**Government of Pakistan**

**Drug Regulatory Authority of Pakistan**

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

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**MINUTES OF THE 6TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**HELD ON 20TH JULY, 2017**

6th meeting of the Medical Device Board (MDB) was held in the Committee Room of Drug Regulatory Authority of Pakistan, TF Complex, G-9/4, Islamabad on 20th July, 2017. The meeting was chaired by Dr. Sheikh Akhter Hussain, Director Medical Devices & Medicated Cosmetics, Drug Regulatory Authority of Pakistan. The meeting was attended by the following:-

|  |  |  |
| --- | --- | --- |
| **S.No.** | **Name and Designation / Department** | **Position in the MDB** |
|  | Dr. Sheikh Akhter Hussain,  Director Medical Devices & Medicated Cosmetics, DRAP, Islamabad. | Chairman |
|  | Dr. Mohammad Shoaib Akhtar,  Director Drug Testing Laboratory,  Rawalpindi.  (Nominee of Director General Health, Punjab) | Ex-officio Member |
|  | Mr. M. Jalil Anwar,  Officer Incharge Government Medicine Coordinator Cell, Health Department, Khyber Pakhtunkhwa,  Peshawar.  (Nominee of Director General Health, Khyber Pakhtunkhwa) | Ex-officio Member |
|  | Syed Abdul Saleem,  Chief Drug Inspector,  Health Department, Balochistan  (Nominee of Director General Health, Balochistan) | Ex-officio Member |
|  | Brig. (R) Dilshad Ahmed Khan,  Professor of Pathology & Director Research, National University of Medical Sciences, Rawalpindi. | Member |
|  | Prof. Dr. Umar Hayat, Professor and Head of Interventional Cardiology, Ayub Medical College, Abbottabad. | Member |
|  | Prof. Dr. Muhammad Nadeem Ahmad,  Department of Radiology, Aga Khan University Hospital, Karachi. | Member |
|  | Miss. Tazeen S. Bukhari,  TRF Technical Consultant for Medical Devices, Technical Resource Facility, 16-BB, Defence Housing Authority, Phase-IV, Lahore. | Member |
|  | Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad. | Member |
|  | Mr. Muhammad Tahir Aziz  Chief Operating Officer,  Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar. | Member |
|  | Dr. Farhat Ullah, Assistant Professor, Department of Pharmacy, University of Malakand. | Member |
|  | Dr. Ghazanfar Ali Khan,  Deputy Director (MDMC),  Drug Regulatory Authority of Pakistan,  Islamabad. | Member/Secretary |

The meeting started with recitation of the Holy Quran by the Chairman MDB.

**Item No. I.** **CONFIRMATION OF MINUTES OF 5TH MEETING OF THE MEDICAL DEVICE BOARD (MDB)**

**Decision:** The Board confirmed the minutes of the 5th meeting of MDB.

**Item No. II**. **UPDATE REGARDING THE PROVISIONAL ESTABLISHMENT CERTIFICATE (PEC) AND PRODUCT REGISTRATION ACKNOWLEDGEMENTS (PRA) ISSUED.**

The Board was briefed regarding the Provisional Establishment Certificate (PEC) and Product Registration Acknowledgements issued as follow:

On the directions of the Honorable Supreme Court of Pakistan on March 2, 2017 during Human Rights Case No. 623-P/2017, Prime Minister’s office convened two extensive meetings chaired by Secretary to the Prime Minister held on 6th March and 10th March, 2017 involving all the relevant stakeholders and as an outcome of these meetings, SRO. 167(I)/2017 was issued by the Federal Government dated 15-03-2017 for regulation of medical devices including cardiac stents. The salient features of the said SRO are as under:-

* The said SRO has a Schedule “A” of 134 life saving medical devices including cardiac stents, legalizing the import, sale and usage of these medical devices, if these were already approved for use and sale by regulatory authorities of USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherland, Norway, Spain, Sweden, Switzerland, UK or CE Mark by notified bodies of European Union.
* The said Notification empowered CEO, DRAP to amend the Schedule “A” from time to time.
* Schedule “A” devices cannot be imported, sold or used in Pakistan except from above sources.
* In addition, a firm has to submit provisional registration application along with original Free Sale Certificate.
* The previous SROs declaring medical devices as drugs are repealed.
* Medical Devices Board shall issue Provisional Establishment Certificate for a period of 06 months, within 07 working days, on submission of original valid authorized agency agreement.
* The rest of the medical devices, not included in the Schedule “A”, have been exempted from the operation of Medical Devices Rules, 2015 for six months.
* All medical devices registered as drug and qualifying above said criteria shall be deemed to be registered as medical device under the Medical Devices Rules, 2015.

Medical Device Board in its 4th meeting convened on 24th March, 2017 approved application forms for grant of Provisional Establishment Certificate, application form for Provisional Registration of medical devices for import and Provisional Establishment Certificate. So far, **68** Provisional Establishment Certificates under this SRO have been issued to the applicant firms and **206** acknowledgements for Provisional Registration of medical devices have also been issued.

**Decision:** The Board appreciated the efforts made so far by the Division of Medical Devices & Medicated Cosmetics.

**Item No.III. REVISION OF MEDICAL DEVICES RULES, 2015.**

As an outcome of Prime Minister’s office meeting, a Committee including stakeholders under the Chair of Additional Secretary, M/o National Health Services, Regulation and Coordination has been constituted on 21st March, 2017 to review the existing Medical Devices Rules, 2015 in order to make them implementable.

In this regard 4 meetings of the committee were held and after thorough deliberations the committee proposed and drafted amendments in Medical Devices Rules, 2015 namely Medical Devices Rules, 2017 which were also placed before the MDB, in its 5th meeting. Each amendment was discussed in length and the Board agreed with amendments with few valuable suggestions which were taken care in the draft rules. They were approved by the Authority in its 48th meeting held on 21st June, 2017. The rules are under process for approval by the Federal Government.

In this regard, Secretary MDB gave a detailed presentation on Steps taken in drafting Medical Devices Rules, 2017 and salient features of the draft rules with special focus on amendments done in existing rules.

**Decision:** The Board after thorough discussion endorsed the amendments proposed in Medical Devices Rules, 2017.

**Item No. IV.** **IT BASED NATIONAL REGISTRY FOR CARDIAC STENTS**

Under SRO. 167(I)/2017, DRAP has launched and activated the first IT based National Registry for cardiac stents which shall provide a mechanism for manufacturers / importers and Cath Laboratories to compulsory enter the data of manufacturing / importation and utilization of cardiac stents in National Registry. Under the aforesaid SRO, all Cath Labs are required to be registered with the Pakistan Society of Interventional Cardiology (PSIC). Information of **21** importers of cardiac stents has been entered and verified by DRAP in the National Registry while Cath Labs shall enter utilization data of cardiac stents after registration with PSIC.

Three meetings of DRAP have been held so far on 10th April, 2017, 1st June, 2017 and 6th July, 2017 with the representative of PSIC and stakeholders to update on the actions taken so far by the PSIC regarding framing of rules, regulations and code of conduct for registration of Cath Labs and to discuss the way forward. The salient features of the meetings are as follow:-

* A comprehensive document for Cath Labs has been prepared based on international standards including requirements for Cath Labs, its equipments, personnel, pre-, inter-and post-procedures.
* Three months time will be required for Cath Laboratories to be registered with the PSIC.
* Capacity building of Cath Labs is required and type of training and experience required by the interventional cardiologist/operators running Cath Labs shall be defined.
* Regarding fixation of prices it was suggested that matter should be handled with care so that the multinational companies should not quit from the market and shortages of stents should not arise.
* Disciplinary Committee of PSIC shall make interventional cardiologist/Cath Labs accountable if found violating the code of conduct.
* Misunderstandings in the minds of young doctors regarding registration of Cath Labs has been removed.
* The heads of an institutes shall provide the list of their Cath Labs along with names of operators, their skills, training, number of procedures carried out and no. of years of relevant experience in Cath labs to the PSIC, which then be enlisted along with their operators on the recommendations of the heads of an institutes making both the head and the operator(s) responsible. The said list shall be provided to the DRAP at the earliest.
* Disciplinary Committee to hold Cath Labs and operators accountable shall be provided to the DRAP at the earliest.

**Decision:** The Board discussed the matter in detail. Dr. Umer Hayat appreciated DRAP for successfully launching the first IT based National Registry for cardiac stents which shall provide a mechanism for manufacturers / importers and Cath Laboratories to compulsory enter the data of manufacturing / importation and utilization of cardiac stents in National Registry. However, he expressed his concerns regarding registration of Cath Labs with the Pakistan Society of Interventional Cardiology. He said that Pakistan Society of Interventional Cardiology (PSIC) has no legal standings for registering Cath Labs and Pakistan Society of Interventional Cardiology would not be able to successfully complete the task without any Law/Act. He recommended that the registration of Cath labs should be with the regulatory body like Provincial Health Care Commissions.

Chairman MDB replied that during hearing in the Honorable Supreme Court of Pakistan in Human Rights Case No. 623-P/2017 (In the matter of embedding sub-standard cardiac stents), PSIC in the presence of stakeholders took this responsibility of registering Cath Labs. On the directions of the Honorable Supreme Court of Pakistan on March 2, 2017, Prime Minister’s office convened two extensive meetings chaired by Secretary to the Prime Minister held on 6th March and 10th March, 2017 involving all the relevant stakeholders including PSIC, Pakistan Cardiac Society and their Lawyer. During the aforesaid meetings, PSIC and their Lawyer again emphasized that Cath Labs should be registered with PSIC. As an outcome of these meetings, SRO. 167(I)/2017 was issued by the Federal Government dated 15-03-2017 for regulation of medical devices including cardiac stents wherein all Cath Labs are required to be registered with the PSIC.

After thorough discussion, the Board appreciated the efforts so far made by DRAP regarding first IT based National Registry for cardiac stents.

**Item No. V.** **MEDICAL DEVICES ALREADY REGISTERED AS DRUGS**

The erstwhile Ministry of Health, keeping in view the risks posed to the patient and in exercise of the powers conferred by sub clause (vi) of the clause (g) of section 3 of the Drugs Act, 1976, declared some medical devices to be drugs for the purpose of said Act**.** These devices includes disposable syringes, disposable sets for collection or transfusion of blood or giving any infusion, canula, catheter, stent, auto-disable syringes and butterfly needles. Since then many devices have been registered.

The Federal Government issued SRO. 167(I)/2017 on 15-03-2017 for regulation of medical devices. The said SRO has a Schedule “A” of 134 life saving medical devices legalizing the import, sale and usage of these medical devices, if these were already approved for use and sale by regulatory authorities of USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherland, Norway, Spain, Sweden, Switzerland, UK or CE Mark by notified bodies of European Union. Schedule “A” devices cannot be imported, sold or used in Pakistan except from above sources. In addition, a firm has to submit provisional registration application along with original Free Sale Certificate. The previous SROs declaring medical devices as drugs are repealed. Medical Devices Board shall issue Provisional Establishment Certificate for a period of 06 months, within 07 working days, on submission of original valid authorized agency agreement. The rest of the medical devices, not included in the Schedule “A”, have been exempted from the operation of Medical Devices Rules, 2015 for six months. All medical devices registered as drug and qualifying above said criteria shall be deemed to be registered as medical device under the Medical Devices Rules, 2015.

Matter was discussed in length and the board members were of the view that the list should be categorized in two categories as per SRO 167(I)/2017 and those medical devices which do not fall under Schedule A but were previously registered as drugs should be listed out and should be reviewed as per the Medical Devices Rules, 2017 upon their promulgation.

**Decision:** MDB thoroughly discussed the matter and recommended as follow:

1. Those medical devices which fall under Schedule "A" of SRO 167(I)/2017 but were previously registered as drugs shall be dealt as per the said SRO.
2. Those medical devices which do not fall under Schedule "A" but were previously registered as drugs shall be listed out and shall be reviewed as per the Medical Devices Rules. However, in the meantime validity of registration of these devices shall be confirmed.

**Item No. VI.** **MEDICAL DEVICES PROVIDED IN SCHEDULE-A AND ALREADY REGISTERED AS DRUGS**

MDB in its 5th meeting decided as follows:-

*"For those Schedule "A" medical devices already registered as drug, having valid registration, originating from reference countries mentioned in the SRO.167(I)/2017 and having Provisional Establishment Certificate shall be treated as registered medical device under the Medical Devices Rules, 2015. A list in this regard shall be issued by the MDMC Division."*

In this regard, as decided by the MDB, a draft list of medical devices already registered as drug, having valid registration, originating from reference countries mentioned in SRO. 167(I)/2017 and having Provisional Establishment Certificate has been prepared and placed at **Annex-I.**

**Decision:** The Board thoroughly reviewed and discussed Medical Devices mentioned in Annex-I. As these Medical Devices are fulfilling the criteria prescribed in the SRO, therefore, the Board approved these devices as registered medical devices under Medical Devices Rules, 2015 and accordingly a list of these medical devices shall be issued by the MDMC Division. New registration numbers shall be allotted to these registered devices.

**Item No. VII. FEE FOR INCLUSION OF ADDITIONAL MANUFACTURERS IN**

**PROVISIONAL ESTABLISHMENT CERTIFICATE** .

It is submitted the Medical Device Board is issuing provisional establishment certificates. The importers are applying for additional manufacturers for provisional establishment certificates without any fee. Rule 138 (8) of Medical Devices Rules, 2015 states that fee for any other activity having commercial significance shall be treated as miscellaneous and will be charged Rs.5000/-. It is proposed that we may charge Rs.5000/- (per application) for inclusion of additional manufacturers in Form-3.

**Decision:** The Board discussed the matter in length and decided that fee of Rs.5000/- shall be charged for each further application regarding inclusion of additional manufacturers in Form-3 (Provisional Establishment Certificate).

**Item No.VIII. FORMAT OF LETTER OF AUTHORIZATION FROM THE MANUFACTURER ABROAD.**

There is no specific format for the letter of Authorization for Agency Agreement. In some cases the product is manufactured in one country, it is owned by some person in another country and authorization is passed on to some other distributor and then the authorized agent in Pakistan.

The case is placed before the MDB for consideration to standardize the Letter of Authorization for Agency Agreement.

**Decision:**  The Board decided as follow:

1. Letter of Authorization or agreement shall only be considered if issued by manufacturer (legal) / owner or Marketing Authorization Holder or its own Distribution Center being authorized to issue authorization for Pakistan or this region.
2. Letter of Authorization or agreement shall be original, signed & stamped, having validity, names and addresses of both manufacturer and importer and having name or category of medical devices.

**Item No. IX. MEDICAL DEVICES WHICH ARE NEITHER DEFINED NOR DECLARED AS DRUG.**

It is submitted that medical devices like Blood bags, Hyaluronic acid injection, Incise Drapes, Surgical dressing, Surgical tapes etc are neither defined nor declared as drug under the Drugs Act, 1976. Moreover, internationally these are regulated as medical devices. However, these devices are being registered as drug under the Drug Act, 1976. DRAP Act, 2012 was promulgated on 13th November, 2012 where drugs and medical devices were separately defined. For this purpose, Medical Devices Rules, 2015 were notified on 9th March, 2015 wherein all medical devices has to be regulated under these rules except those defined as drug. Fate of these subject devices neither defined nor declared as drug has to be decided.

**Decision:** The Board discussed the matter at length. As the medical devices like Blood bags, Hyaluronic acid injection, Incise Drapes, Surgical dressing, Surgical tapes and like devices are being regulated as medical devices internationally and the DRAP Act, 2012 has also separately defined drugs and medical devices, therefore, the Board decided that these devices shall be regulated under the Medical Devices Rules. Division of PE&R shall be asked to transfer their files to Division of MDMC for further processing in compliance to new medical devices rules.

**Item No.X. POST-FACTO APPROVAL FOR ISSUANCE NOC FOR MITRAL VALVE CLIP PROCEDURE ITEMS FOR PERSONAL USE.**

A request was made by Maj.Gen. ® Prof. Dr. Azhar Kayani, ED, RIC, Rawalpindi for the issuance of NOC for Mitral Valve Clip Procedure items for the first ever procedure in patient at Rawalpindi Institute of Cardiology, Rawalpindi. The said items are said to be imported as same are not available in Pakistan and therefore NOC was requested. The said items are to be imported through M/s Digital Imaging System.

Keeping in view the need of the said items, an NOC was issued with the approval of Director MDMC / Chairman MDB as provision for import of medical devices for personal use is given in Rule 100 (c) of Medical Devices Rules, 2015.

**Decision:** The Board approved the case and also authorized Chairman MDB for future approval for issuance of NOC for import of medical devices for personal use under the prescribed rules.

**Item No.XI. SCHEDULE "A" MEDICAL DEVICES ALREADY REGISTERED AS DRUG, AND THE FIRMS NOT APPLIED FOR PROVISIONAL ESTABLISHMENT CERTIFICATE.**

As per SRO.167(I)/2017, dated 15th March, 2017, the previous SROs declaring medical devices as drugs are repealed and all products registered under the provisions of previous SROs, if qualify the prescribed criteria in the said SRO, shall be deemed to be registered as medical devices under the Medical Devices Rules, 2015. For those Schedule "A" medical devices already registered as drug, having valid registration, originating from reference countries mentioned in the SRO.167(I)/2017 and having Provisional Establishment Certificate shall be deemed to be registered as medical devices under the Medical Devices Rules, 2015.However,some of the firms have not applied for PEC having Schedule "A" medical devices. Medical Device Board in its 5th meeting held on 25th May, 2017 decided as under:-

*"For those Schedule "A" medical devices already registered as drug, having valid registration, originating from reference countries mentioned in the SRO.167(I)/2017 but the firms have still not applied for Provisional Establishment Certificate, these firms shall be asked to apply for Provisional Establishment Certificate within 7 days otherwise further necessary action shall be taken by the MDB."*

The following firms have not applied for Provisional Establishment Certificate and they were issued letters on 10-07-2017 with directions to apply for Provisional Establishment Certificate within 7 days otherwise further necessary action shall be taken by the MDB which may lead to cancellation of registration of their product(s).

1. M/s Johnson & Johnson Pakistan (Pvt) Limited, Karachi.
2. M/s Universal Trades, Quetta.
3. M/s. SES Associate, Lahore.
4. M/s. Nabiqasim Industries (Private) Limited, Karachi.
5. M/s. Trans Angio System, Karachi.
6. M/s Radiant Devices Biomedical Pvt. Ltd, Lahore.

The above firms have still not applied for PEC and have been issued letters on 18-07-2017 for personal hearing before the MDB on 20th July, 2017 to explain their position in the subject matter along with details of all of their imported medical devices. The following firms appeared before the Board and the Board decided as mentioned against each:

**Decision:**

1. Miss Ayesha Zaman, Manager Regulatory affairs M/s Johnson & Johnson Pakistan (Pvt) Limited, Karachi appeared before the Board and informed the reason for not applying for Provisional Establishment Certificate (PEC) in writing. She submitted that due to relocation of their office, issuance of drug sale license is awaited and the firm will apply PEC as soon as they secure Drug Sale License. Furthermore she also informed that they are now only dealing with registered products from Codman Portfolio namely Prowler Micro Catheters (Reg No. 074692). Their registered products from Cordis portfolio have been globally transferred from Johnson & Johnson to Cardinal Health. These products will be imported by Cardinal Health's appointed authorized agent M/s Global Marketing Services, 111, Hali Road,Westridge I, Rawalpindi, Pakistan who have already secured Provisional Establishment Certificate for the said products. Therefore Johnson & Johnson will not be importing the following Cordis products namely:
2. Cordis catheters (Diagnostic Catheter and Guiding Catheter) (Reg No. 071628)

* Infiniti
* Super Torque
* Super Torque Plus
* Tempo
* High Flow
* Nylex
* Vista Brite

1. Empira RX PTCA Dilatation Catheter (Reg No. 074705)
2. Empira NC RX PTCA Dilatation Catheter (Reg No. 074706)
3. Palmaz Genesis Stent (Reg No. 071629)
4. SES Precise RX stent (Reg No. 071630)
5. S.M.A.R.T. Control Nitinol Stent System (Reg No. 074662)

**(i)** The Board cancelled the registrations of above mentioned Cordis products already registered in the name of M/s Johnson & Johnson Pakistan (Pvt) Limited, Karachi due to reasons as submitted above by M/s Johnson & Johnson Pakistan (Pvt) Limited.

**(ii)** For Codman Portfolio product namely Prowler Micro Catheters (Reg No. 074692), the Board again directed the firm to apply for Provisional Establishment Certificate within 15 days otherwise further necessary action shall be taken by the MDB which may lead to cancellation of registration of their product.

1. Mr. Mubashir Iqbal representing M/s SES Associates, Lahore appeared before the Board and submitted written reply that Mr. Shahid Ikram,(Chief Executive) of the firm is out of country and he will come back next week and shall appear in person in DRAP in next week on Tuesday.

The Board directed Mr. Mubashir Iqbal to inform Mr. Shahid Ikram to personally appear in DRAP on upcoming Tuesday to clarify his position regarding the subject matter for not applying for Provisional Establishment Certificate despite the written directions of the MDB. The Board further directed the firm to apply for Provisional Establishment Certificate within 15 days otherwise further necessary action shall be taken by the MDB which may lead to cancellation of registration of their product(s).

1. Mr. Munawar, Liason Manager of M/s Nabiqasim Industries (Private) Limited, Karachi appeared before the Board and submitted written reply of the firm that on receipt of original agency agreement from principal abroad, they will apply for Provisional Establishment Certificate within 15 days.

The Board directed the firm to apply for Provisional Establishment Certificate within 15 days otherwise further necessary action shall be taken by the MDB which may lead to cancellation of registration of their product(s).

1. Mr. Asghar Khattak, Regional Sales Coordinator (North) of M/s Trans Angio Systems, Karachi appeared before the Board and submitted written reply of the firm wherein the firm requested the Board to allow them to submit their application of Provisional Establishment Certificate by 30th August, 2017 due to the reason that documents are pending at their end of their principal in Germany.

The Board directed the firm to apply for Provisional Establishment Certificate within 15 days otherwise further necessary action shall be taken by the MDB which may lead to cancellation of registration of their product(s). The representative agreed and submitted written statement in writing.

1. M/s Radiant Devices Biomedical Pvt. Limited, Lahore did not appear before the Board, however, Mr. Rashid Ahmed, Director, Radiant Devices Biomedical Pvt. Limited sent a letter wherein he has informed that they have discontinued their services and do not wish to apply for Provisional Establishment Certificate.

The Board cancelled the registrations of the products namely PTA Self Expandable Stent System “Resistant” (Reg No. 074671) and PTCA Coronary Drug Eluting Stent System “euca TAX” (Reg No. 074672) already registered in the name of M/s Radiant Devices Biomedical Private Limited, Lahore due to the reason that the firm has informed in writing that they have discontinued their services and do not wish to apply for Provisional Establishment Certificate.

1. M/s Universal Trades, Quetta did not appear before the Board, however, Mr. Javed, Managing Director, Universal Trades, Quetta informed telephonically that he is unable to come due to his personal issues.

The Board again directed the firm to apply for Provisional Establishment Certificate within 15 days otherwise further necessary action shall be taken by the MDB which may lead to cancellation of registration of its product(s).

Meeting ended with vote of thanks to and from the Chair.

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**ANNEX-I**

**LIST OF MEDICAL DEVICES DEEMED TO BE REGISTERED**

**UNDER MEDICAL DEVICES RULES, 2015 UNDER SRO. 167(I)/2017**

**(AS PER INITIAL REGISTRATION LETTER)**

**CATHETERS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No** | **Name of Firm/ Importer.** | **Name of Manufacturer** | **Reg.No.** | **Name of Medical Device** | **Date of**  **Registration** |
|  | M/s Iqbal & Company,  Islamabad. | M/s. Arrow International, Inc (subsidiary of Teleflex, Incorporated) 2400 Bernville Road, Reading PA 19605, USA) | 074635 | Arrow Central Venous Catheterization Set. | 21-2-2013 |
|  | -do- | -do- | 074636 | Arrow Intra Aortic Balloon Catheters. | 21-2-2013 |
|  | -do- | -do- | 074637 | Arrow Two Lumen Haemodialysis Catheterization Set. | 21-2-2013 |
|  | -do- | -do- | 074638 | Arrow Balloon Wedge Pressure Catheters | 21-2-2013 |
|  | -do- | -do- | 074639 | Arrow Arterial Catheterization Set. | 21-2-2013 |
|  | -do- | -do- | 074640 | Arrow Berman Angiographic Balloon Catheters. | 21-2-2013 |
|  | -do- | -do- | 074641 | Arrow Multi Lumen Access Catheters. | 21-2-2013 |
|  | M/s Digital Imaging Systems, Lahore. | Responsible Manufacturer: M/s. Abbott Vascular Lakeside Drive, California, USA.  Manufacturing Site: M/s. Abbott Vascular Cashel Road, Clonmel, County Tipperary, Ireland). | 074648 | Trek RX Coronary Dilatation Catheter | 12-4-2013 |
|  | -do- | -do- | 074649 | Mini Trek RX Coronary Dilatation Catheter | -do- |
|  | -do- | -do- | 074650 | NC Trek RX Coronary Dilatation Catheter. | -do- |
|  | M/s Intek Corporation, Rawalpindi | M/s. OrbusNeich Medical B.V. Drs, W. Van Royenstraat, AN Hoevelaken, The Netherlands. | 074673 | Scoreflex Coronary Dilatation Catheter. | 1-1-2014 |
|  | -do- | -do- | 074674 | Sapphire NC Coronary Dilatation Catheter | 1-1-2014 |
|  | -do- | -do- | 074675 | “Sapphire II (Rx)” Coronary Dilatation Catheter | 1-1-2014 |
|  | -do- | -do- | 074677 | Sapphire Coronary Dilatation Catheter | 1-1-2014 |
|  | M/s Cor-Med, Rawalpindi. | M/s. IHT, Iberhospitex S.A, Barcelona, Spain) | 074689 | Fairway Rapid Exchange Dilatation Catheter for PTCA | 25-4-2014 |
|  | M/s. B.Braun Pakistan (Pvt) Ltd., Karachi. | Legal Manufacturer: M/s. PendraCare International B.V., Van der Waalspark- 22, VC Leek, Netherland.  Marketing Authorization Holder & Central Distributors: M/s. B.Braun Melsungen AG, Vascular System, Sieversufer 8, D-12359, Berlin, Germany). | 080168 | Angiodyn” Angiographic Catheter. | 10-02-2016 |
|  | -do- | Legal Manufacturer: M/s. B.Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany.  Manufacturing Site: B. Braun Melsungen AG, Vascular Systems, Sieversufer 8, 12359 Berlin, Germany. | 080169 | SeQuent Neo Rapid Exchange Coronary (PTCA) Balloon Catheter. | 10-02-2016 |
|  | M/s Healthtec, Rawalpindi. | (Manufacturer: Blue Medical Device B.V, Steenovemweg 19, 5708 NH Helmond, The Netherlands.  Production plant: Panovenweg 7, 5708 HR Helmond, The Netherlands). | 080409 | Force NC Balloon Dilatation Catheter | 08-03-2016 |
|  | -do- | -do- | 080410 | Everest SC Balloon Dilatation Catheter | 08-03-2016 |
|  | -do- | -do- | 080411 | Summit CTO Balloon Dilation Catheter | 08-03-2016 |
|  | M/s Healthtec, Rawalpindi. | **Manufacturer:** Blue Medical Device B.V, Steenovemweg 19, 5708 NH Helmond, The Netherlands  **Production plant:** Panovenweg 7, 5708 HR Helmond, The Netherlands). | 082017 | Protégé DEB Dilatation Catheter  (Paclitaxel Eluting Balloon Dilatation Catheter) | 30-9-2016 |
|  | M/s Intek,  Rawalpindi. | **Legal Manufacturer:** M/s Terumo Corporation-1,2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan.  **Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya city, Shizuoka Prefecture, Japan. | 083119 | Progreat  (Micro Catheter System) | 09-02-2017 |
|  | -do- | **-do-** | 083120 | Heartrail II PTCA Guiding Catheter. | 09-02-2017 |
|  | -do- | **Manufactured by:** M/s OrbusNeich Medical B.V. Drs. W.Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands. | 083121 | Sapphire II NC Coronary Dilatation Catheter | 09-02-2017 |
|  | -do- | **-do-** | 083122 | Sapphire II PRO Coronary Dilatation Catheter | 09-02-2017 |
|  | M/s Healthtec,  Rawalpindi. | **Manufacturer:** M/s PendraCAre International B.V. Vander Waals Park 22, 9351 VC Leek, The Netherlands. | 083123 | Primum Hydrophilic Guiding Catheter | 07-03-2017 |
|  | M/s Intek,  Rawalpindi. | **Legal Manufacturer:**M/s Terumo Corporation, 44-1,2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan.  **Manufacturing Site:** M/s Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya city, Shizuoka Prefecture, Japan. | 083127 | Radifocus Optitorque  (Angiographic Catheter)   |  |  | | --- | --- | |  |  | |  |  | |  |  | | 06-3-2017 |
|  | -do- | -do- | 083128 | Ryujin Plus PTCA Dilatation Catheter | 06-3-2017 |
|  | M/s ACP System.  Karachi. | **Legal Manufacturer:** M/s Medtronic, Inc, 710 Medtronic Parkway N.E., Minneapolis, 55432,US.  **Manufacturing Facility:** M/s Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah, 10510 El  Lago, C.P.22210 Tijuana, Baja California, Mexico. | 083130 | Euphora Rapid Exchange Balloon Dilatation Catheter | 07-03-2017 |
|  | M/s Intek,  Rawalpindi. | Manufactured By:  M/s Lepu Medical Technology (Beijing) Co., Ltd., no 37 Chaoqian Rd, Changping district, Beijing, China.  (Free sale certificate from regulatory authority of Netherlands also provided) | 083134 | Hoper PTCA Balloon Dilatation Catheter | 06-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera.** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. | 083135 | Emerge Over-The-Wire PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | -do- | 083136 | Emerge MONORAIL TM PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | -do- | 083137 | NC Quantum Apex TM Monorail TM PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | -do- | 083138 | Maverick 2TM Monorail TM PTCA Dilatation Catheter | 08-03-2017 |
|  | -do- | **Legal Manufacturer**: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlbnorough, Massachusetts 01752, USA.  **Manufacturing Site**: M/s. Boston Scientific Ltd, Ballybrit Business Park, Galway, Ireland. | 083390 | Flextome TM Cutting Balloon TM Monorail TM Microsurgical Dilatation Device | 09-03-2017 |
|  | M/s B.Braun Pakistan (Pvt) Limited,  Karachi. | **Manufacturer:**  B.Braun Melsungen AG Carl-Braun –Stabe 1 34212 Melsungen, Germany.  **Manufacturing Site:** B.Braun Melsungen AG Vascular Systems Sieversufer 8, 12359 Berlin, Germany. | 083393 | Sequent Please Neo Paclitaxel Releasing Rapid Exchange PTCA Balloon Catheter | 10-03-2017 |
|  | M/s Hashir Surgical Services,  Peshawar. | **Manufactured By:** M/s Intra Special Catheter GmbH, Oststrasse 2, 66780 Rehlingen-Siersburg,  Germany | 083396 | Trilucath Central Venous Catheter-3 Lumen | 10-03-2017 |
|  | -do- | -do- | 083397 | Venoseld Central Venus Catheter-I Lumen. | 10-03-2017 |
|  | -do- | -do- | 083398 | Duocath Central Venus Catheter 2-Lumen. | 10-03-2017 |
|  | -do- | -do- | 083399 | Duocath Hemodialysis Catheter 2-Lumen. | 10-03-2017 |
|  | -do- | -do- | 083400 | Quadrocath Central Venus Catheter 4-Lumen | 10-03-2017 |
|  | -do- | -do- | 083401 | Trilucath Hemodialysis Catheter 3-Lumen | 10-03-2017 |
|  | M/s Digital Imaging Systems, Lahore. | **Name of Owner Operator and manufacturing Facility**:  M/s Volcano Corporation 2870 Kilgore rd, Rancho cordova, CA USA 95670 | 083407 | Eagle Eye Platinum & ST-IVUS Catheter. | 10-03-2017 |
|  | M/s ACP System.  Karachi. | **Legal Manufacturer:** M/s Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432, USA.  **Manufacturing Site**: M/s Medtronic Vascular, 37A Cherry Hill Drive, Danvers, MA 01923, USA. | 083410 | Export Advance Aspiration Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **­­­**  **Manufacturing Site:** M/s. Boston Scientific Limited, Business and Technology Park, Model Farm Road CORK, Ireland. | 083413 | CRE Pulmonary Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083414 | Coyote TM Monorail TM PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083415 | Coyote TM ES Monorail TM PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083416 | Coyote TM Over-The-Wite PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083417 | Coyote TM ES Over-The-Wire PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083418 | Sterling TM Monorail TM PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN, USA | 083419 | Mustang TM Over-The-Wire PTA Balloon Dilatation Catheter | 10-03-2017 |
|  | M/s. Promed International,  Rawalpindi. | **Legal Manufacturer:** M/s Biosensors Interventional Technologies Pte Ltd, 36 Jalan Tukang, Singapore 619266, Singapore.  **Manufacturing Site:** M/s Biosensors Interventional Technologies Pte Ltd, 36 Jalan Tukang, Singapore 619266, Singapore.  (Free sale certificate from regulatory authority of Switzerland provided) | 083420 | Powerline TM PTCA Catheter | 14-03-2017 |
|  | M/s Genus, Karachi. | **Manufactured by:** M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida, 34450 USA. | 083421 | Hawk TM-SC- PTCA Balloon Catheter Semi-Compliant | 15-03-2017 |
|  | -do- | **-do-** | 083422 | Falcon Guiding Catheter | 15-03-2017 |
|  | -do- | **-do-** | 083423 | Hawk TM NC- PTCA Balloon Catheter Non-Compliant | 15-03-2017 |
|  | M/s Hakimsons (Pvt) Limited, Karachi. | **Manufactured by:** M/s Life Vascular Devices Biotech, S.L., C.I.F. B-65405169, Cami de Can’Ubach, 11 (pol. IND. Les Fallulles), 08620 SANT VICENC, DELS HORTS, Barcelona, Spain. | 083430 | Ivascular Xperience  Cateter Balon De Dilatacion Coronario  (Coronary Dilatation Balloon Catheter ) | 15-03-2017 |
|  | -do- | **-do-** | 083431 | Ivascular Oceanus 35  Cateter balon de predilatacion periferico para guia de alambre de 0.014 (PTA Balloon Dilatation Catheter ) | 15-03-2017 |
|  | -do- | **-do-** | 083432 | Oceanus 14 Peripheral Balloon Dilatation Catheter | 15-03-2017 |

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|  | M/s Digital Imaging Systems, Lahore. | Responsible Manufacturer: M/s. Abbott Vascular Lakeside Drive, California, USA.  Manufacturing Site: M/s. Abbott Vascular Cashel Road, Clonmel, County Tipperary, Ireland. | 074642 | Xience V Everolimus Eluting Coronary Stent System. | 12-4-2013 |
|  | -do- | -do- | 074643 | Xience Prime Everolimus Eluting Coronary Stent System | -do- |
|  | -do- | -do- | 074644 | Omnilink Elite Peripheral Stent System. | -do- |
|  | -do- | -do- | 074645 | Multi-Link Vision Coronary Stent System | -do- |
|  | -do- | -do- | 074646 | Multi-Link Minivision Coronary Stent System | -do- |
|  | -do- | -do- | 074647 | Multi-Link Zeta Coronary Stent System | -do- |
|  | -do- | Responsible Manufacturer and Manufacturing Site: M/s. Abbott Vascular Lakeside Drive, California, USA | 074651 | RX Acculink Carotid Stent System | -do- |
|  | -do- | -do- | 074652 | RX Herculink Elite Peripheral Stent System. | -do- |
|  | M/s Intek Corporation, Rawalpindi | M/s. OrbusNeich Medical B.V. Drs, W. Van Royenstraat, AN Hoevelaken, The Netherlands. | 074676 | Genous Bioengineered Cobalt Chromium Stent Delivery System. | 1-1-2014 |
|  | -do- | -do- | 074678 | Azule CoCr Alloy Coronary Stent Delivery System | 1-1-2014 |
|  | M/s Cor-Med, Rawalpindi. | M/s. IHT, Iberhospitex S.A, Barcelona, Spain | 074690 | Bionert Inert Coronary Stent (Bare Metal Stent) | 25-4-2014 |
|  | -do- | -do- | 074691 | Active Paclitaxel Eluting Coronary Stent | 25-4-2014 |
|  | M/s Ferozsons Laboratories Limited, Nowshera. | Legal Manufacturer : M/s. Boston Scientific Corporation, USA  Manufacturing Site : M/s Boston Scientific Ireland Ltd, Ireland. | 074716 | Promus ® Element-Plus Monorail TM  (Everolimus-Eluting Coronary Artery Stent) | 8-4-2015 |
|  | M/s Intek Corporation, Rawalpindi. | M/s. OrbusNeich Medical B.V. Drs, W. Van Royenstraat, AN Hoevelaken, The Netherland. | 080003 | Combo Bio-Engineered Sirolimus Eluting Stent.  (Combo Dual Therapy Stent) | 26-1-2016 |
|  | -do- | Legal Manufacturer: M/s Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium.  Manufacturing Site: Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya | 080004 | Nobori Drug Eluting Stent System  (Biolimus A-9 Eluting Stent) | 26-1-2016 |
|  | -do- | Legal Manufacturer: M/s Terumo Europe N.V., Interleuvenlaan 40, 3001 Leuven, Belgium.  Manufacturing Site: Ashitaka Factory of Terumo Corporation, 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418-0015, Japan.  Design Site: Terumo Corporation, R&D Centre, 1500, Inokuchi, Nakai-Machi, Ashigarakami-gun,  Kanagawa, Perfecture, Japan. | 080005 | Ultimaster Sirolimus Eluting Coronary Stent System | 26-1-2016 |
|  | M/s. B.Braun Pakistan (Pvt) Ltd., Karachi. | Legal Manufacturer: M/s. B.Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany.  Manufacturing Site: B. Braun Melsungen AG, Vascular Systems, Sieversufer 8, 12359 Berlin, Germany. | 080170 | Coroflex ISAR  (Sirolimus Eluting Polymer-Free Coronary Stent System) | 10-02-2016 |
|  | M/s Healthtec, Rawalpindi. | Manufacturer: Blue Medical Device B.V, Steenovemweg 19, 5708 NH Helmond, The Netherlands.  Production plant: Panovenweg 7, 5708 HR Helmond, The Netherlands. | 080412 | Track CoCr Coronary Stent System  (Bare Metal) | 08-03-2016 |
|  | M/s Ferozsons Laboratories Limited, Nowshera. | Owner Operator: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA 01752, USA.  Manufacturing Site: M/s Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland | 080719 | Promus Premier TM Monorail TM Everolimus-Eluting Platinum Chromium Coronary Stent System | 10-5-2016 |
|  | M/s. Promed International,  Rawalpindi. | Legal Manufacturer : M/s Biosensor Europe SA,. Rue de Lausanne 29, 1110 Morges, Switzerland.  Manufacturing Site: Biosensor Interventional Technologies Pte Ltd, 36 Jalan Tukang, Singapore 619266.  Sterilization Sites: BGS Beta-Gamma-Service GmbH & Co KG. Fritz-Kotz-Strasse 16, 51674 Wiehi, Germany.  Electron Beam Sdn, Bhd, Lot 7, Jalan Sungai Pinang 4/3, Taman Perindustrian Pulau Indah (Fasa 2), 42920 Port Kalang, Selangor, Malaysia. | 081522 | BioMatrix Flex TM Drug Eluting Coronary Stent System  (Biolimus A9) | 19-8-2016 |
|  | -do- | -do- | 081523 | Biofreedom Drug Coated Coronary Stent System  (Biolimus A9) | 19-8-2016 |
|  | M/s Cardiovascular Medical System, Lahore. | **Owner/Legal Manufacturer:** M/s amg International GmbH Lohnfeld 26, D-21423 Winsen-Luhe, Germany.  **Manufactured by:** M/s QualiMed Innovative Medizinprodukte GmbH, BoschstraBe 16, 21423, Winsen- Luhe, Germany. | 082105 | ITRIX Rapamycin Eluting Coronary Stent Implantation System | 30-9-2016 |
|  | -do- | **-do-** | 082016 | ARTHOS Pico Stent Implantation System | 30-9-2016 |
|  | M/s Healthtec,  Rawalpindi. | **Manufacturer:** Blue Medical Device B.V,Steenovenweg 19, 5708 HN Helmand Netherlands  **Production plan**t: Panoverweg 7 5708 HR Helmond, Netherlands. | 082020 | Pioneer    (Cobalt Chromium Stent mounted on Paclitaxel Eluting Balloon Catheter) | 09-02-2017 |
|  | M/s. Intek Corporation,  Rawalpindi. | **Legal Manufacturer:** M/s Terumo Europe N.V. Interleuvenlaan 40, 3001 Leuven, Belgium.  **Manufacturing Site:** M/s Terumo Corporation Ashitaka Plant, 150, Maimaigi-cho, Fujinomiya city, Shizuoka Prefecture 418-0015, Japan. | 082021 | Kaname Cobalt Chromium Coronary Stent System | 09-02-2017 |
|  | M/s Digital Imaging Systems,  Lahore. | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  **Manufacturing Site:** M/s Abbott Vascular, Cashel Road, Clonmel, County Tipperary, Ireland. | 083124 | Xience Xpedition Everolimus Eluting Coronary Stent System | 06-03-2017 |
|  | M/s Digital Imaging Systems,  Lahore. | **Responsible Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  **Manufacturing Site:** M/s Abbott Vascular, 26531 Ynez Road, Temecula, CA 92591, USA. | 083125 | Absorb GT1 Bioresorbable Vascular Scaffold System | 06-03-2017 |
|  | M/s B.Braun Pakistan (Pvt) Limited,  Karachi/ | **Responsible Manufacturer:** M/s B.Braun Melsungen AG, Caril-Braun-StraBe 1, 34212 Melsungen, Germany.  **Manufacturing Site:** M/s B.Braun Melsungen AG Vascular System Sieversufer 8, 12359 Berlin Germany. | 083129 | Coroflex Blue Neo Coronary Stent System | 07-03-2017 |
|  | M/s ACP System.  Karachi. | **Legal Manufacturer:** M/s Medtronic, Inc, 710 Medtronic Parkway, Minneapolis, Minnesota  55432, USA.  **Manufacturing Site:** M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. | 083131 | Resolute Onyx Zotarolimus-Eluting Coronary Stent System | 07-03-2017 |
|  | M/s Promed International,  Rawalpindi. | **Legal Manufacturer:** M/s Biosensors Europe SA, Rue De Lausanne 29, 1110 Morges,  Switzerland.  **Manufacturing Site:** M/s Biosensors Interventional Technologies Pte Ltd, 36 Jalan Tukang, Singapore 619266, Singapore. | 083132 | BioMatrix Neoflex TM Drug Eluting Coronary Stent System. | 07-03-2017 |
|  | M/s Intek Corp. Rawalpindi. | Manufactured By:  M/s Lepu Medical Technology (Beijing) Co., Ltd., no 37 Chaoqian Rd, Changping district, Beijing, China.  (Free sale certificate from regulatory authority of Netherlands also provided) | 083133 | Partner Sirolimus-Eluting Coronary Stent System | 06-03-2017 |
|  | M/s Ferozsons Laboratories Limited, Nowshera. | **Legal Manufacturer**: M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlbnorough,  Massachusetts 01752, USA.  **Manufacturing Site**: M/s. Boston Scientific Ltd, Ballybrit Business Park, Galway, Ireland. | 083389 | Synergy TM Monorail TM Everolius Eluting Platinum Chromium Coronary Stent System | 09-03-2017 |
|  | M/s B.Braun Pakistan (Pvt) Limited,  Karachi. | **Manufacturer:** B.Braun Melsungen AG Carl-Braun –Stabe 1 34212 Melsungen, Germany.  **Manufacturing Site:** B.Braun Melsungen AG Vascular Systems Sieversufer 8, 12359 Berlin, Germany. | 083394 | Coroflex ISAR NEO  Sirolimus-eluting Coronary Stent System | 10-03-2017 |
|  | M/s Promed International,  Rawalpindi. | **Legal Manufacturer:** M/s Biosnsor Europe SA, Rue De Lausanne 29, 1110 Morges, Switzerland.  **Manufacturing Site:** M/s Biosensors Interventional Technologies Pte Ltd, 36 Jalan Tukang, Singapore 619266, Singapore. | 083402 | BioMatrix Alpha TM Drug Eluting Coronary Stent System  (Biolimus A9) | 10-03-2017 |
|  | M/s Digital Imaging Systems, Lahore. | **Legal Manufacturer:** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  **Manufacturing Site:** M/s Abbott Vascular, Cashel Road, Clonmel, County Tipperary, Ireland. | 083404 | Xience Alpine Everolimus Eluting Coronary Stent System | 10-03-2017 |
|  | -do- | **-do-** | 083405 | Graft Master RX Coronary Stent Graft System | 10-03-2017 |
|  | M/s Digital Imaging Systems,  Lahore. | **Manufactured By:** M/s Abbott Vascular, Cashel Road, Clonmel, County Tipperary, Ireland.  **Legal Manufacturer :** M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA. | 083406 | Multi link 8 Coronary Stent System  (Cobalt Chromium) | 10-03-2017 |
|  | M/s ACP System.  13 &23,Naval Fleet Club, Iqbal (S.J) Shaheed Road,  Karachi. | Legal Manufacturer: M/s Medtronic, Inc.710 Medtronic Parkway NE Minneapolis, MN 55432, USA.  Manufacturing Site: M/s Medtronic Ireland, Parkmore Business Park West Galway, Ireland. | 083411 | Driver Sprint Rapid Exchange Coronary Stent System | 10-03-2017 |
|  | M/s Ferozsons Laboratories Limited,  P.O.Ferozsons, Amangarh,  **Nowshera** | **Legal Manufacturer:** M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.  **Manufacturing Site:** M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. | 083412 | RebelTM MonorailTM PtCr Coronary Stent System | 10-03-2017 |
|  | F.W Distributors, Rawalpindi. | M/s Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark. | 083425 | Biosoft Duo Mujolti Length Hydro-Coated Urethral Stent Kit (long term) | 15-03-2017 |
|  | -do- | -do- | 083426 | Double Loop Urethral Stent in PA OR PU (Short Term) | 15-03-2017 |
|  | Hakimsons (Pvt) Limited, Karachi | **Manufactured by:** M/s Life Vascular Devices Biotech, S.L., C.I.F. B-65405169, Cami de Ca n’Ubach, 11 (pol. IND. Les Fallulles), 08620 SANT VICENC, DELS HORTS, Barcelona, Spain. | 083429 | IVASCULAR ARCHITECT  Sistema de Stent Coronario CoCr (CoCr Coronary Stent System) | 15-03-2017 |
|  | M/s Genus, Karachi. | **Manufactured by:** M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA. | 083408 | Silver Stent-CC Cobalt Chromium Drug Eluting Stent | 15-03-2017 |
|  | -do- | **-do-** | 083409 | Affinity CC Cobalt Chromium Sirolimus Eluting Stent. | 15-03-2017 |

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