. The exterior sheath serves to constrain the stent until retracted during deployment. The exterior sheath can reconstrain the stent a maximum of two times after partial deployment of the stent. The radiopaque marker band on the exterior sheath facilitates the positioning of the exterior sheath, during the procedure. Radiopaque marker bands located on the interior, situated adjacent to the proximal and distal ends of the stent facilitate imaging during deployment. A radiopaque marker band, at a medial position on the interior tube, acts as a deployment limit marker. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89 mm) guidewire. A stainless steel tube is positioned at the proximal end of the interior tube. A valve body attached to the proximal end of the exterior sheath, slides along the length of the stainless steel tube to facilitate the deployment and reconstrainment of the stent. |  |
| 40 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Limited Ballybrit Business Park Galway Ireland(FSC Ireland) | Sterling TMOver-The-Wire PTA Balloon Dilatation CatheterClass BShelf Life: Original Sizes36 MonthsExpansion Sizes18 Months(Sterling OTW PTA Balloon Dilatation Catheter with balloons diameters of 5.0, 6.0,and 7.0mmin diameter with lengthsof 120, 150,200and 220mm)H7493903215021008714729859857 Sterling OTW 1.5mmx20mmx150cmH7493903215029008714729859864 Sterling OTW 1.5mmx20mmx90cmH7493903215041008714729859871 Sterling OTW 1.5mmx40mmx150cmH7493903215049008714729859888 Sterling OTW 1.5mmx40mmx90cmH7493903220021008714729859895 Sterling OTW 2mmx20mmx150cmH7493903220029008714729859901 Sterling OTW 2mmx20mmx90cmH7493903220031008714729859918 Sterling OTW 2mmx30mmx150cmH7493903220039008714729859925 Sterling OTW 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6mmx20mmx80cmH7493903260209008714729845461 Sterling OTW 6mmx200mmx90cmH7493903260211008714729845478 Sterling OTW 6mmx200mmx150cmH7493903260221008714729845485 Sterling OTW 6mmx220mmx1 50cmH7493903260229008714729845492 Sterling OTW 6mmx220mmx90cmH7493903260301008714729123767 Sterling OTW 6mmx30mmx135cmH7493903260308008714729123774 Sterling OTW 6mmx30mmx80cmH7493903260401008714729122784 Sterling OTW 6mmx40mmx135cmH7493903260404008714729123781 Sterling OTW 6mmx40mmx40cmH7493903260408008714729123798 Sterling OTW 6mmx40mmx80cmH7493903260601008714729123804 Sterling OTW 6mmx60mmx135cmH7493903260608008714729123811 Sterling OTW 6mmx60mmx80cmH7493903260801008714729123828 Sterling OTW 6mmx80mmx135cmH7493903260808008714729123965 Sterling OTW 6mmx80mmx80cmH7493903270101008714729123972 Sterling OTW 7mmx100mmx135cmH7493903270108008714729123989 Sterling OTW 7mmx100mmx80cmH7493903270121008714729845508 Sterling OTW 7mmx120mmx150cmH7493903270129008714729845515 Sterling OTW 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7mmx80mmx135cmH7493903270808008714729124146 Sterling OTW 7mmx80mmx80cmH7493903280201008714729720621 Sterling OTW 8mmx20mmx135cmH7493903280204008714729720638 Sterling OTW 8mmx20mmx40cmH7493903280208008714729720645 Sterling OTW 8mmx20mmx80cmH7493903280301008714729720652 Sterling OTW 8mmx30mmx135cmH7493903280308008714729720669 Sterling OTW 8mmx30mmx80cmH7493903280401008714729720676 Sterling OTW 8mmx40mmx135cmH7493903280404008714729720683 Sterling OTW 8mmx40mmx40cmH7493903280408008714729720690 Sterling OTW 8mmx40mmx80cmH7493903280601008714729720706 Sterling OTW 8mmx60mmx135cmH7493903280608008714729720713 Sterling OTW 8mmx60mmx80cmH7493903280801008714729720720 Sterling OTW 8mmx80mmx135cmH7493903280808008714729720737 Sterling OTW 8mmx80mmx80cmH7493903290201008714729720744 Sterling OTW 9mmx20mmx135cmH7493903290208008714729720751 Sterling OTW 9mmx20mmx80cmH7493903290301008714729720768 Sterling OTW 9mmx30mmx 135cmH7493903290308008714729720775 Sterling OTW 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Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature |  |
| 41 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Limited Business and Technology Park Model farm Road Cork, Ireland(FSC Ireland) | RotalinkTM Plus Pre-Connected Exchangeable Burr Catheter and Burr Advancing DeviceClass DShelf Life: 24MonthH749236310020Rotalink Plus / 1.25mm burr, 135 cm longH749236310030Rotalink Plus / 1.50mm burr, 135 cm longH749236310040Rotalink Plus / 1.75mm burr, 135 cm longH749236310050Rotalink Plus / 2.00mm burr, 135 cm longH749236310150Rotalink Plus / 2.15mm burr, 135 cm longH749236310060Rotalink Plus / 2.25mm burr, 135 cm longH749236310160Rotalink Plus / 2.38mm burr, 135 cm longH749236310070Rotalink Plus / 2.50mm burr, 135 cm long | Percutaneous rotational coronary angioplasty with the Rotablator Rotational Atherectomy System, as a sole therapy or with adjunctive balloon angioplasty, is indicated in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery and who meet one of the following selection criteria:• Single vessel atherosclerotic coronary artery disease with a stenosis that can be passed with a guide wire;• Multiple vessel coronary artery disease that in the physician’s judgment does not pose undue risk to the patient;• Certain patients who have had prior percutaneous transluminal coronary angioplasty (PTCA), and who have a restenosis of the native vessel; or• Native vessel atherosclerotic coronary artery disease that is less than 25 mm in length.The RotaLink Advancer and Catheter are intended for use with the Rotablator Rotational AtherectomySystem.The advancer houses the air turbine and functions as a guide for the sliding elements that control burr advancement. The turbine is designed with low torque so that it will stall if it encounters resistance. This feature prevents inadvertent damage to the artery. The advancer has an air-actuated guide wire brake which is automatically actuated when the operator steps on the foot pedal (approved as part of the console) to activate the device. This feature prevents movement of the guide wire when the drive shaft is turning. This advancer is also known as the A21 Advancer |  |
| 42 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA 47460(FSC USFDA) | LeVeenTM Standard Needle Electrode SystemClass CShelf Life: 36MonthM001262020 08714729300601 LeVeen Standard Needle Electrode System 3.5cm x 12cmM001262030 08714729300618 LeVeen Standard Needle Electrode System 3.5cm x 15cmM001262040 08714729300625 LeVeen Standard Needle Electrode System 3.0cm x 12cmM001262050 08714729300632LeVeen Standard Needle Electrode System 3.0cm x 15cmM001262130 08714729295594 LeVeen Standard Needle Electrode System 4.0cm x 15cmM001262150 08714729349594 LeVeen Standard Needle Electrode System 3.5cm x 25cmM001262160 08714729454915 LeVeen Standard Needle Electrode System 5.0cm x 15cmM001262170 08714729767619 LeVeen Standard Needle Electrode System 5.0cm x 25cmM001262310 08714729120735 LeVeen Standard Needle Electrode System 4.0cm x 25cm | The LeVeen Needle Electrode Family / Soloist Single Needle Electrode is intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved. |  |
| 43 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Corporation 780 Brookside Drive Spencer, IN USA 47460(FSC USFDA) | Epic™ Over The Wire Self-Expanding Nitinol Stent with Delivery SystemClass CShelf Life: 36MonthH74939054051070 Epic 5mm x 100mm x 75cmH74939054051270 Epic 5mm x 120mm x 75cmH74939054052070 Epic 5mm x 20mm x 75cmH74939054053070 Epic 5mm x 30mm x 75cmH74939054054070 Epic 5mm x 40mm x 75cmH74939054055070Epic 5mm x 50mm x 75cmH74939054056070 Epic 5mm x 60mm x 75cmH74939054057070 Epic 5mm x 70mm x 75cmH74939054058070Epic 5mm x 80mm x 75cmH74939054061070 Epic 6mm x 100mm x 75cm H74939054061270 Epic 6mm x 120mm x 75cm H74939054062070 Epic 6mm x 20mm x 75cm H74939054063070 Epic 6mm x 30mm x 75cm H74939054064070 Epic 6mm x 40mm x 75cm H74939054065070 Epic 6mm x 50mm x 75cm H74939054066070 Epic 6mm x 60mm x 75cm H74939054067070 Epic 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14mm x 40mm x 120cm H74939054145020 Epic 14mm x 50mm x 120cm H74939054146020 Epic 14mm x 60mm x 120cm | The Epic Nitinol Vascular Stent System is indicated for the treatment of peripheral vascular lesions and obstructions.NOTE: This product is marketed with different indications in other geographies; the DFU contained with the product serves to differentiate the different uses.The Epic Nitinol Vascular Stent System is comprised of two (2) components: the implantable endoprosthesis (stent) and the stent delivery system. The endoprosthesis is a laser cut self-expanding stent composed of a nickel titanium alloy (nitinol). On both the proximal and distal ends of the stent, radiopaque tantalum markers increase visibility of the stent to aid in placement. The stent is available in diameters ranging from 5 mm to 14 mm and lengths ranging from 20 mm to 120 mm. Stent diameters 5, 6, and 7 mm are part of the Small Diameter (SD) model family; stent diameters 8, 9, and 10 mm are part of the Large Diameter (LD) model family; and stent diameters 12 and 14 mm are part of the Extra Large Diameter (XLD) model family. Stents 5-7 mm in diameter have four (4) tantalum markers on each end and stents 8-14 mm in diameter have five (5) tantalum markers on each end. The stent is constrained within a 6F (2.1 mm) maximum outside diameter (OD) delivery system |  |
| 44 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA (FSC USFDA) | Rubicon TM35 Support CatheterClass BShelf Life: 36MonthH74939240035061 08714729832065 RUBICON 35, 65cm (box/5)H74939240035091 08714729832041 RUBICON 35, 90cm (box/5)H7493924003513108714729832072 RUBICON 35, 135cm (box/5)H74939240035151 08714729832058 RUBICON 35, 150cm (box/5) | The Rubicon Support Catheter is intended to facilitate placement and support of guidewires and other interventional devices within the peripheral vasculature and to allow for exchange of guidewires, and provide a conduit for the delivery of saline or contrast solutions. The Boston Scientific Rubicon™ 14, 18 and 35 Support Catheters (Rubicon) are Over-the-Wire (OTW) catheters with a single lumen shaft design. The lumen is used to pass the catheter over the appropriately sized 0.014", 0.018", or 0.035" guidewire. The lumen terminates at the proximal end of the catheter in a hub with a female luer-lock portThree radiopaque marker bands spaced equally along the distal shaft are designed to aid in estimating geometry within the vascular system. The distal marker band is approximately 2mm away from the distal end of the catheter tip to aid in positioning the system during the procedure. A coating is applied to the distal 40 cm of the shaft to aid with inserting/withdrawing the catheter from the guide sheath/catheter. The tip of the catheter is gradually tapered to facilitate advancement of the catheter through the stricture/lesion following the guidewire |  |
| 45 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/ Boston Scientific Limited Ballybrit Business Park Galway Ireland (FSC Ireland) | Express LD Vascular Over The Wire Premounted Stent SystemClass CShelf Life: 36MonthH74938162520750 Vascular LD 5-2 x 75cmH74938162530750 Vascular LD 5-3 x 75cmH74938162540750 Vascular LD 5-4 x 75cmH74938162560750 Vascular LD 5-6 x 75cmH74938162620750 Vascular LD 6-2 x 75cmH74938162630750 Vascular LD 6-3 x 75cmH74938162640750 Vascular LD 6-4 x 75cmH74938162660750 Vascular LD 6-6 x 75cmH74938162720750 Vascular LD 7-2 x 75cmH74938162730750 Vascular LD 7-3 x 75cmH74938162740750 Vascular LD 7-4 x 75cmH74938162760750 Vascular LD 7-6 x 75cmH74938162820750 Vascular LD 8-2 x 75cmH74938162830750 Vascular LD 8-3 x 75cmH74938162840750 Vascular LD 8-4 x 75cmH74938162860750 Vascular LD 8-6 x 75cmH74938162920750 Vascular LD 9-3 x 75cmH74938162940750 Vascular LD 9-4 x 75cmH74938162960750 Vascular LD 9-6 x 75cmH74938162102070 Vascular LD 10-3 x 75cmH74938162104070 Vascular LD 10-4 x 75cmH74938162106070 Vascular LD 10-6 x 75cmH74938162520130 Vascular LD 5-2 x 135cmH74938162530130 Vascular LD 5-3 x 135cmH74938162540130 Vascular LD 5-4 x 135cmH74938162560130 Vascular LD 5-6 x 135cmH74938162620130 Vascular LD 6-2 x 135cmH74938162630130 Vascular LD 6-3 x 135cmH74938162640130 Vascular LD 6-4 x 135cmH74938162660130 Vascular LD 6-6 x 135cmH74938162720130 Vascular LD 7-2 x 135cmH74938162730130 Vascular LD 7-3 x 135cmH74938162740130 Vascular LD 7-4 x 135cmH74938162760130 Vascular LD 7-6 x 135cmH74938162820130 Vascular LD 8-2 x 135cmH74938162830130 Vascular LD 8-3 x 135cmH74938162840130 Vascular LD 8-4 x 135cmH74938162860130 Vascular LD 8-6 x 135cmH74938162920130 Vascular LD 9-3 x 135cmH74938162940130 Vascular LD 9-4 x 135cmH74938162960130 Vascular LD 9-6 x 135cmH74938162120130 Vascular LD 10-3 x 135cmH74938162140130 Vascular LD 10-4 x 135cmH74938162160130 Vascular LD 10-6 x 135cm | The Express LD Vascular device is indicated for use in the treatment of peripheral vascular lesions.The Express LD Vascular device consists of a 316 L surgical grade stainless steel balloon expandable stent. The stent is pre-mounted on an over-the-wire (OTW) Stent Delivery System (SDS), equipped with a non-compliant balloon. The SDS balloon catheter has two radiopaque markers embedded in the shaft to aid in the placement of the stent. The SDS is compatible with 0.035 in (0.89 mm) guidewires. The SDS balloon has a nominal inflation pressure of 8 atm (5 mm thru 9 mm product codes) or 10 atm (10 mm product codes) that can be used for initial stent placement and post stent dilatation. The maximum inflation pressure or rated burst pressure (RBP) is 12 atm (1216kPa) for all product codes.The Express LD Vascular product is available with stent lengths of 17 mm, 25 mm, 27 mm, 37 mm or 57 mm, stent and balloon diameters ranging from 5 mm to 10 mm and balloon lengths from 20 mm to 60 mm. The Express LD Vascular product is offered in two catheter lengths: 75cm and 135cm. See Figure 1 for Express LD Vascular image and Figure 2 for Express LD Vascular schematic. |  |
| 46 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/ Teleflex MedicalUnit 7 8 & 9, Anncotty Business Park, Anncotty, Co Limerick, Ireland(FSC Ireland) | Imager II Angiographic CathetersClass DShelf Life: 24MonthM001315250737193 4F Flush / 4F Contra / 65cmM001315251 355991 4F Flush / 4F Contra / 65cm (5pk)M001315260 737209 4F Flush / 4F Contra / 90cmM001315261 356004 4F Flush / 4F Contra / 90cm (5pk)M001315270 737216 4F Flush/4F Contra/100cmM001315271 356011 4F Flush / 4F Contra /100cm (5pk)M001315090 737032 4F Flush / 4F Pigtail / 65cmM001315091 355830 4F Flush / 4F Pigtail / 65cm (5pk)M001315110 737056 4F Flush / 4F Pigtail / 90cmM001315111 355854 4F Flush / 4F Pigtail / 90cm (5pk)M001315100 737049 4F Flush / 4F Straight / 65cmM001315101 355847 4F Flush / 4F Straight / 65cm (5pk)M001315120 737063 4F Flush / 4F Straight / 90cmM001315121 355861 4F Flush / 4F Straight / 90cm (5pk)M001315000 736943 4F Flush / 4F Tennis Racquet / 65cmM001315001 355748 4F Flush / 4F Tennis Racquet / 65cm (5pk)M001315010 736950 4F Flush / 4F Tennis Racquet / 90cmM001315011 355755 4F Flush / 4F Tennis Racquet / 90cm (5pk)M001315020 736967 4F Flush / 4F Tennis Racquet /100cmM001315021 355762 4F Flush / 4F Tennis Racquet /100cm (5pk)M001316040 737346 4F Selective / 4F BARNH /100cmM001316041 404385 4F Selective / 4F BARNH /100cm (5pk)M001316130 737438 4F Selective / 4F H1 / 65cmM001316131 404477 4F Selective / 4F H1 / 65cm (5pk)M001316210 737513 4F Selective / 4F JB1 / 65cmM001316211 404552 4F Selective / 4F JB1 / 65cm (5pk)M001316380 737681 4F Selective /4F SIM4/100cmM001316381 404729 4F Selective / 4F SIM4 / 100cm (5pk)M001316020 737322 4F Selective / 4F STR / 65cmM001316021 404361 4F Selective / 4F STR / 65cm (5pk)M001316030 737339 4F Selective / 4F STR /100cmM001316031 404378 4F Selective / 4F STR /100cm (5pk)M001316060 737360 4F Selective / 4F BERN /100cmM001316061 404408 4F Selective / 4F BERN /100cm (5pk)M001316070 737377 4F Selective / 4F BERN / 40cmM001316071 404415 4F Selective / 4F BERN / 40cm (5pk)M001316090 737391 4F Selective / 4F BERN / 65cmM001316091 404439 4F Selective / 4F BERN / 65cm (5pk)M001316120 737421 4F Selective / 4F WEIN /100cmM001316121 404460 4F Selective / 4F WEIN / 100cm (5pk)M001316150 737452 4F Selective / 4F H1 /100cmM001316151 404491 4F Selective / 4F H1 / 100cm (5pk)M001316170 737476 4F Selective / 4F H3 /100cmM001316171 404514 4F Selective / 4F H3 /100cm (5pk)M001316190 737490 4F Selective/4FH1H/100cmM001316191 404538 4F Selective / 4F H1H / 100cm (5pk)M001316200737506 4F Selective / 4F H3H /100cmM001316201404545 4F Selective / 4F H3H / 100cm (5pk)M001316230737537 4F Selective / 4F JB1 / 100cmM001316231404576 4F Selective / 4F JB1 / 100cm (5pk)M001316250737551 4F Selective / 4F JB2 / 100cmM001316251404590 4F Selective / 4F JB2 / 100cm (5pk)M001316270737575 4F Selective / 4F JB3 / 100cmM001316271404613 4F Selective / 4F JB3 / 100cm (5pk)M001316290737599 4F Selective / 4F MAN / 100cmM001316291404637 4F Selective / 4F MAN / 100cm (5pk)M001316310737612 4F Selective / 4F SIM1 / 65cmM001316311404651 4F Selective / 4F SIM1 / 65cm (5pk)M001316330737636 4F Selective / 4F SIM1 / 100cmM001316331404675 4F Selective / 4F SIM1 / 100cm (5pk)M001316350737650 4F Selective / 4F SIM2 / 100cmM001316351404699 4F Selective / 4F SIM2 / 100cm (5pk)M001316370737674 4F Selective / 4F SIM3 / 100cmM001316371404712 4F Selective / 4F SIM3 / 100cm (5pk)M001316390737698 4F Selective .038 GW/ 4F HN1 / 100cmM001316391404736 4F Selective .038 GW/4F HN1 / 100cm (5pk)M001316400737704 4F Selective / 4F HN1 / 100cmM001316401404743 4F Selective / 4F HN1 / 100cm (5pk)M001316420737728 4F Selective / 4F HN2 / 100cmM001316421404767 4F Selective / 4F HN2 / 100cm (5pk)M001316440737742 4F Selective / 4F HN3 / 100cmM001316441404781 4F Selective / 4F HN3 / 100cm (5pk)M001316460737766 4F Selective / 4F HN4 / 100cmM001316461404804 4F Selective / 4F HN4 / 100cm (5pk)M001316470737773 4F Selective .038 GW / 4F HN5 / 100cmM001316471404811 4F Selective .038 GW / 4F HN5 / 100cm (5pk)M001316480737780 4F Selective / 4F HN5 / 100cmM001316481404828 4F Selective / 4F HN5 / 100cm (5pk)M001316490737797 4F Selective / 4F CK /100cmM001316491404835 4F Selective / 4F CK / 100cm (5pk)M001316500737803 4F Selective / 4F GEN / 100cmM001316501404842 4F Selective / 4F GEN / 100cm (5pk)M001316510737810 4F Selective / 4F GEN / 2S /100cmM001316511404859 4F Selective / 4F GEN / 2S / 100cm (5pk)M001316530737834 5F Flush .035 GW / 4F CHGB / 65cmM001316531404873 5F Flush .035 GW / 4F CHGB / 65cm (5pk)M001316550737858 5F Flush .035 GW / 4F CHGC / 65cmM001316551404897 5F Flush .035 GW / 4F CHGC / 65cm (5pk)M001316570737872 5F Flush .035 GW / 4F CHG2.5 / 65cmM001316571404910 5F Flush .035 GW / 4F CHG2.5 / 65cm (5pk)M001316580737889 5F Flush .035 GW / 4F Contra 2 / 65cmM001316581404927 5F Flush .035 GW / 4F Contra 2 / 65cm (5pk)M001316610737919 5F Flush .035 GW / 4F DUCK / 65cmM001316611404958 5F Flush .035 GW / 4F DUCK / 65cm (5pk)M001316630737933 5F Flush .035 GW / 4F C1 / 65cmM001316631404972 5F Flush .035 GW /4FC1 / 65cm (5pk)M001316650737957 5F Flush .035 GW / 4F C1/ 2S / 65cmM001316651404996 5F Flush .035 GW/4F C1/2S/65cm(5pk)M001316670737971 5F Flush .035 GW / 4F C2/65cmM001316671405016 5F Flush .035 GW/4F C2 / 65cm (5pk)M001316690737995 5F Flush .035 GW/4F C2/ 2S / 65cmM001316691405030 5F Flush .035 GW/4F C2/ 2S / 65cm (5pk)M001316710738015 5F Flush .035 GW / 4F C3 / 65cmM001316711405054 5F Flush .035 GW / 4F C3 / 65cm (5pk)M001316730738039 5F Flush .035 GW/4F C3 / 2S / 65cmM001316731405078 5F Flush .035 GW/4F C3 / 2S / 65cm (5pk)M001316740738046 5F Flush .035 GW/4F VAN / 2S / 65cmM001316741405085 5F Flush .035 GW/4F VAN / 2S / 65cm (5pk)M001316750738053 5F Flush .035 GW/4F TRAIN / 65cmM001316751405092 5F Flush .035 GW/4F TRAIN /65cm(5pk)M001316770738077 5F Flush .035 GW / 4F MIK/65cmM001316771405115 5F Flush .035 GW/4F MIK / 65cm (5pk)M001316790738091 5F Flush .035 GW/4F HK1 / 65cmM001316791405139 5F Flush .035 GW/4F HK1 / 65cm (5pk)M001316810738114 5F Flush .035 GW/4F SHK0.8 / 65cmM001316811405153 5F Flush .035 GW/4F SHK0.8 / 65cm (5pk)M001316830738138 5F Flush .035 GW7 4F SHK1.0/65cmM001316831405177 5F Flush .035 GW/4F SHK1.0/ 65cm (5pk)M001316850738152 5F Flush .035 GW/4F RC1 / 65cmM001316851405191 5F Flush .035 GW/4F RC1 / 65cm (5pk)M001316870738176 5F Flush .035 GW/4F RC2 / 65cmM001316871405214 5F Flush .035 GW/4F RC2 / 65cm (5pk)M001316890738190 5F Flush .035 GW/4F RDC / 65cmM001316891405238 5F Flush .035 GW/4F RDC / 65cm (5pk)M001316910738213 5F Flush .035 GW/4F RDC / 2S / 65cmM001316911405252 5F Flush .035 GW/4F RDC / 2S / 65cm (5pk)M001316000737308 5F Flush .035 GW/4F LEV / 65cmM001316001404347 5F Flush .035 GW/4F LEV / 65cm (5pk)M001316010737315 5F Flush .035 GW/4F LEV / 100cmM001316011404354 5F Flush .035 GW/4F LEV / 100cm (5pk)M001316050737353 5F Flush .035 GW/4F LEV2 / 65cmM001316051404392 5F Flush .035 GW/4F LEV2 / 65cm (5pk)M001316080737384 5F Flush .035 GW/4F LEV2/100cmM001316081404422 5F Flush .035 GW/4F LEV2/100cm (5pk)M001316300737605 5F Flush .035 GW/4F OSB/ 100cmM001316301404644 5F Flush .035 GW/4F OSB/ 100cm (5pk)M001316320737629 5F Flush .035 GW/4F OSB / 65cmM001316321404668 5F Flush .035 GW/4F OSB / 65cm (5pk)M001315280737223 5F Flush .035 GW/5F Contra / 65cmM001315281356028 5F Flush .035 GW/5F Contra / 65cm (5pk)M001315290737230 5F Flush .035 GW/5F Contra / 90cmM001315291356035 5F Flush .035 GW/5F Contra / 90cm (5pk)M001315300737247 5F Flush .035 GW / 5F Contra / 100cmM001315301356042 5F Flush .035 GW/5F Contra / 100cm (5pk)M001315190737131 5F Flush .035 GW/5F Pigtail / 65cmM001315191355939 5F Flush .035 GW/5F Pigtail / 65cm (5pk)M001315210737155 5F Flush .035 GW/5FPigtail / 90cmM001315211355953 5F Flush .035 GW /5F Pigtail/90cm (5pk)M001315230737179 5F Flush .035 GW /5F Pigtail/100cmM001315231355977 5F Flush .035 GW / 5F Pigtail/100cm (5pk)M001315200737148 5F Flush .035 GW /5F Straight /65cmM001315201355946 5F Flush .035 GW / 5F Straight /65cm (5pk)M001315220737162 5F Flush .035 GW / 5F Straight /90cmM001315221355960 5F Flush .035 GW / 5F Straight /90cm (5pk)M001315240737186 5F Flush .035 GW / 5F Straight /100cmM001315241355984 5F Flush .035 GW / 5F Straight /100cm (5pk)M001315030736974 5F Flush .035 GW /5F Tennis Racquet /65cmM001315031355779 5F Flush .035 GW / 5F Tennis Racquet /65cm (5pk)M001315040736981 5F Flush .035 GW /5F Tennis Racquet /90cmM001315041355786 5F Flush .035 GW /5F Tennis Racquet /90cm (5pk)M001315050736998 5F Flush .035 GW /5F Tennis Racquet /100cmM001315051355793 5F Flush .035 GW / 5F Tennis Racquet /100cm (5pk)M001315310737254 5F Flush .038 GW /5F Contra /65cmM001315311356059 5F Flush .038 GW / 5F Contra /65cm (5pk)M001315320737261 5F Flush .038 GW /5F Contra /90cmM001315321356066 5F Flush .038 GW /5F Contra /90cm (5pk)M001315330737278 5F Flush .038 GW /5F Contra /100cmM001315331356073 5F Flush .038 GW / 5F Contra /100cm (5pk)M001315130737070 5F Flush .038 GW / 5F Pigtail/ 65cmM001315131355878 5F Flush .038 GW / 5F Pigtail/ 65cm (5pk)M001315140737087 5F Flush .038 GW /5F Pigtail/90cmM001315141355885 5F Flush .038 GW / 5F Pigtail/90cm (5pk)M001315150737094 5F Flush .038 GW / 5F Pigtail/100cmM001315151355892 5F Flush .038 GW / 5F Pigtail/100cm (5pk)M001315160737100 5F Flush .038 GW / 5F Straight /65cmM001315161355908 5F Flush .038 GW / 5F Straight / 65cm (5pk)M001315170737117 5F Flush .038 GW / 5F Straight / 90cmM001315171355915 5F Flush .038 GW / 5F Straight / 90cm (5pk)M001315180737124 5F Flush .038 GW / 5F Straight /100cmM001315181355922 5F Flush .038 GW / 5F Straight /100cm (5pk)M001315060737001 5F Flush .038 GW / 5F Tennis Racquet /65cmM001315061355809 5F Flush .038 GW /5F Tennis Racquet /65cm (5pk)M001315070737018 5F Flush .038 GW /5F Tennis Racquet /90cmM001315071355816 5F Flush .038 GW /5F Tennis Racquet /90cm (5pk)M001315080737025 5F Flush .038 GW /5F Tennis Racquet /100cmM001315081355823 5F Flush .038 GW / 5F Tennis Racquet /100cm (5pk)M001314630736653 5F Selective .035 GW /5F C1/65cmM001314631 355458 5F Selective .035 GW /5F C1/65cm (5pk)M001314650 736677 5F Selective .035 GW /5F C1/2S /65cmM001314651 355472 5F Selective .035 GW /5F C1 /2S /65cm (5pk)M001314670 736691 5F Selective .035 GW /5F C2/65cmM001314671 355496 5F Selective .035 GW /5F C2/65cm (5pk)M001314690 736714 5F Selective .035 GW /5F C2/2S /65cmM001314691 355519 5F Selective .035 GW /5F C2/2S /65cm (5pk)M001314710 736738 5F Selective .035 GW /5F C3/65cmM001314711 355533 5F Selective .035 GW /5F C3/65cm (5pk)M001314730 736752 5F Selective .035 GW / 5F C3 / 2S / 65cmM001314731 355557 5F Selective .035 GW / 5F C3 / 2S /65cm (5pk)M001314570 736592 5F Selective .035 GW /5F CHG2.5/65cmM001314571 355397 5F Selective .035 GW / 5F CHG2.5/65cm (5pk)M001314530 736554 5F Selective .035 GW /5F CHGB /65cmM001314531 355359 5F Selective .035 GW / 5F CHGB / 65cm (5pk)M001314550 736578 5F Selective .035 GW / 5F CHGC / 65cmM001314551 355373 5F Selective .035 GW / 5F CHGC /65cm (5pk)M001314590 736615 5F Selective .035 GW / 5F Contra 2 / 65cmM001314591 355410 5F Selective .035 GW / 5F Contra 2 / 65cm (5pk)M001314610 736639 5F Selective .035 GW /5F Duck /65cmM001314611 355434 5F Selective .035 GW / 5F Duck / 65cm (5pk)M001314790 736813 5F Selective .035 GW / 5F HK1.0 /65cmM001314791 355618 5F Selective .035 GW / 5F HK1.0 /65cm (5pk)M001314400 736424 5F Selective .035 GW /5F HN1 /100cmM001314401 355229 5F Selective .035 GW / 5F HN1/100cm (5pk)M001314770 736790 5F Selective .035 GW /5F MIK /65cmM001314771 355595 5F Selective .035 GW / 5F MIK /65cm (5pk)M001314850 736875 5F Selective .035 GW /5F RC1/65cmM001314851 355670 5F.Selective .035 .GW /5F RC1 /65cm (5pk)M001314870 736899 5F Selective .035 GW /5F RC2 / 65cmM001314871 355694 5F Selective .035 GW /5F RC2/65cm (5pk)M001314890 736912 5F Selective .035 GW /5F ROC /65cmM001314891 355717 5F Selective .035 GW /5F ROC /65cm (5pk)M001314910 736936 5F Selective .035 GW /5F ROC /2S /65cmM001314911 355731 5F Selective .035 GW /5F ROC /2S /65cm (5pk)M001314810 736837 5F Selective .035 GW /SF SHK 0.8/65cmM001314811 355632 5F Selective .035 GW / 5F SHK 0.8 / 65cm (5pk)M001314830 736851 5F Selective .035 GW / 5F SHK 1.0 /65cmM001314831 355656 5F Selective .035 GW / 5F SHK 1.0 /65cm (5pk)M001314020 736042 5F Selective .035 GW / 5F Straight / 65cmM001314021 354840 5F Selective .035 GW /5F Straight /65cm (5pk)M001314030 736059 5F Selective .035 GW / 5F Straight / 100cmM001314031 354857 5F Selective .035 GW / 5F Straight / 100cm (5pk)M001314070 736097 5F Selective .035 GW /5F Bern / 40cmM001314071 354895 5F Selective .035 GW /5F Bern /40cm (5pk)M001314090 736110 5F Selective .035 GW /5F Bern /65cmM001314091 354918 5F Selective .035 GW /5F Bern /65cm (5pk)M001314060 736080 5F Selective .035 GW / SF Bern /100cmM001314061 354888 5F Selective .035 GW / 5F Bern /100cm (5pk)M001314490 736516 5F Selective .035 GW / 5F CK /100cmM001314491 355311 5F Selective .035 GW / 5F CK / 100cm (5pk)M001314500 736523 5F Selective .035 GW /5F GEN /100cmM001314501 355328 5F Selective .035 GW / 5F GEN /100cm (5pk)M001314510 736530 5F Selective .035 GW /5F GEN /2S /100cmM001314511 355335 5F Selective .035 GW / 5F GEN / 2S /100cm (5pk)M001314150 736172 5F Selective .035 GW /5F H1 / 100cmM001314151 354970 5F Selective .035 GW /5F H1 /100cm (5pk)M001314190 736219 5F Selective .035 GW /5F H1H /100cmM001314191 355014 5F Selective .035 GW / 5F H1H / 100cm (5pk)M001314170 736196 5F Selective .035 GW / 5F H3 /100cmM001314171 354994 5F Selective .035 GW / 5F H3 /100cm (5pk)M001314200 736226 5F Selective .035 GW / 5F H3H /100cmM001314201 355021 5F Selective .035 GW / 5F H3H /100cm (5pk)M001314420 736448 5F Selective .035 GW / 5F HN2 /100cmM001314421 355243 5F Selective .035 GW /5F HN2/100cm (5pk)M001314440 736462 5F Selective .035 GW /5F HN3/100cmM001314441 355267 5F Selective .035 GW /5F HN3/100cm (5pk)M001314460 736486 5F Selective .035 GW / 5F HN4 /100cmM001314461 355281 5F Selective .035 GW / 5F HN4 /100cm (5pk)M001314480 736509 5F Selective .035 GW /5F HN5/100cmM001314481 355304 5F Selective .035 GW / 5F HN5 /100cm (5pk)M001314230 736257 5F Selective .035 GW /5F JB1/100cmM001314231 355052 5F Selective .035 GW /5F JB1 /100cm (5pk)M001314250 736271 5F Selective .035 GW /5F JB2/100cmM001314251 355076 5F Selective .035 GW /5F JB2/100cm (5pk)M001314270 736295 5F Selective .035 GW /5F JB3/100cmM001314271 355090 5F Selective .035 GW /5F JB3/100cm (5pk)M001314290 736318 5F Selective .035 GW /5F MAN /100cmM001314291 355113 5F Selective .035 GW / 5F MAN /100cm (5pk)M001314310 736332 5F Selective .035 GW /5F SIM1/65cmM001314311 355137 5F Selective .035 GW /5F SIM1/65cm (5pk)M001314330 736356 5F Selective .035 GW /5F SIM1/100cmM001314331 355151 5F Selective .035 GW /5F SIM1 /100cm (5pk)M001314350 736370 5F Selective .035 GW /5F SIM2/100cmM001314351 355175 5F Selective .035 GW /5F SIM2/100cm (5pk)M001314370 736394 5F Selective .035 GW /5F SIM3/100cmM001314371 355199 5F Selective .035 GW / 5F SIM3 /100cm (5pk)M001314120 736141 5F Selective .035 GW /5F WEIN /100cmM001314121 354949 5F Selective .035 GW /5F WEIN /100cm (5pk)M001314620 736646 5F Selective .038 GW /5F C1/65cmM001314621 355441 5F Selective .038 GW /5F C1 /65cm (5pk)M001314640 736660 5F Selective .038 GW /5F C1/ 2S /65cmM001314641 355465 5F Selective .038 GW /5F C1/2S /65cm (5pk)M001314660 736684 5F Selective .038 GW / 5F C2 / 65cmM001314661 355489 5F Selective .038 GW /5F C2/65cm (5pk)M001314680 736707 5F Selective .038 GW / 5F C2 / 2S / 65cmM001314681 355502 5F Selective .038 GW /5F C2 /2S /65cm (5pk)M001314700 736721 5F Selective .038 GW /5F C3/65cmM001314701 355526 5F Selective .038 GW /5F C3/65cm (5pk)M001314720 736745 5F Selective .038 GW /5F C3/2S /65cmM001314721 355540 5F Selective .038 GW /5F C3/2S /65cm (5pk)M001314560 736585 5F Selective .038 GW /5F CHG2.5/65cmM001314561 355380 5F Selective .038 GW /5F CHG2.5/65cm (5pk)M001314520 736547 5F Selective .038 GW /5F CHGB /65cmM001314521 355342 5F Selective .038 GW / 5F CHGB / 65cm (5pk)M001314540 736561 5F Selective .038 GW /5F CHGC /65cmM001314541 355366 5F Selective .038 GW /5F CHGC /65cm (5pk)M001314580 736608 5F Selective .038 GW / 5F Contra 2 / 65cmM001314581 355403 5F Selective .038 GW / 5F Contra 2 / 65cm (5pk)M001314600 736622 5F Selective .038 GW /5F Duck /65cmM001314601 355427 5F Selective .038 GW / 5F Duck /65cm (5pk)M001314780 736806 5F Selective .038 GW / 5F HK1.0 /65cmM001314781 355601 5F Selective .038 GW /5F HK1.0 / 65cm (5pk)M001314760 736783 5F Selective .038 GW /5F MIK /65cmM001314761 355588 5F Selective .038 GW / 5F MIK / 65cm (5pk)M001314840 736868 5F Selective .038 GW /5F RC1 /65cmM001314841 355663 5F Selective .038 GW /5F RC1 /65cm (5pk)M001314860 736882 5F Selective .038 GW /5F RC2/65cmM001314861 355687 5F Selective .038 GW / 5F RC2 /65cm (5pk)M001314880 736905 5F Selective .038 GW /5F ROC /65cmM001314881 355700 5F Selective .038 GW / 5F ROC /65cm (5pk)M001314900 736929 5F Selective .038 GW / 5F RDC /2S / 65cmM001314901 355724 5F Selective .038 GW / 5F ROC /2S /65cm (5pk)M001314800 736820 5F Selective .038 GW / 5F SHK 0.8 / 65cmM001314801 355625 5F Selective .038 GW /5F SHK 0.8/65cm (5pk)M001314820 736844 5F Selective .038 GW /5F SHK 1.0 /65cmM001314821 355649 5F Selective .038 GW /5F SHK 1.0 /65cm (5pk)M001314000 736028 5F Selective .038 GW /5F Straight /65cmM001314001 354826 5F Selective .038.GW / 5F Straight / 65cm (5pk)M001314010 736035 5F Selective .038 GW / 5F Straight /100cmM001314011 354833 5F Selective .038 GW / 5F Straight /100cm (5pk)M001314750 736776 5F Selective .038 GW / 5F Train / 65cmM001314751 355571 5F Selective .038 GW / 5F Train / 65cm (5pk)M001314740 736769 5F Selective .038 GW / 5F VAN /2S / 65cmM001314741 355564 5F Selective .038 GW /5F VAN /2S / 65cm (5pk)M001315360 737285 5F Selective .038 GW / 5F Yashiro / 65cmM001315361 356080 5F Selective .038 GW / 5F Yashiro / 65cm (5pk)M001315370 737292 5F Selective .038 GW / 5F Yashiro / 100cmM001315371 356097 5F Selective .038 GW / 5F Yashiro / 100cm (5pk)M001314080 736103 5F Selective .038 GW / 5F Bern / 40cmM001314081 354901 5F Selective .038 GW / 5F Bern / 40cm (5pk)M001314100 736127 5F Selective .038 GW / 5F Bern / 65cmM001314101 354925 5F Selective .038 GW / 5F Bern / 65cm (5pk)M001314050 736073 5F Selective .038 GW / 5F Bern / 100cmM001314051 354871 5F Selective .038 GW / 5F Bern /100cm (5pk)M001314040 736066 5F Selective .038 GW / 5F BARNH / 100cmM001314041 354864 5F Selective .038 GW / 5F BARNH /100cm (5pk)M001314130 736158 5F Selective .038 GW / 5F H1 /65cmM001314131 354956 5F Selective .038 GW / 5F H1 /65cm (5pk)M001314140 736165 5F Selective .038 GW / 5F H1 /100cmM001314141 354963 5F Selective .038 GW /5F H1 /100cm (5pk)M001314180 736202 5F Selective .038 GW / 5F H1H / 100cmM001314181 355007 5F Selective .038 GW /5F H1H /100cm (5pk)M001314160 736189 5F Selective .038 GW /5F H3/100cmM001314161 354987 5F Selective .038 GW / 5F H3 /100cm (5pk)M001314390 736417 5F Selective .038 GW /5F HN1/ 100cmM001314391 355212 5F Selective .038 GW / 5F HN1 / 100cm (5pk)M001314410 736431 5F Selective .038 GW / 5F HN2 / 100cmM001314411 355236 5F Selective .038 GW /5F HN2 / 100cm (5pk)M001314430 736455 5F Selective .038 GW / 5F HN3 /100cmM001314431 355250 5F Selective .038 GW /5F HN3/100cm (5pk)M001314450 736479 5F Selective .038 GW /5F HN4/100cmM001314451 355274 5F Selective .038 GW / 5F HN4/100cm (5pk)M001314470 736493 5F Selective .038 GW /5F HN5/100cmM001314471 355298 5F Selective .038 GW /5F HN5/100cm (5pk)M001314210 736233 5F Selective .038 GW / 5F JB1/65cmM001314211 355038 5F Selective .038 GW /5F JB1 / 65cm (5pk)M001314220 736240 5F Selective .038 GW /5F JB1/100cmM001314221 355045 5F Selective .038 GW /5F JB1/100cm (5pk)M001314240 736264 5F Selective .038 GW /5F JB2/100cmM001314241 355069 5F Selective .038 GW /5F JB2 / 100cm (5pk)M001314260 736288 5F Selective .038 GW /5F JB3 / 100cmM001314261 355083 5F Selective .038 GW / 5F JB3 / 100cm (5pk)M001314280 736301 5F Selective .038 GW / 5F MAN / 100cmM001314281 355106 5F Selective .038 GW /5F MAN /100cm (5pk)M001314300 736325 5F Selective .038 GW /5F SIM1/65cmM001314301 355120 5F Selective .038 GW /5F SIM1/65cm (5pk)M001314320 736349 5F Selective .038 GW /5F SIM1/ 100cmM001314321 355144 5F Selective .038 GW /5F SIM1/100cm (5pk)M001314340 736363 5F Selective .038'GW / 5F 81M2 /100cmM001314341 355168 5F Selective .038 GW /5F 81M2 /100cm (5pk)M001314360 736387 5F Selective .038 GW /5F SIM3/100cmM001314361 355182 5F Selective .038 GW /5F SIM3/100cm (5pk)M001314380 736400 5F Selective .038 GW /5F SIM4/100cmM001314381 355205 5F Selective .038 GW /5F SIM4/100cm (5pk)M001314110 736134 5F Selective .038 GW /5F WEIN /100cmM001314111 354932 5F Selective .038 GW / 5F WEIN /100cm (5pk) | The Imager™ II angiographic catheters are sterile, single-use intravascular catheters that are used for diagnostic angiography, and are offered in a variety of flush and selective shapes.Imager II catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system. Imager II 5F Selective catheters may also be used to deliver Interlock™ 0.035” detachable coils to specified sites in the peripheral vasculature. |  |
| 47 | M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan | **Legal Manufacturer:**M/s Boston Scientific Corporation300, Boston Scientific Way, Marlborough, MA 01752 USA**Manufacturing Site:**M/s Boston Scientific Limited Ballybrit Business Park Galway Ireland(FSC Ireland) | Wallgraft TM Over the Wire Endoprosthesis with Unistep Plus Delivery SystemClass CShelf Life: 36MonthH965520010 WALLGRAFT PKG/6X30 9FR COMMLH965520020WALLGRAFT PKG/6X50 9FR COMMLH965520030 WALLGRAFT PKG/6X70 9FR COMMLH965520050 WALLGRAFT PKG/7X30 9FR COMMLH965520060 WALLGRAFT PKG/7X50 9FR COMMLH965520070 WALLGRAFT PKG/7X70 9FR COMMLH965520090 WALLGRAFT PKG/8X30 9FR COMMLH965520100 WALLGRAFT PKG/8X50 9FR COMMLH965520110 WALLGRAFT PKG/8X70 9FR COMMLH965520130 WALLGRAFT PKG/9X30 10FR COMMLH965520140 WALLGRAFT PKG/9X50 10FR COMMLH965520150 WALLGRAFT PKG/9X70 10FR COMMLH965520170 WALLGRAFT PKG/10X30 10FR COMMLH965520180 WALLGRAFT PKG/10X50 10FR COMMLH965520190 WALLGRAFT PKG/10X70 10FR COMMLH965520210 WALLGRAFT PKG/12X30 11FR COMMLH965520220 WALLGRAFT PKG/12X50 11FR COMMLH965520230 WALLGRAFT PKG/12X70 11FR COMMLH965520250 WALLGRAFT PKG/6X20 9FR COMMLH965520260 WALLGRAFT PKG/7X20 9FR COMMLH965520270 WALLGRAFT PKG/8X20 9FR COMMLH965520280 WALLGRAFT PKG/9X20 10FR COMMLH965520290 WALLGRAFT PKG/10X20 10FR COMMLH965520320 WALLGRAFT PKG/14X50 12FR COMMLH965520330 WALLGRAFT PKG/14X70 12FR COMML | The WALLGRAFT Endoprosthesis is indicated for use for treatment of:• Complex iliac artery stenoses (lesion ≥ 3 cm in length or a calcified or eccentric lesion < 3 cm in length) and iliac occlusions in vessels 7-12 mm in diameter.• Exclusion of atherosclerotic arterial aneurysms and traumatic vessel disruptions in peripheral vessels 5-12 mm in diameter.The WALLGRAFT Endoprosthesis with Unistep Plus Delivery System is comprised of two components: The implantable endoprosthesis (stent-graft) and the delivery system. The stent-graft is pre-mounted onto the delivery system. |  |
| **Decision:** The Board approved the products at serial no. 38-47 for import in the name of M/s Ferozsons Laboratories Limited, Nowshera, KPK. |
| 48 | M/s Roche Pakistan Limited, 37-C, Bi-6, P.E.C.H.S, Karachi(ELI-00009) | **Legal Manufacturer/ Manufacturing Site:**M/s Roche Diagnostics GmbH,Sandhofer Str.116,68305 Mannheim, Germany(FSC Germany) | Elecsys HBsAg II. KitClass DShelf Life:(i) 22Month(ii) 12Month(iii) 18Month(iv) 12Month(v) 12Month(i) HBsAg Confirmatory TestCode: 11820648(ii) HBsAgllSize: 100Code: 06487787(iii) PreciControlHBsAgllSize: 16x1.3mLCode: 04687876(iv)ElecsysHBsAgllSize: 200Code: 07914482190(v)ElecsysHBsAgllSize: 300Code: 07251076190 | Immunoassay for the in vitro confirmation of the presence of Hepatitis B surface antigen (HBsAg) in human serum & plasma samples. |  |
| 49 | M/s Roche Pakistan Limited, 37-C, Bi-6, P.E.C.H.S, Karachi(ELI-00009) | **Legal Manufacturer/ Manufacturing Site:**M/s Roche Diagnostics GmbH,Sandhofer Str.116,68305 Mannheim, Germany(FSC Germany) | Class DShelf Life:(i) 18Month(ii) 15Month(iii) 15Month(iv) 18Month(v) 15Month(i) PreciControl HIV Gen llSize: 6x2.0mLCode: 06924107190(ii) HIVCombi PTSize: 200Code: 07914504190(iii) HIV Combi PTSize: 100Code: 05390095(iv) PreciControl HIVSize: 6x2.0mLCode: 05162645(v) Elecsys HIV DuoSize: 300Code: 07229542190 |  |  |
| 50 | M/s Roche Pakistan Limited, 37-C, Bi-6, P.E.C.H.S, Karachi(ELI-00009) | **Legal Manufacturer/ Manufacturing Site:**M/s Roche Diagnostics GmbH,Sandhofer Str.116,68305 Mannheim, Germany(FSC Germany) | Class DShelf Life:(i) 10Month(ii) 10Month(iii) 18Month(iv) 10Month(i) Anti-HCV llSize: 100Code: 06368921(ii) Anti-HCV llSize: 200Code: 06427405(iii) PreciControl Anti-HCVSize: 16x1.3mLCode: 03290379(iv) Elecsys Anti-HCV llSize: 300Code: 07026889190 | In-vitro diagnostics test for the qualitative detection of antibodies to Hepatitis C Virus (HCV) in human serum & plasma |  |
| **Decision:** The Board approved the products at serial no. 48-50 for import in the name of M/s Roche Pakistan Limited, Karachi. |
| 51 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore(ELI-00094) | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA(FSC USFDA) | Hi-Torque Whisper Guide WireSizes and codes as per submitted Free Sale Certificate.Class DShelf Life: 2Year |  PTCA Guide Wire |  |
| 52 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore.(ELI-00094) | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA(FSC USFDA) | Hi-Torque Balance Middle Weight Guide WireSizes and codes as per submitted Free Sale Certificate.Class DShelf Life: 2Year | PTCA Guide Wire |  |
| 53 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore(ELI-00094) | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA(FSC USFDA) | Hi-Torque Pilot Guide WireSizes and codes as per submitted Free Sale Certificate.Class DShelf Life: 2Year | PTCA Guide Wire |  |
| **Decision:** The Board approved the products at serial no. 51-53 for import in the name of M/s Digital Imaging Systems, Lahore. |
| 54 | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi (ELI-00034) | **Legal Manufacture/ Distributor:**M/s Terumo Medical Corporation 2101 Cottontail Lane Somerset, New Jersey 08873 USA**Manufacturer:**M/s Terumo Puerto Rico, LLC Caguas West Industrial Park Lot 21-B StreetCaguas, Puerto Rico 00725 USAM/s St. Jude Medical, 14901 Deveau Pl. Minnetonka, MN 55345, USA(FSC USFDA valid till 17-04-2019) | Angio-Seal VIP Vascular Closure DeviceClass DShelf Life: 1 Year AngioSeal VIP 610132 6FrAngioSeal VIP 610133 8Fr | The Angio-Sealdevice is composed of an absorbable collagen spongeand a specially designed absorbable polymer anchorthat are connected by an absorbable self-tighteningsuture (STS). The device seals and sandwiches thearteriotomy between its two primary members, the anchorand collagen sponge. |  |
| 55 | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi (ELI-00034) | **Legal Manufacture/ Distributor:**M/s Microvention Europe: 30 bis rue du Vieil Abreuvior, 78100 Saint Germain en Laye, France**Design & Development/ Production Sites:**M/s MicroVention, Inc.1311 Valencia Avenue Tustin, California, 92780 USA**Production Sites:**M/s MicroVention Costa Rica S.R.LEdificio B33Zona Franca CoyolAlajuela, Costa Rica(FSC France Issue Date 02-12-2016) | LVIS Intraluminal Support DeviceClass DShelf Life: 3 Years212517-CAS 3.5 x 17 212525-CAS 3.5 x 22213015-CAS 4.5 x 18213025-CAS 4.5 x 23213041-CAS 4.5 x 32214035-CAS 5.5 x 30214049-CAS 5.5 x 33 | The LVIS Intraluminal Support Device is intended for use with embolic coils for the treatment of intracranial neurovascular diseases. The LVIS is also intended to be used in the peripheral vasculature. |  |
| 56 | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi (ELI-00034) | **Legal Manufacture/ Distributor:**M/s Microvention Europe: 30 bis rue du Vieil Abreuvior, 78100 Saint Germain en Laye, France**Design & Development/ Production Sites:**M/s MicroVention, Inc.1311 Valencia AvenueTustin, California, 92780 USA**Production Sites:**M/MicroVention, Inc.35 EnterpriseAliso Viejo, CA 92656 USA(FSC France Issue Date 25-01-2016) | ERICTM Retrieval Device Class DShelf Life: 5YearsCodes Spheres SizesER173015 3 3 x 15ER173020 4 3 x 20ER174024 4 4 x 24ER174030 5 4 x 30ER176044 5 6 x 44 | The ERIC Retrieval Device is a mechanical thrombectomy device designed to restore blood flow be effectively removing clots from occlusive vasculature in patients suffering from acute ischemic strok |  |
| 57 | M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi (ELI-00034) | **Legal Manufacture/ Distributor:**M/s MicroVention, Inc.1311 Valencia AvenueTustin, California, 92780 USA**Manufacturer:**M/s Ashitaka Factory of Terumo Corporation150, Maimaigi-choFujinomiya-shi,Shizuoka, 418-0015 Japan(FSC USFDA valid till 31-08-2019) | CHAPERON Guiding Catheter System Class DShelf Life: 3YearsCodes Shape**5Fr Guiding Catheter System**.GC595ST STRGC595M2 MP2GC595STJB STR/JB2GC595STVT STR/VTRGC595STSI STR/SIMGC595M2JB MP2/JB2GC595M2VT MP2/VTRGC595M2SI MP2/SIM**6Fr Guiding Catheter System.**GC695ST STRGC695M2 MP2GC595STJB STR/JB2GC595STVT STR/VTRGC595STSI STR/SIMGC595M2JB MP2/JB2GC595M2VT MP2/VTRGC595M2SI MP2/SIMGC695BUJB BUR/JB2GC695BUVT BUR/VTR | The Chaperon Guiding Catheter is a two-catheter system comprised of the outer catheter and the inner catheter. Used to access and deliver stent, balloon, microcatheter and other devices to Neuro arteries. |  |
| **Decision:** The Board approved the products at serial no. 54-57 for import in the name of M/s Intek Corporation, Rawalpindi. |

**Item No. XIII:- RENEWAL OF REGISTRATION OF MEDICAL DEVICES FOR IMPORT ALREADY REGISTERED AS DRUG.**

Following firms has applied for the renewal of registration of medical devices for import on prescribed form 7-A:-

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. No** | **Name and Addresses of Establishment** | **Manufacture Details** | **Name of Medical Device with sizes/Class/Shelf Life** | **Brief Description** | **Remarks** |
| 1 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | Xience Prime Everolimus Eluting Coronary Stent System(Reg No.74643)Class DShelf Life: 2YearDiameter(mm) Length (mm)2.25 x 8,12,15,18,23,282.50 x 8,12,15,18,23,28,33,382.75 x 8,12,15,18,23,28,33,383.0 x 8,12,15,18,23,28,33,383.50 x 8,12,15,18,23,28,33,384.0 x 8,12,15,18,23,28,33,38 | DrugEluting Coronary Stent System |  |
| 2 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | NC Trek RX Coronary Dilatation Catheter(Reg No. 74650)Class DShelf Life: 2Year1.50 mm x 06 mm1.50 mm x 08 mm1.50 mm x 12 mm1.50 mm x 15 mm1.50 mm x20 mm2.0 mm x 06 mm2.0 mm x 08mm2.0 mm x 12 mm2.0 mm x 15 mm2.0 mm x20 mm2.25 mm x 06 mm2.25 mm x 08mm2.25 mm x 12 mm2.25 mm x 15 mm2.25mm x20 mm2.5 mm x 06 mm2.5 mm x 08mm2.5 mm x 12 mm2.5 mm x 15 mm2.5mm x20 mm2.75 mm x 06 mm2.75 mm x 08mm2.75 mm x 12 mm2.75 mm x 15 mm2.75mm x20 mm3.0 mm x 06 mm3.0 mm x 08mm3.0 mm x 12 mm3.0 mm x 15 mm3.0 mm x20 mm3.25 mm x 06 mm3.25 mm x 08mm3.25 mm x 12 mm3.25 mm x 15 mm3.25mm x20 mm3.5 mm x 06 mm3.5 mm x 08mm3.5 mm x 12 mm3.5 mm x 15 mm3.5mm x20 mm3.75 mm x 06 mm3.75 mm x 08mm3.75 mm x 12 mm3.75 mm x 15 mm3.75mm x20 mm4.0 mm x 8 mm4.0 mm x 12 mm4.0 mm x 15 mm4.0 mm x 20 mm4.5 mm x 8 mm4.5 mm x 12 mm4.5 mm x 15 mm4.5 mm x 20 mm5.0 mm x 8 mm5.0 mm x 12 mm5.0 mm x 15 mm5.0mm x 20 mm | Coronary Dilatation Catheter |  |
| 3 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | RX Herculink Elite Peripheral Stent System(Reg No. 74652)Class DShelf Life: 3YearDiameter(mm) Length (mm)4.00 x 12,15,184.5 x 12,15,185.00 x 12,15,185.5 x 12,15,186.00 x 12,15,186.5 x 12,15,187.00 x 12,15,18 | Peripheral Stent System |  |
| 4 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | Omnilink Elite Peripheral Stent System(Reg No. 74644)Class DShelf Life: 3Year 4.00 x 12,16,195.00 x 12,16,19,29,39,596.00 x 12,16,19,29,39,597.00 x 12,16,19,29,39,598.00 x 19,29,39,599.00 x 19,29,39,5910.00 x 19,29,39,59 | Peripheral Stent System |  |
| 5 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | RX Acculink Carotid Stent System(Reg No. 74651)Class DShelf Life: 2YearDiameter(mm) Length (mm)5.00 x 20,30,406.00 x 20,30,407.00 x 20,30,408.00 x 20,30,409.00 x 20,30,4010.00 x 20,30,406.0-8.0 x 30,407.0-10.0 x 30,40 | Carotid Stent System |  |
| 6 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | Mini Trek RX Coronary Dilatation Catheter(Reg No. 74649)Class DShelf Life: 2Year 1.20 mm x 06 mm1.20 mm x 08 mm1.20 mm x 12 mm1.20 mm x 15mm1.20 mm x 20 mm1.50 mm x 06 mm1.50 mm x 08 mm1.50 mm x 12 mm1.50 mm x 15 mm1.50 mm x20 mm2.0 mm x 06 mm2.0 mm x 08mm2.0 mm x 12 mm2.0 mm x 15 mm2.0 mm x20 mm2.0 mm x 25 mm2.0 mm x 30 mm | Coronary Dilatation Catheter |  |
| 7 | M/s Digital Imaging Systems, 121 Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore | **Legal Manufacture:**M/s Abbott Vascular 3200 Lakeside Drive, Santa Clara, CA 95054, USA**Manufacturing Sites:**(1) M/s Abbott Vascular Cashel Road, Clonmel, Tipperary, Ireland(2) M/s Abbott Vascular 26531, YNEZ Road, Temecula CA 92591, USA(3) M/s Abbott Vascular 52 Calle 3, B31 Coyol Free Zone, El Coyol, Aljuela, Costa Rica(4) M/s Abbott Vascular Road No.2, KM 58, Cruce Davila, Barceloneta, PR 00617, USA | Trek RX Coronary Dilatation Catheter(Reg No. 74648)Class DShelf Life: 2Year2.25 mm x 06 mm2.25 mm x 08mm2.25 mm x 12 mm2.25 mm x 15 mm2.25mm x20 mm2.25 mm x 25 mm2.25mm x30 mm2.5 mm x 06 mm2.5 mm x 08mm2.5 mm x 12 mm2.5 mm x 15 mm2.5mm x20 mm2.5 mm x 25 mm2.5mm x30 mm2.75 mm x 06 mm2.75 mm x 08mm2.75 mm x 12 mm2.75 mm x 15 mm2.75mm x20 mm2.75 mm x 25 mm2.75mm x30 mm3.0 mm x 06 mm3.0 mm x 08mm3.0 mm x 12 mm3.0 mm x 15 mm3.0 mm x20 mm3.0 mm x 25 mm3.0 mm x30 mm3.25 mm x 06 mm3.25 mm x 08mm3.25 mm x 12 mm3.25 mm x 15 mm3.25mm x20 mm3.25 mm x 25 mm3.25mm x30 mm3.5 mm x 06 mm3.5 mm x 08mm3.5 mm x 12 mm3.5 mm x 15 mm3.5mm x20 mm3.5 mm x 25 mm3.5mm x30 mm3.75 mm x 06 mm3.75 mm x 08mm3.75 mm x 12 mm3.75 mm x 15 mm3.75mm x20 mm4.0 mm x 8 mm4.0 mm x 12 mm4.0 mm x 15 mm4.0 mm x 20 mm4.0 mm x 25 mm4.0 mm x 30 mm4.5 mm x 12 mm4.5 mm x 15 mm5.0 mm x 12 mm5.0 mm x 15 mm | Coronary Dilatation Catheter |  |
| **Decision:** The Board approved the products at serial no. 1-7 for renewal in the name of M/s s Digital Imaging Systems, Lahore. |
| 8 | M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi | **Manufacture By:**M/s Wuxi Yushou Medical Appliances Co. Ltd., China | Yushou Sterile Latex Free Disposable Syringes3ml, 5ml, 10ml & 20ml(Reg No. 59223)Class BShelf Life: 5Year | Disposable Syringes |  |
| 9 | M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi | **Manufacture By:**M/s Wuxi Yushou Medical Appliances Co. Ltd., China | Yushou Sterile Latex Free Disposable Syringes50ml(Reg No. 59224)Class BShelf Life: 5Year | Disposable Syringes |  |
| 10 | M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahrah e Faisal, Karachi | **Manufacture By:**M/s Wuxi Yushou Medical Appliances Co. Ltd., China | Yushou Sterile Disposable Insulin Syringes1.0ml(Reg No. 59222)Class BShelf Life: 5Year | Disposable Insulin Syringes |  |
| **Decision:** The Board approved the products at serial No. 8-10 for renewal subject to the foreign inspection of the manufcturer.  |

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

 Medical Devices Board (MDB), DRAP in its 9th meeting held on 5th July, 2018 decided to constitute a committee under the Chairmanship of Dr. Abdul Haleem Khan, member MDB to examine the petition of the Pakistan Medical Devices Manufacturers Association regarding hardships faced by its members in term of levy of different taxes by Federal Board of Revenue (FBR).

 In pursuance of the decision of the MDB, the Committee held its meeting along with representatives of Pakistan Medical Devices Manufacturers Association (PMDMA) under the Chairmanship of Dr. Abdul Haleem Khan on August 3, 2018 in DRAP. The following were in attendance:

1. Dr. Abdul Haleem Khan In Chair

Member, MDB

1. Dr. Sajid Bashir Via Videophone

Member, MDB

1. Ms. Hira Bhutto Focal Person

Assistant Director-I, MDB

1. Mr. Tariq Mahmood

Member, PMDMA

1. Mr. QamarZaman

Member, PMDMA

1. Mr. SirajMehmood

Member, PMDMA

**Recommendations of the Committee:**

 The Committee was of the considered opinion that imposition of sales tax on finished and raw material of medical devices is an extra burden on patients since it is passed on to patients by the firms. Therefore MDB should take a sympathetic view and address the concern of medical device manufacturers and importers by recommending waver of sales tax on both imported raw material used in manufacturing of medical devices and finished medical devices previously declared or defined as drugs. The MDB should send a proposal to Federal Board of Revenue (FBR) to exempt the levy of sales tax on imported raw materials used in manufacturing of medical devices and finished medical devices of following categories:

**MEDICAL DEVICES PREVIOUSLY DECLARED AS DRUGS UNDER VARIOUS SROs**

|  |  |  |
| --- | --- | --- |
| **S.No.** | **SRO No.** | **Products** |
|  | **S.R.O 324(I)/94** | Disposable SyringesDisposables Set for collection or transfusion of blood of giving any infusion. |
|  | **S.R.O 957(I)/2009** | CannulaCatheterStent |
|  | **S.R.O 349(I)/2010** | Auto-Disable Syringes and butterfly needles. |

**MEDICAL DEVICES PREVIOUSLY DEFINED AS DRUGS**

|  |  |  |
| --- | --- | --- |
| **S.No.** | **SRO No.** | **Products** |
|  | **S.R.O 824(I)/2018** | 1. Abortive and contraceptive devices
2. Surgical Ligatures
3. Sutures
4. Bandages
5. Absorbent cotton
6. Adhesive plasters
 |

Submitted for wisdom and consideration of the Medical Device Board.

**Decision :** The Board deliberated on the report of the Committee and after discussion agreed to write a letter to the Federal Board of Revenue (FBR) for exempetion of sales tax on raw material imported for manufactring and import of finished form of above referred medical devices or otherwise. The Board authorised the Chairman MDB to include any other medical device(s) or class(es) of medical device in a letter to FBR for exemption of sales tax.

**Item No. XV M/S B. BRAUN PAKISTAN PVT. LTD APPLICATION FOR TRANSFER OF REGISTRATION FROM IMPORT TO LOCAL MANUFACTURING OF MEDICAL DEVICE NAMELY “ INJECTOCAN” DISPOSABLE SYRINGE UNDER CONTRACT MANUFACTURING BY M/S AMSON VACCINES & PHARMA PVT. LIMITED**

 It is submitted that M/s B. Braun Pakistan Pvt. Ltd has applied for transfer of registration from import to local manufacturing of medical device Namely “ Injectocan” Disposable Syringe under Contract Manufacturing by M/s Amson Vaccines & Pharma Pvt. Limited.

 Firm has submitted following documents in support of their application.

1. Copy of Registration Letter
2. Application on Form 7 by M/s B.Braun (contract giver)
3. Copy of Agreement between M/s B.Braun Pakistan & M/s Amsons Vaccine & Pharma.
4. Bank Deposit ChallanRs. 25,000/-
5. Manufacturing and Quality control documentation.
6. Label artwork.
7. Undertaking on stamp paper.

 It is submitted that under rule 67 of Medical Devices Rules, 2017 Out sourcing of manufacturing of medical devices may be allowed subject to fulfillment of the following conditions:-

1. the establishment for manufacturing medical device being contract giver, intending to outsource, has been licensed and its medical device enlisted or registered by the MDB or approved by any regulatory authority of USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland and United Kingdom or pre-qualified by World Health Organization or CE marked by manufacturer whose conformity assessment is performed by conformity assessment bodies notified in NANDO database under the relevant European directive for medical devices subject to evidence and supporting document;
2. the contract giver shall possess establishment licence issued by the MDB; and
3. if the contract giver is of foreign jurisdiction, the MDB shall determine the conditions of out sourcing.

(2) Outsourcing of manufacturing processes or analysis of medical devices may be allowed subject to the conditions as may be prescribed”

Submitted for wisdom and consideration of Medical Device Board.

**Decision:** The Board acceeded to the request of the firm, namely M/s B. Braun Pakistan Pvt. Ltd for outsource / contract manufacturing of “Injectocan” Disposable Syringe from M/s Amson Vaccines & Pharma Pvt. Limited, Islamabad. The outsource / contract manufactruing shall be for a period of 2 years and the registration shall stand cancelled after 2 years without any further renewal of the product. M/s B. Braun Pakistan Pvt. Ltd shall inform the period for outsource / contract manufacturing.

**Item No. XVI. CONVERSION OF DRUG MANUFACTURING LICENCE (BY WAY OF FORMULATION)ISSUED BY LICENCING DIVISION UNDER THE DRUGS ACT, 1976 TO ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES UNDER MEDICAL DEVICES RULES, 2017.**

 Certain Medical Devices were declared or defined as drugs such as sutures, bandages, ligatures, adsorbent cotton, adhesive plasters, syringes, I.V. Catheters, etcthrough various SROs under the Drugs Act, 1976 and in Schedule-I of DRAP Act, 2012. These products are also treated as medical devices internationally and now declared by Federal Government as medical devices.

 Drug Licencing Division of Drug Regulatory Authority of Pakistan has issued Drug Manufacturing Licence by way of formulation to the manufacturers of above referred medical devices. Since these medical devices are required to be dealt under Medical Devices Rules, 2017. Therefore, they require to be manufactured under Establishment Licence to Manufacture Medcial Devices in order to streamline/ regularize their transition. Therefore, matter is put up for consideration and wisdom of Medical Device Board.

**Decision:** The Board discussed the matter at length and acceeded to the immediate conversion of Drug Manufacturing Licence (DML) to Establishment Licence to Manufacture Medcial Devices. The firms manufacturing medical devices previously defined or declared as drugs shall be asked to surrender their DML.

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**Item No. XVII. DELEGATION OF POWER TO CHAIRMAN MEDICAL DEVICES BOARD FOR CHANGE IN PARTICULARS AND ANY MINOR CORRECTION IN PARTICULARS OF ESTABLISHMENT LICENCE AND ENLISTMENT / REGISTRATION CERTIFICATES.**

 The Secretary of the MDB with the permission of the Chair presented before the Board that Board may delegate power to Chairman, MDB for change in particulars such as change in qualified staff of the firm etc, minor changes in inclusion of directors name or correction of spellings of directors or firm / company name so as to smoothly run the day to day business of Medical Devices Division rather than bringing to the MDB.

**Decision:** MDB delegated the powers and authorised the Chairman MDB to approve change in particulars and approve minor changes such as mentioned above on behalf of MDB for smooth working of the Medical Devices Division.

**Item No. XVIII. REGULATION OF SURGICAL INSTRUMENTS MANUFACTURERS:**

 Chairman MDB also informed the Board that the Surgical Instruments Manufacturers Association of Pakistan (SIMAP) is continuously pursuing for exemption of surgical instruments from regulation under Medical Devices Rules, 2017. He further informed that surgical instruments industry is an important industry earning much needed foreign exchange for the country and we have no intention to hamper the export. The exemption of regulation of surgical instruments needed to be looked under the DRAP Act, 2012.

**Decision:** The Board agreed that the exemption under the DRAP Act, 2012 cannot be allowed since medical devices are required to be regulated under the existing law of land, however, the Board and the Medical Devices Division is ready to facilitate them. The Board asked the Chairman to bringforth the complete case and proposal for regulation of surgical instruments in the next Board meeting.

**Annexure-I**

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

**Issued after 9th Meeting**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.#** | **PR.No.** | **Issue Date** | **Name of Importer** | **Product Name** | **Name of Manufacturer** |
|  | 00552-PR-MD | 13-07-2018 | M/s Cardiac Care,848-C, Shadman-I, Lahore | Sterile Single use epicardial electrodes Myopace, unipolar, adult, straight chest needle, L 60cm | **Manufactured By**M/s FIAB S.p.A., Via P. Costoli 4, 50039 Vicchio (FI) Italy |
|  | 00553-PR-MD | 13-07-2018 | -do- | Pro-Active (Pro-Long Tube) | **Manufactured By**M/s PRO-ACTIVE S.r.l., Via del Commercio 12, 45100 Rovigo (RO), Italy |
|  | 00554-PR-MD | 13-07-2018 | M/s B. Braun Pakistan (Pvt) Ltd,The Forum, Suite 216, Kh-e-Jami, Block 9, Clifton, Karachi | Combidyn PVC Press, Tubing Transp | **Manufacturer**M/s B. Braun Melsungen AG Carl-Braun-Strabe 1 34212 Melsungen, Germany |
|  | 00555-PR-MD | 13-07-2018 | M/s Intra Health,56/A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS,Karachi | Thermo Sheild (Adult Viral/Bacterial Filter + HME )(038-41-350) | **Manufactured By**M/s Flexicare Medical Limited Cyon Valley Business Park, Mountain Ash, CF45 4ER, UK |
|  | 00556-PR-MD | 13-07-2018 | M/s Fresenius Medical Care (Pvt) Ltd,TAMC, First Floor, 27C III, M.M. Alam Road Gulberg-III,Lahore | Tenckhoff-Catheter 180 & 215 | **Legal Manufacturer**M/s Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg, Germany**Manufacturing Site**M/s Fresenius Medical Care Deutschland GmbH Werk St. Wendel Frankfurter Strabe 6 - 8 66606 St. Wendel Germany |
|  | 00557-PR-MD | 13-07-2018 | -do- | Swan-Neck-Catheter 416 | -do- |
|  | 00558-PR-MD | 13-07-2018 | M/s JK Traders,Suite No. 13, 2nd Floor Majeed Plaza Bank Road, Saddar,Rawalpindi | Balloon Inflation Devices | **Manufactured By**M/s Anntom Medica Limited, 5/F, Building A6 Yinlong Industrial Zone, 292 Shenshan Road, Longgang District Shenzhen, China |
|  | 00559-PR-MD | 03-10-2018 | M/s Iqbal & Company,Alfalah Manzil Opp. National Police Foundation,Street # 26, Sector E-11/4,Islamabad. | Quad Lumen Multi-Cath Catheter Sets | **Manufacturer:** M/s Medical Components Inc., DBA - Medcomp 1499, Delp Drive Harleysville, PA 19438, USA**Contract Manufacturer:**M/s Martech Medical Products Calle Mercurio N 46, Parque Industrial Mexicali 1Mexicali, Baja California 21210, Mexico |
|  | 00560-PR-MD | 03-10-2018 | -do- | Duo-Flow® Catheter Sets | **-do-** |
|  | 00561-PR-MD | 03-10-2018 | -do- | Double Lumen Multi-Cath Catheter Sets | **-do-** |
|  | 00562-PR-MD | 03-10-2018 | -do- | Triple Lumen Multi-Cath Catheter Sets | **-do-** |
|  | 00563-PR-MD | 03-10-2018 | M/s Verizon,60-D, F.C.C. Zahoor Elahi Road, Gulberg IV,Lahore. | Biocor TM Valve Aortic – Sizes 21mm – 29mm (St. Jude Medical ® Tissue Valve) | **Legal Manufacturer:** M/s St. Jude Medical 177, County Road B.E, Saint Paul, MN 55117,USA**Manufacturing Site:**1. M/s St. Jude Medical Costa Rica Ltda., Edificio No. 44, Calle 0, Ave. 2, Zona Franca Coyol, El Coyol, Alajuela 1897-4050 Costa Rica
2. M/s St. Jude Medical Brasil Ltda., Rua Professor Jose Vieria de Meddonca, 1301 Bairro Engenho Nogueira Belo Horizonte, Minas Gerais 31.310-260, Brazil
 |
|  | 00564-PR-MD | 03-10-2018 | -do- | Trifecta TM Valve Aortic – Sizes 19mm – 29mm (St. Jude Medical ® Tissue Valve) | **-do-** |
|  | 00565-PR-MD | 03-10-2018 | -do- | Biocor TM Valve Mitral – Sizes 25mm – 33mm (St. Jude Medical ® Tissue Valve) | **-do-** |
|  | 00566-PR-MD | 03-10-2018 | -do- | Aortic Expanded Hemodynamic Plus – Sizes 17mm – 27mm (St. Jude Medical® Mechanical Heart Valve SJM® Masters Series (Rotatable)) | **Legal Manufacturer:** M/s St. Jude Medical 177, County Road B.E, Saint Paul, MN 55117, USA**Manufacturing Facility:** M/s St. Jude Medical, Puerto Rico, LLC Lot 20-B St. Caguas, PR 00725, USA |
|  | 00567-PR-MD | 03-10-2018 | -do- | SJM® Tailor TM Annuloplasty Ring | **-do-** |
|  | 00568-PR-MD | 03-10-2018 | -do- | SJM Regent TM Mechanical Heart Valve – Sizes 19mm – 27mm (St. Jude Medical® Regent TM Mechanical Heart Valve (Rotatable)) | **-do-** |
|  | 00569-PR-MD | 03-10-2018 | -do- | Mitral Expanded – Sizes 19mm – 33mm (St. Jude Medical® Mechanical Heart Valve SJM® Masters Series (Rotatable)) | **-do-** |
|  | 00570-PR-MD | 03-10-2018 | -do- | St. Jude Medical® SJM® Masters Series Coated Aortic Valved Graft (Rotatable) | **-do-** |
|  | 00571-PR-MD | 03-10-2018 | -do- | Inoue-Balloon (PMTC Catheter) | **Manufacturer:** M/s Toray Industries, Inc., 1-1, Nihonbashi-Muromachi 2-Chome, Chou-ku, Tokyo, 103-8666, Japan**Manufacturing Site:** M/s Toray Industries, Inc. Seta Plant 1-1, Oe 1-Chome, Otsu, Shiga, 520-2141, Japan |
|  | 00572-PR-MD | 04-10-2018 | M/s Digital Imaging Systems, 121-Habitat Apartments, Shadman II, Ghaus-ul-Azam Road, Lahore. | SightRail Manual Dilator Sheath | **Manufacturer:** M/s Spectranetics Corp., 9965 Federal Drive, Colorado Springs, CO 80921,USA |
|  | 00573-PR-MD | 04-10-2018 | -do- | TightRail Rotating Dilator Sheath | -do- |
|  | 00574-PR-MD | 04-10-2018 | -do- | Bridge Occlusion Balloon Catheter | -do- |
|  | 00575-PR-MD | 04-10-2018 | -do- | GlideLight Laser Sheath Kit | -do- |
|  | 00576-PR-MD | 04-10-2018 | -do- | ELCA (Coronary Laser Atherectomy Catheters) | -do- |
|  | 00577-PR-MD | 04-10-2018 | M/s Intek Corporation,Office No. 30, First Floor Al Amin Plaza, The Mall, Rawalpindi. | Thrombuster II | **Marketed By:** M/s Kaneka Corporation, 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, Osaka, 530-8288, Japan.**Manufacturing Site:** M/s Kaneka Medix Corporation Kanagawa Plant 225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun, Kanagawa, 258-0113, Japan |
|  | 00578-PR-MD | 04-10-2018 | -do- | TR Band | **Marketed By:** M/s Terumo Corporation, 44-1, 2-Chome, Hatagaya, Shibuya-ku, Tokoyo, Japan.**Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture, Japan |
|  | 00579-PR-MD | 04-10-2018 | -do- | Azur Peripheral Embolization Coil System | **Manufacturer/****Manufacturing Site:**1. M/s Microvention, Inc.1311 Valencia Avenue Tustin, CA 92780 USA
2. M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol Alajuela Costa Rica.
 |
|  | 00580-PR-MD | 04-10-2018 | -do- | Angioway Manifold | **Legal Manufacturer:** M/s Lepu Medical (Europe) Cooeratief UA Abe Lenstra boulevard 36 8448JB Heerenveen, The Netherlands.**Manufacturer:** M/s Lepu Medical Technology (Beijing) Co., Ltd No.37 Chaoqian Rd., Changping District Beijing 102200 China |
|  | 00581-PR-MD | 04-10-2018 | -do- | Rayband TM Radial Artery Compression Tourniquets | -do- |
|  | 00582-PR-MD | 04-10-2018 | -do- | Angioway High Pressure Extension Tubings | **Legal Manufacturer:** M/s Lepu Medical (Europe) Cooeratief UA Abe Lenstra boulevard 36 8448JB Heerenveen, The Netherlands.**Manufacturer:** M/s Lepu Medical Technology (Beijing) Co., Ltd No.37 Chaoqian Rd., Changping District Beijing 102200 China |
|  | 00583-PR-MD | 04-10-2018 | -do- | Shoocin TM Introducer Kit | **-**do- |
|  | 00584-PR-MD | 04-10-2018 | -do- | Brilliant TM Introducer Kit | do- |
|  | 00585-PR-MD | 04-10-2018 | -do- | Inflation Device Kits (Y-Hemostasis Valve Sets and Inflation Devices) | do- |
|  | 00586-PR-MD | 04-10-2018 | -do- | Contrast Medium Injection Manifolds Kits | do- |
|  | 00587-PR-MD | 04-10-2018 | -do- | OrienTM Guiding Catheter | **Legal Manufacturer:** M/s Lepu Medical (Europe) Cooeratief UA Abe Lenstra boulevard 36 8448JB Heerenveen, The Netherlands.**Manufacturer:** M/s Lepu Medical Technology (Beijing) Co., Ltd No.37 Chaoqian Rd., Changping District Beijing 102200 China |
|  | 00588-PR-MD | 04-10-2018 | -do- | Occlutech® PDA Occluder | **Manufacturer:** M/s Occlutech GmbH Wildenbruchstrasse 15 07745 Jena Germany.**Manufacturing Site:** M/s Occlutech Tibbi Urunler San. Ve Tic Ltd. Sti AHL Serbest Bolgesi, E-5 Blok 34149 Barkirkoy/Istanbul, Turkey |
|  | 00589-PR-MD | 04-10-2018 | -do- | Occlutech® Muscular VSD Occluder | -do- |
|  | 00590-PR-MD | 04-10-2018 | -do- | Occlutech® Delivery Set | **Manufacturer/****Manufacturing Site:** M/s Occlutech GmbH Wildenbruchstrasse 15 07745 Jena Germany |
|  | 00591-PR-MD | 04-10-2018 | -do- | Figulla® Flex II ASD | -do- |
|  | 00592-PR-MD | 04-10-2018 | -do- | Angio-Seal VIP | **Legal Manufacturer:** M/s Terumo Medical Corp. 2101 Cottontail LN. Somerset, NJ 08873 USA.**Manufacturer(s):**1. M/s Terumo Puerto Rico LLC Innovacion Street Lot 21 Caguas West Industrial Park Caguas, PR 00725 USA2. M/s St. Jude Medical 14901 Deveau PL. Minnetonka, MN 55345 USA |
|  | 00593-PR-MD | 04-10-2018 | -do- | Ultimaster Tansei Sirolimus Eluting Coronary Stent System | **Manufacturer:** M/s Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium. |
|  | 00594-PR-MD | 04-10-2018 | -do- | PBMV Balloon Catheters Sets | **Manufacturer:** M/s Shenzhen Shineyard Medical Device co., Ltd., 3 F, Changfeng Industrial Block no.3, Liuxian Road, Xin'an Bao'an District, Shenzhen, Guangdong, China. |
|  | 00595-PR-MD | 04-10-2018 | -do- | MemopartTM ASD Occluder | **Legal Manufacturer:** M/s Lepu Medical (Europe) Cooperatief UA Abe Lenstra Boulevard 36, 8448 JB Heerenveen, The Netherlands.**Manufacturer:** M/s Shanghai Shape Memory Alloy Co., Ltd., 1F and 5F, Tower 41, No.258Xinzhuan Rd., Songjiang High-Tech Park, CaoHejing Shanghai 201612, China |
|  | 0096-PR-MD | 04-10-2018 | -do- | MemopartTM PDA Occluder | -do- |
|  | 00597-PR-MD | 04-10-2018 | -do- | MemopartTM Occluder Delivery System | -do- |
|  | 00598-PR-MD | 04-10-2018 | -do- | MemopartTM VSD Occluder | -do- |

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