

**Government of Pakistan**  
**Drug Regulatory Authority of Pakistan**  
**Ministry of National Health Services, Regulations & Coordination**  
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**MINUTES OF THE 3<sup>RD</sup> MEETING OF THE MEDICAL DEVICE BOARD (MDB)**  
**HELD ON 10<sup>TH</sup> NOVEMBER, 2016**

3<sup>rd</sup> meeting of the Medical Device Board (MDB) was held in the committee room of TF Complex, G-9/4, Islamabad on 10<sup>th</sup> November, 2016. 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 :-

<b>S.No.</b>	<b>Name and Designation / Department</b>	<b>Position in the MDB</b>
(1)	Dr. Sheikh Akhter Hussain, Director Medical Devices & Medicated Cosmetics, DRAP, Islamabad.	Chairman
(2)	Mrs. Tehreem Sara, Additional Director (MD&MC), DRAP, Islamabad.	Ex officio Member/ Secretary MDB
(3)	Dr. Muhammad Saleem But, Director Drug Testing Laboratory Punjab, Rawalpindi.  (Nominee of Director General Health, Punjab)	Ex-Officio Member
(4)	Dr. M.Saleem Memon, Additional Director (PH), Directorate General Health Services, Sindh, Hyderabad.  (Nominee of Director General Health, Sindh)	Ex-officio Member
(5)	Dr. Muhammad Saleem, Deputy Director (Admn), Health Department, Khyber Pakhtunkhwa  (Nominee of Director General Health, Khyber Pakhtunkhwa)	Ex-officio Member
(6)	Brig. (R) Dilshad Ahmed Khan, Professor of Pathology & Director Research, National University of Medical Sciences, Rawalpindi.	Member

(7)	Prof. Dr. Umar Hayat, Professor and Head of Interventional Cardiology, Ayub Medical College, Abbottabad.	Member
(8)	Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi.	Member
(9)	Mr. Luqman Ali, System Analyst, Pakistan Institute of Medical Sciences, Islamabad.	Member
(10)	Mr. Muhammad Tahir Aziz Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar	Member
(11)	Dr. Farhat Ullah Assistant Professor, Department of Pharmacy, University of Malakand	Member

The meeting started with recitation of the Holy Quran. Prof. A.K.Tanwani, Chairman of Pathology Department, PIMS & Dean Faculty of Basic Medical Sciences, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad also attended the meeting on request of Director MDMC/Chairman MDB.

Mr. Asif Jalil, Assistant Director-I (MDMC), Mr. Muhammad Ayub Naveed, Assistant Director-II (MDMC), Hafiz Muhammad Jawad Ali, Assistant Director-III (MDMC), Mrs. Unum Zia Shamsi, Assistant Director-IV(MDMC) and Mr. Ghayour Ahmed, Assistant Director-V (MDMC) assisted the Secretary of the MDB while presenting the agenda before the Board.

**Item No. I. Briefing regarding medical devices regulations.**

Chairman, Medical Device Board gave a detailed briefing on Medical Device Rules, 2015 to worthy Board Members as follow:-

The Drug Regulatory Authority of Pakistan Act, 2012 was promulgated on 13<sup>th</sup> November, 2012 by the Parliament for the establishment of Drug Regulatory Authority of Pakistan to regulate the manufacture, import, export, storage, distribution and sale of therapeutic goods including drugs, alternative medicines, medical devices, biologicals and other related products as may be notified by the Authority. The medical devices were thus brought under regulation.

The Division after its establishment started framing the rules for regulation of the medical devices, the legal requirement under the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and also continued the process of registration of medical devices declared as drugs under the Drug Act, 1976 with the aim to protect public health by not disrupting the system of regulation of high risk medical devices as drugs and to prevent the shortage of these devices in the market till notification of the rules for regulation of medical devices.

The division drafted the medical device rules after detail examination of the medical device regulations of the Asian countries being harmonized by Asian Harmonization Working Party (AHWP) and the international regulations being harmonized by International Medical Device Regulators Forum (IMDRF) having World Health Organization (WHO) as its official observer.

The draft medical device rules recommended by the ECMD were placed before the Drug Regulatory Authority of Pakistan for its consideration. The Authority after detailed deliberation approved in principle the draft medical device rules. The draft rules were accordingly uploaded on the official website of the Authority and hard copies were also sent to all the provincial governments, FATA, Azad Jammu & Kashmir and Commissioner Islamabad Capital Territory for comments. The draft rules were also sent to the stake holders and WHO Representative in Pakistan. The Rules were redrafted in the light of Act.

The Medical Device Rules after vetting by the Law and Justice Division and approval by the Federal Government were notified by the Authority on 9<sup>th</sup> March, 2015.

In these rules medical devices including in vitro diagnostic medical devices have been classified into Class A, Class B, Class C & Class D medical devices depending upon risk they pose to the patients where Class D represents the highest risk posing medical devices. Expert members of the Medical Device Board (MDB) were nominated by the Authority.

The Director briefed the following Salient Points of the Rules:

- Definition of technical terms used in the rules.
- Role of conformity assessment body (CAB), a third party, responsible for the confirmation of medical devices to the essential principles of safety and performance.
- Procedures for grant of registration of CABs.

- Licensing system for establishments including manufacturers and importers.
- Classification of medical devices and in vitro diagnostic medical devices into Class A, B, C and D, depending upon the level of risk they pose to patients, users and other persons, where class D represents the highest risk class.
- Methods/Rules of classification of medical devices on the basis of intended purpose, mechanism of action, duration of use etc.
- Grouping procedure/methods for medical devices into single; system; *in vitro* test kit etc.
- Procedure for registration of medical devices keeping in view the classification and grouping systems.
- Procedure for import of medical devices, components and raw materials for commercial, personal and investigational purposes.
- Procedure at custom port for clearance of medical devices, components and raw materials
- Procedure for export of medical devices for commercial, personal and investigational purposes.
- Labeling requirements for general and in vitro diagnostic medical devices.
- Responsibilities and obligations of licensees and registration holders.
- Post market surveillance and vigilance system.
- Exemptions, prohibitions and sampling.
- Usage, operation and maintenance.
- Qualification and competency of persons using, operating, installing and testing medical device.
- Medical Device Board for registration of conformity assessment bodies, licensing of establishments, registration of medical devices and issuance of permits for import and export of medical devices.
- Inclusion of the technical experts like biomedical, software and electromechanical engineers, cardiac, general and orthopedic surgeons, urologists, radiologists, pathologists, pharmacists and medical administrators in MDB.
- Maintenance of the Medical Device Register of Pakistan, containing information of all the registered medical devices, licensed establishments and CABs.
- Fee structure of all the procedures performed by MDB or on its behalf.
- Outsourcing of the manufacturing of medical devices, processes or testing of the medical devices.
- Declaration of the standards of testing for medical devices.

- Procedure for advertisement of medical devices.
- Repeal of the provisions of rules made under the Drugs Act, 1976.

The Director further briefed that those Conformity Assessment Bodies (CABs) accredited by PNAC with required scope have been exempted from the registration with the Board by the Authority. Furthermore, exemption period for Class C and Class D medical devices from operation of Medical Devices Rules, 2015 was also extended till 8<sup>th</sup> December, 2015 and 30<sup>th</sup> September, 2016 respectively.

**Item No.II. Enlistment Rules for regulation of Class A Medical Devices (non-measuring function, non-active or non-sterile) under rule 86 (2) of the Medical devices Rules, 2015.**

Under Medical devices Rules, 2015 (MDR, 2015), those Class A medical devices having measuring function, active or sterile and their establishments shall be regulated under these rules. However, according to Rules 86 (2) of the MDR, 2015, all those Class A medical devices having no measuring functions, non-active or non-sterile and their establishments shall be regulated according to the enlistment rules to be notified by the Authority. Rules 86 (2) of the MDR, 2015 is reproduced as under:-

*“All Class A medical devices and establishments manufacturing, importing, exporting or selling Class A devices, other than those having measuring functions, active or sterile, shall be regulated according to the enlistment rules to be notified by the Authority.”*

**Decision: The Board unanimously decided to constitute a working group for drafting Enlistment Rules for Class-A medical devices (non-measuring function, non-active or non-sterile) under rule 86 (2) of the Medical Devices Rules, 2015. The Enlistment Rules shall be placed before the MDB in its next meeting. The working group shall include the following:-**

1. **Prof. Dr. Umar Hayat, Member MDB.**
2. **Dr. Muhammad Nadeem Ahmad, Member MDB.**
3. **Mr. Muhammad Tahir Aziz, Member MDB.**

**Mr. Asif Jalil, Assistant Director-I (MDMC) will act as coordinator of the committee.**

**Item No.III. Pharmacovigilance of Medical Devices.**

Rule 125 of MDR, 2015 is reproduced as below:-

“Post-marketing surveillance and vigilance system.— (1) For the purpose of post-marketing surveillance and vigilance of marketed medical devices, a licensee shall establish, maintain and implement an appropriate and effective post-marketing surveillance and vigilance system of medical devices he is dealing with which shall also include the following elements, namely: —

- (a) distribution records;
- (b) complaint handling system;
- (c) mandatory problem reporting, including investigation of problem or incident;
- (d) field corrective action; and
- (e) recall procedure.”

Hafiz Muhammad Jawad Ali, Assistant Director-III (MDMC) explained the international scenario of vigilance system on medical devices to the members of the Board and placed before the Board Medical Device Adverse Event Reporting Form. The Board members thoroughly discussed at large the mechanism in public and private sector for reporting of medical device adverse events. Hafiz Muhammad Jawad Ali, Assistant Director-III (MDMC) coordinated with Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi and formulated the medical device adverse event reporting form for Pakistan.

**Decision: The Board approved the following medical device adverse event reporting form for Pakistan which shall be sent to Division of Pharmacy Services, DRAP for further necessary action:-**



## Drug Regulatory Authority of Pakistan (MDMC-Division)

### MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

<b>A. Patient Information</b>			
Name		Age & Gender	
Weight in Kilograms			
List of Devices involved with each patient			
Patient-focused Resolution of Events, any corrective action & Outcomes.			
<b>B. Name of the Person Reporting</b>			
Email Address		Fax/Phone No#	
Correspondence Address			
<b>1. Clinical Event Information</b>			
Event Description			
No# Devices involved		No# Patients involved	
<b>2. Health Care Facility Information (If Applicable)</b>			
Organization Name		Fax/Phone No#	
Contact name at the site of event		E-mail	
<b>3. Device Information</b>			
Manufacturer name			
Address			
Email		Fax/ Phone No#	
<b>3a. Generic Information</b>			
Brand Name		Catalogue No#	
Software Version		Batch No #	
<b>3b. Usage of Device (Select from the list below)</b>			
Initial use	Reuse of Reusable	Refurbished	
<b>3c. Operator of Device at Time of Adverse Event (Select from the list below)</b>			
Healthcare Professional	Patient	Other Care giver	
<b>Define Problem:</b>			
<b>3d. Device Disposition/Current Location Y/N?</b>			
Device has been Destroyed?			

Remains Implanted with Patient	
Return to the Manufacturer/ Supplier	
Remains under Investigation etc.	

<b>For Office/ Administrative Use Only</b>			
<b>Report Control Number</b>			
Manufacturer/Supplier No#		User facility No#	
Assigned by MDMC to whom		User Facility Report#	
<b>Report Type(Select Anyone)</b>	Initial	Follow-up	Final
Date of Adverse Event Occurred		Date of Report	
<b>Classification of Event (Select Anyone)</b>	Unanticipated Death	Unanticipated Serious Injury	Serious Public Health Threat
All Other Reportable Events			
Manufacturer Awareness Date			
<b>Device Approval Information</b>			
Regulatory Authority who Approved the Device		Notified body who certify device	
Document Approval No#		Notified Body ID No#	
<b>4. Comments:</b>			
<b>5. Timing of Adverse Event Reports (Appendix B)</b>			
All reportable events must be reported as soon as possible by not later than 30-elapsd calendar days following the date of awareness of the event.			
<b>(For institutions organization or Hospitals only)</b>			
<ul style="list-style-type: none"> <li>• Serious public threat within two calendar days after the date of awareness.</li> <li>• Death or serious deterioration in state of health within 10 elapsed calendar days after the date of awareness.</li> <li>• Other incidents, immediately after assessing the link between the device and the event within 30 elapsed calendar days.</li> <li>• Manufacturer’s written acknowledgment of user reports from NCA to manufacturer within three working days of receiving user report.</li> <li>• Voluntary reports may be submitted at any time, and may be on the events other than death, serious injury, or malfunction as defined.</li> </ul>			

**Item No.IV. Applications for Establishment Licence for Import.**

Following firms have submitted applications for grant of establishment licence for import of medical devices as detailed below for consideration of Medical Device Board. Evaluation of the applications revealed deficiencies mentioned against each:-



S. No	Name & Address of firms/ importer and date of application.	Name of Proprietors & residential address, CNIC.	Name, Registration No. residential address & CNIC of qualified person	Address of Godown/ Warehouse	Remarks/ Deficiencies
1.	M/s Nismedical, Suite No. 511, 5 <sup>th</sup> Floor, Mashriq Center, Gulshan-e-Iqbal, Block-14, Karachi.  21-12-2015	Syed Hameed Ahmed, Flat No.C-20, Saghir Center, Federal B Area, Block-16, Karachi. 42101-2761524-9	Not mentioned.	Flat No.C-20, Saghir Center, Federal B Area, Block-16, Karachi.	Establishment details, post marketing surveillance system, detail of medical devices intended to be imported Qualified person (Pharmacist) Quality management system
2.	M/s Abbott Laboratories (Pakistan) Limited, Opp Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.  02-01-2016	Munir Ahmed Sheikh, 96, Cairnhill Road, Singapore, 229692 Passport No.488072827  Arshad Saeed Husain, 91/11, 12 <sup>th</sup> Street of Khayaban-e-Sehar, Phase-VI, DHA, Karachi. CNIC.42000-0504011-9  Syed Anis Ahmed,B-140, Block N. North Nazimabad, Karachi. CNIC.42101-9990908-5  Kamran Y Mirza, H.No.79, St.4, Phase-VI, Khayaban-e-Sehat, DHA,	Not provided.	Opp Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.	Not applied on prescribed form 3-A, Audit report and present investment, Detail of premises including covered area and dimension, copies of CNIC, photographs, registration certificates of Directors and qualified person. Post market surveillance system. complete information of medical device  Quality management system

		<p>Karachi. CNIC.42301-1126838-3</p> <p>Shamim Ahmed Khan, H.No.108, St. No.60, Sector I-8/3, Islamabad. CNIC.61101-7006861-7</p> <p>Ehsan Ali Malik, 41-A-1, South Central Avenue, Phase-II, DHA, Karachi. CNIC.42301-7554100-1</p> <p>Zehra Naqvi, 27-B, Circular Avenue, Phase-I, DHA, Karachi. CNIC.42301-0639182-0</p>			
3.	<p>M/s Hooraa Pharma, WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi.</p> <p>15-01-2016</p>	<p>Abdul Rasheed Chohan, H.No.121, Main Khayaban-e-Shaheen, Phase-VI, DHA, Karachi. CNIC.42301-9006690-1</p>	Not provided	<p>WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi.</p>	<p>Establishment details, copies of CNIC, photographs, registration certificates of qualified person. Post market surveillance system. complete information of medical device Quality management system</p>
4.	<p>M /s Eli Lilly Pakistan (Pvt) Limited, 5-A, 5<sup>th</sup> Office Floor (10<sup>th</sup> Building Floor), Al Tijarah Center, 32-1-A, Block-6,</p>	<p>Kazim Husnain, H.No.8/1, St.15, Phase- V, DHA, Karachi. CNIC.42301-5589403-5</p>	<p>Fayyaz Ahmed (Pharmacist) Reg.No.1187 H.31, ST.21, Park Lane- 2, Phase-VI, DHA,</p>	<p>B-23, SITE, Karachi</p>	<p>Establishment details, Post market surveillance system. Quality management system</p>

	PECHS, Main Shahrah e Faisal, Karachi  10-02-2016		Karachi. CNIC.42201-0242368-9		
5.	M/s Johnson & Johnson Pakistan (Pvt) Limited, FL-19, Sub Plot F-1, Kehkashan Scheme No.5 Main Boat Basin, Clifton, Karachi.  18-01-2016	Not provided.	Muhammad Sufian Saeed, (Pharmacist) Reg.No.06836 H.No.31/1- A, Block-14, Gulistan-e-Johar, Karachi. CNIC.42501-7435903-1	<u>Through Indenting</u> Muller & Phipps Pakistan (Pvt) Limited, Plot 208&208\1 Sector 23. Industrial Area Karachi.	Establishment details, Post market surveillance system, Own Warehouse facility. Quality management system The said firm is utilizing the storage facility of M/s Muller & Phipps which itself its has applied for establishment licence as well as registration of medical devices for import. Board decided that the firm should develop its own establishment for the storage and distribution of registered medical devices.
6.	M/s Roche Pakistan Limited, 37-C, Block- 6, PECHS Karachi.  16-02-2016	Badaruddin Fateh Ali Vellani, 14 Khayaban-e-Janbaz, Phase-V, DHA, Karachi. CNIC.42301-0918221-7  Muhammad Zaheer Babar, H.No.155-B/II, St.16, Khayaban-e-Iqbal,	Wahaj-us-Saeed (MBA) H.No.B-71, Block 10, Naseerabad, F.B.Area, Karachi. CNIC.42101-8276022-9  Maqsood Ahmed Khan (MBA), H.No.37-A, Sector-X-II, Gulshan-e-	<u>Diagnostic Office</u>  39-C /1, Block-6, PECHS, Karachi.  800 Shadman-01, Lahore.  Plot No.5, Bazar No.2,	3 different locations, Initial and present investment detail, Detail of premises, qualified person not as per prescribed criteria. Post market surveillance system, Class of medical devices.

		DHA Phase-8, Karachi. CNIC.42201-9017129-9  Abdus Samad, H.No.146/2, St.8 off Khayaban-e-Bukhari, Phase-VI, DHA, Karachi. CNIC.42301-1927826-3	Muamar, Malir, Karachi. CNIC.42501-4405143-9	Sulaiman Market, F- 11/2, Islamabad.	Quality management system
7.	M/s Biocare Enterprises, 5-A Block, Satellite Town, Rawalpindi  24-02-2016	Muhammad Asif, H.No.1743-L, St.60-A, Behria Town, Phase-III, Islamabad. CNIC.37405-4005565-1	Not provided.	5-A Block, Satellite Town, Rawalpindi	Establishment details, Post market surveillance system, Qualified person details. Quality management system
8.	M/s Sind Medical Stores, 13-B, Block 6, PECHS, Shahra- e- Faisal, Karachi  22-02-2016	Muhammad Sharif Ibrahim Billoo, Flat No.7-8, 2 <sup>nd</sup> Floor, Hill View Apartment, Block- 6, KMCH Society, Karachi. CNIC.42201-6841105-3  Muhammad Younas Billoo, Flat No.8-9, 2 <sup>nd</sup> Floor, Hill View Apartment, Block-6, KMCH Society, Karachi. CNIC.42201-4966404-5	Muhammad Nasir Khateeb (Pharmacist), Reg.No....., D-98, Block-13-D-1, Gulshan-e-Iqbal, Karachi. CNIC.422017-013551-1	13-B, Block 6, PECHS, Shahra- e- Faisal, Karachi	Initial and present investment detail, Audit report, Class & detail of medical devices. Affidavit not signed by qualified person. Quality management system
9.	M/s Briogene (Pvt) Limited, 303 Progressive Center, 30- A, Block 6, PECHS, Shahrah- e-Faisal, Karachi	Javed Gjhulam Muhammad, Flat No.B- 404, Royal Apartment, KDA Scheme, Karachi	Sadaf Naeem (Pharmacist), Reg.No.07099 Flat No.D-7, Crown	<u>Through Indenting</u> Muller & Phipps Pakistan (Pvt) Limited, Plot 208-1 Sector 23.	Not on prescribed on prescribed form. Dealing through indenter M&P,

	17-02-2016	CNIC.42201-0556944-9 Muhammad Umer, Flat No.702, Mehran Estate, Doctor Daud Pota Road, Karachi Cantt. CNIC.42301-0890753-5	Shopping Centre, Shadman-II, North Nazimabad, Town Sector 14-B, Karachi. CNIC.42101-1426418-0	Industrial Area, Karachi.	Establishment details, post market surveillance, Quality management system
10.	M/s Muller & Phipps Pakistan (Pvt) Limited, Uzma Court, Main Clifton Road, Karachi.  03-03-2016	Mujeeb Ali Khan, H.No.B-86, St.15, Block-N, North Nazimabad,Karachi. CNIC.42101-1577258-3  Jahanzeb Saeed, Flat No.46-E, Askari H, School Road, Karachi Cantt, Clifton, Karachi. CNIC.15402-2888041-5  Najeeb-ur-Rehman, H.No.15-C, Block-A, Kazimabad Model Colony, Karachi. CNIC.42201-0773305-3	Muhammad Ahmed Hashmi (Pharmacist), Reg.No.103, H.No.10-A, Shamim Compound, Near Yasinabad, F.B.Area, Block-9, Karachi. CNIC.42101-1729433-5  Mahmood Ahmed (Pharmacist), Reg.No.2645, H.No.B-38, Hajirabad, Shah Faisal Colony-III, Karachi. CNIC.42201-4824025-5	Plot No.208&208/1 Sector 23, Korangi Industrial Area, Karachi	Establishment details, post market surveillance, Detail and class of medical devices. Quality management system
11.	M/s IHI (Integrated Human Initiative), Elaaf Center #1, First Floor,C-5/C -1 Lane 3, Khayaban-e- Nishat, Phase 6. DHA, Karachi.  03-03-2016	Muhammad Khalid Qureshi, Flat No.1, Plot-5-C, St.Nishat Lane-3, Khayaban-e-Nishat, Phase-VI, DHA, South Karachi. CNIC.61101-3617275-9	Saqib Ghulam Hussain, (Pharmacist) Reg.No.1568, H.No.40/A-1, Awami Colony, Mills Area, Korangi , Karachi,. CNIC.42201-4066008-7	Elaaf Center #1, First Floor,C-5/C -1 Lane 3, Khayaban-e- Nishat, Phase 6. DHA, Karachi.	Establishment details, Affidavit not signed by qualified person, Detail and class of medical devices, Quality management system

12.	M/s 3M Pakistan (Pvt) Limited, Islamic Chamber of Commerce Building, St. 2A, Block 9, KDA Scheme-5 Clifton, Karachi.  08-03-2016	Jarri Masood Zaidi, B-18, Block-3, Gulshan-e-Iqbal, Karachi. CNIC.42201-3462739-5  Ernest Terrence Zwambila, 3M Gulf Limited, Building No.11, 3 <sup>rd</sup> Floor, Internet City, Dubai UAE. Passport No. EN470840	Not provided.	H-2/II, Sector –V, Cooperative Housing Society, Korangi Industrial Area, Karachi.	Establishment details, Affidavit not signed by qualified person, Detail and class of medical devices. Quality management system
13.	M/s Hospital Supply Corporation, 46-E/2, Block 6, PECHS Karachi  16-03-2016	Mehtabuddin Feroz, H.No.323/7, Mohallah Dehli Mercantile Society, Karachi. CNIC.42201-1613369-5  Muhammad Yahya Feroz, H.No.70, Haider Ali Road, Faran Society, Karachi. CNIC.42000-0546630-5  Sohail Feroz, H.No.304/7, Dehli Mercantile Society, Karachi. CNIC.42301-0841143-9	Muhammad Yousaf, (Pharmacist) Reg.No.5946, H.No.H-8, Cantt Bazar, Malir Cantt, Karachi. CNIC.44103-0378217-7	42, Darulaman Housing Society, Block 7 & 8, Karachi.  46-E/2, Block 6, PECHS Karachi  152-A, Shah Jamal Colony, Lahore.  18-A, Gulgasht Colony, Multan.  House No.13, I-8/3, Islamabad.	Establishment details, Affidavit not signed by qualified person, post market surveillance, Detail and class of medical devices. Quality management system
14.	M/s Sure Bio-Diagnostics & Pharmaceuticals, EE-10 Defence View Phase-	Sheikh Shakeel Ahmed, H.No.X-25/1, East Street, Phase-I, DHA, Karachi.	Yasir Khan, (Bio Medical Engr) Reg.No.Biomedical/582	EE-10 Defence View Phase-II, Near Iqra University, Shaheed-e-	Establishment details, Qualified person not as per requirement,

	II, Near Iqra University, Shaheed-e-Millat Express Way, Karachi. 24-03-2016	CNIC.42000-0523785-1	H.No.B/401, Farhan Dreamland, Gulistan-e- Johar, Karachi. CNIC.44101-4804973-9	Millat Express Way, Karachi.	post market surveillance, Detail and class of medical devices. Quality management system
15.	M/s Shirazi Trading Company (Pvt) Limited, 08 <sup>th</sup> Floor, Adamjee House, I.I.Chundrigar Road, Karachi.  25-03-2016	Muhammad Yousaf Hussain Shirazi, H.No.2, Khayaban-e-Ghazi, Phase-V, DHA, Karachi. CNIC.42000-0509677-9  Aamir Hussain Shirazi, H.No.3, Zaman Park, Lahore. CNIC.35202-3854859-7  Saqib Hussain Shirazi, H.No.12, St.5, Khayaban-e-Bukhari, Phase-VI, DHA, Karachi. CNIC.42000-0509678-5  Ali Hussain Shirazi, H.No.2, Khayaban-e- Ghazi, Phase-V, DHA, Karachi. CNIC.42301-0972346-1  Khaleeq-ur-Rehman Yousafi, H.No.150/1, St.35, Khayaban-e- Muslim, Phase-VI, DHA, Karachi.	Burhan-uddin (Bio- medical Engr) Reg.No.Biomedical/499 E-22, Block-E, Haidri Memorial Market, North Nazimabad, Karachi. CNIC.42101-1200678-9	<u>Main Godown Address</u>  2 <sup>nd</sup> Floor, Nadir House, I.I.Chundrigar Road, Karachi.  <u>Branch Offices/ Godown Address:</u>  3-Bank Square, Shahra-e-Quaid-e- Azam, Lahore.  Basement, Al-Noor Building, 43 Bank Square Shahra-e- Quaid-e-Azam, Lahore.  Ground Floor, 17 <sup>th</sup> Bank Square Shahra-e- Quaid-e-Azam, Lahore.  Atlas Group Building, Azmat Wasti Road, Near Capri Cinema, Multan.	Establishment details, Qualified person not as per requirement, post market surveillance, Detail and class of medical devices. Quality management system

		CNIC.42000-0419183-1 Frahim Ali Khan, H.No.10-B/II, South Park Avenue, Phase-II, DHA, Karachi. CNIC.42301-8765118-9		Plot No.41, Sector F- 6/G-6, Ataturk Avenue, East End Plaza, Blue Area, Islamabad.  4 <sup>th</sup> Floor Marhaba I.T. University Road, Peshawar.	
16.	M/s Fresenius Medical Care Pakistan (Private) Limited, 137-A, Faisal Town, Lahore.  20-03-16	Javed Nasir Qureshi, 57- A, PCSIR Society, Phase-II, Lahore.  Kwong Leung Tsang  Jan Walter.  Roberto Fuste  (No further detail provided)	Muhammad Sohail (Pharmacist), Reg.No.6263-A,/10  CNIC.36203-0941868-7	Not mentioned.	Establishment details, Application not on prescribed form, Qualified person details are missing, post market surveillance, Quality management system
17.	M/s Medical Product Technologies, 61/M, 1 <sup>st</sup> Floor, Block-2, P.E.C.H.S, Karachi.  20-03-2016	Mr. Atif Usman Baig, H.No.D-190, Block-4, FB Area, Karachi. CNIC.42000-0514067-5  Mr. Junaid Ahmed, H.No.A-6, Phase-I, Row- D, Project-II, Gulshan Kaneez Fatima Scheme 33, Karachi Post Office Phase-I Road, Karachi. CNIC.42000-0522991-7	Mr. Atif Usman Baig, (M.Sc Physiology) H.No.D-190, Block-4, FB Area, Karachi. CNIC.42000-0514067-5  Mr. Junaid Ahmed, MBA, H.No.A-6, Phase-I, Row-D, Project-II, Gulshan Kaneez Fatima Scheme 33, Karachi Post Office Phase-I Road, Karachi.	Not mentioned.	Establishment details, Qualified person not as per requirement, post market surveillance. Quality management system



		Muhammad Munawar, H.No.C-1, Datari Villas, Main Clifton Road, Bath Island, Karachi. CNIC.42000-8702184-1	CNIC.42000-0522991-7  Syed Faisal Ali, M.Sc Genetics, P/1014/A, St.3, Angat Pura, Asghar Mall Road, Rawalpindi. CNIC.37405-0653821-9		
18.	M/s A.M Distributers, 4 <sup>th</sup> Floor, 37-C, Lane No.8, Bukhari Commercial Area, Phase-VI, DHA, Karachi.  18-04-2016	Muhamamd Rafiq, H.No.134/2, St.32, Off Khayaban-e-Mohafiz, Phase-VI, DHA, Karachi. CNIC.42301-4500256-1	Jawaid Abdul Ghani (Pharmacist) Reg.No.951, H.No.D-01, Al-Zehra Complex, Sparco Chowk, Gulshan-e- Iqbal, Karachi. CNIC.42201-5401064-3	Plot No 25-C, Lane No 6, Bukhari Commercial Area, Phase-VI, DHA Karachi.  Plot No 28-C, Lane No 6, Bukhari Commercial Area, Phase-VI, DHA Karachi.	Establishment details, post market surveillance. Quality management system
19.	M/s Uniplan Trade International, 132 Quaid e Azam Industrial Estate Kot Lakhpat, Lahore.  27-04-2016	Muhammad Khalid Javed Ch., 66-3, Abid Majeed Road, Lahore. CNIC.35201-9666380-3  Nasir Javed Ch. 7-J I, Noor Vallas, Johar Town, Lahore. CNIC.35202-2509124-1  Muhammad Tahir Javed, 133-F, Model Town, Lahore.	Not provided.	132 Quaid e Azam Industrial Estate Kot Lakhpat, Lahore.	Establishment details, Qualified person not provided, post market surveillance.. Quality management system

		CNIC.35202-2391869-5 Naveed Khalid Ch., 5-J-I, Noor Vallas, Johar Town, Lahore. CNIC.35201-1301165-3			
20.	M/s Novo Nordisk Pharma (Pvt) Limited, 113 Shahrah-e-Iran, Karachi  27-05-2016	Not provided.	Not provided.	<u>Through Indenting</u> Muller & Phipps Pakistan (Pvt) Limited, Plot 208&208\1 Sector 23, Industrial Area Karachi.	Establishment details, Qualified person not provided, post market surveillance. Quality management system
21.	M/s Life Tec, Unit –D, 1st Floor, Block 20- D, G-8 Markaz, Islamabad  19-05-2016	Sana-ur-Rehman, H.No.6, St.43-A, G-8/2, Islamabad. CNIC.61101-5492523-3  Khalid Mehmood Zia, H.No.C/20-D, Sector G- 8 Markaz, Islamabad. CNIC.61101-1776790-7	Imran Shakir (Pharmacist), Reg.No.06613, H.No.43-C/1, Cantt Bazar, Malir Cantt, Karachi. CNIC.42501-6899445-7	Unit –D, 1st Floor, Block 20- D, G-8 Markaz, Islamabad  House No.6, St.43-A, G-8/2, Islamabad.  House No.144, E- Block, Model Town, Lahore.  Unit/Office No.5, Lower Basement, Villys Shoper Mall, Gulistan-e-Johar, Karachi.	Establishment details, post market surveillance, partners detail not provided. Quality management system
22.	M/s Siemens Healthcare (Pvt) Limited, 4 <sup>th</sup> Floor State Life Building, 15-A, Sir Agha Khan Road, Lahore	Khurram Jameel, H.No.337-D-3, Wapda Town, Lahore. CNIC.35202-2745000-9	Azfar Hussain (Biomedical Engr), Reg.Biomedical/12, H.No.A-2019, St.Metrowell III,	4 <sup>th</sup> Floor State Life Building, 15-A, Sir Agha Khan Road, Lahore	Qualified person not available.  Affidavit not provided.

	16-05-2016	Syed Imran Raza, H.No.83/B, Revenue Employees Soceity, Township, Lahore. CNIC.35202-3983056-7	Gulshan-e-Iqbal, Block- 2, Karachi Sharqi. CNIC.42201-7703887-9  Atif Hafeez, BE. Elect, MBA, Reg. Elect/9284, H.No.12, Ittehad Colony, Multan Road, Sheraz Park, Lahore. CNIC.35202-1811054-7		Declaration not signed. SOPs for post surveillance not provided.  Proof of business registration not provided. Quality management system
23.	M/s Universal Enterprises, 29 Block-3, Overseas Co-Operative Housing Society, Stadium Road Karachi.  18-05-2016	Muhammad Aleem Mirza, H.No.B-115, Block-10, Gulshan-e- Iqbal, Karachi Sharqi. CNIC.42201-7437635-5	Not provided.	29 Block-3, Overseas Co-Operative Housing Society, Stadium Road Karachi.	Map and detail of premises not provided. Qualified person not available. Affidavit not provided. Quality management system
24.	M/s Biowel Sciences, Block No 40, I&T Center, G-10/4, Islamabad  27-06-2016	Dr. Waseem Mirza, H.No.28, St.30, Sector F- 6/1, Islamabad. CNIC.61101-7677760-7  Dr. Nasir Mehmood, H.No.MCB-16/219, Mohallah Sar-Pak, Chakwal. CNIC.61101-7983879-3  Abdul Hafeez, Village Bagato, P.O.Hangu, Tehsil & Distt. Hangu. CNIC.14101-9079488-1	Not provided.	Block No 40, I&T Center, G-10/4, Islamabad	Proof of business registration not provided. Qualified person not available. Affidavit not provided. Quality management system

25.	<p>M/s Med Art, Bungalow-59, Petal Residency, Gulistan-e- Johar, Block-9-A, Karachi</p> <p>01-08-2016</p>	<p>Mrs. Sara Ali, Bungalow-59, Petal Residency, Gulistan-e- Johar, Block-9-A, Karachi CNIC.35202-4413705-2</p>	<p>Not provided.</p>	<p>Bungalow-59, Petal Residency, Gulistan-e- Johar, Block-9-A, Karachi</p>	<p>Business registration certificate expired. Audit report not provided. Qualified person not available. Affidavit not provided. SOPs for post surveillance not provided. Quality management system</p>
26.	<p>M/s Indus Pharma (Pvt) Limited, Plot No.26-27 &amp; 63-67, Sector 27, Korangi Industrial Area, Karachi.</p> <p>07-09 2016.</p>	<p>Zahid Saeed, Ameer Khusro Road, House No.12, Block 7/8, Street Overseas Cooperative Housing Society, Karachi Sharqi. CNIC.42201-4791181-1</p> <p>Khalid Saeed, H.No.4, Street Al-Hamra Society, Shaheed-e-Millat Road, Karachi Sharqi. CNIC.42201-7292832-3</p> <p>Anwar Saeed, Overseas Society, Main Ameer Khusro Road, H.No.9, Block-7-8, Karachi Sharqi. CNIC.42201-2319109-9</p>	<p>Muhammad Umair Rafiq (Pharmacist) Reg.No.06719, H.No.185, Mohallah Landhi Colony, 5,1/2 Sector 36-E, Karachi Sharqi. CNIC.42201-8775047-9</p>	<p>Plot No.26-27 &amp; 63- 67, Sector 27, Korangi Industrial Area, Karachi.</p>	<p>CNIC of pharmacist not attested. Quality management system</p>

27.	M/s Cardiac Care, 848-C, Shadman-I, Lahore  06-09-2016.	Waheed Aslam Chathha, H.No.234, Mohallah Revaz Garden, Lahore. CNIC.35202-2297887-9	Maida Akram (Pharmacist), Reg.No.10384-A/13. H.No.307, Mohallah Block-2, Sector D-I, Township, Lahore. CNIC.35202-4401575-4	Godown at Revaz Garden Lahore (Complete address not mentioned).	Fee not deposited. Audit report not provided. Attested copies of registration certificates not provided. All documents not attested. SOPs for post surveillance not provided. Quality management system
28.	M/s Health Tec, 10-B, Street 24, Valley Road, Westridge-I, Rawalpindi.  23-09-2016	Ahmad Ali Aslam, Al-Mustafa House, H.No.1, Street Bani Gala, Hussain Road, Islamabad. CNIC.54400-0452778-9	Syed Adnan Haider (Pharmacist), Reg.No.2641-A/2014- PC. KPK. Village Ali Zai. P.O.Khadi Zai, Tehsil & Distt. Kohat. CNIC.14301-1942106-7	10-B, Street 24, Valley Road, Westridge-I, Rawalpindi.	SOPs for post surveillance not provided. Two attested copies of registration certificates required. Quality management system
29.	M/s Intek Corporation, 25 A, Nagi Road Westridge I, Rawalpindi.	Irfan-ul-Azeem Arain, H.No.75, St. 14, Sector F-11/1, Islamabad. CNIC.61101-1996388-7	Haseeb Ahsan Raja (Pharmacist) Reg.No.11600-A/14 H.No.134, Nai Abadi, Mareer Hasan, Rawalpindi. 37405-7460153-9	25 A, Nagi Road, Westridge I, Rawalpindi	Not on prescribed Form. No investment record. No auditor report. SOPs for Post Marketing Surveillance not provided. No detail of medical devices to be imported. Detail of equipment and machinery not provided.

30.	<p>M/s Ferozsons Laboratories Limited, 5-KM, Sundar Raiwind Road, Raiwind, Lahore.</p> <p>07-11-2016</p>	<p>Mrs. Akhter Khalid Waheed.</p> <p>Mr. Osman Khalid Waheed, H.No.FA-99, Mohallah Murree Road, Faizabad, Rawalpindi. CNIC No.37405-0384955-7</p> <p>Mrs. Amna Piracha Khan</p> <p>Mrs. Munize Azhar Peracha</p> <p>Mr. Farooq Mazhar</p> <p>Mr. Nihal F Cassim</p> <p>Mr.Shahid Anwar</p>	<p>Mr. Afzaal (Technical Person) H.No.5/63, Mohallah Sabri Lala Moosa, Tehsil Kharian, Distt. Gujrat.</p>	<p>5-KM, Sundar Raiwind Road, Raiwind, Lahore.</p>	<p>To be evaluated.</p>
31.	<p>M/s Global Marketing Services, 111 Hali Road, Westridge-I, Cantt. Rawalpindi.</p> <p>07-11-2016</p>	<p>Zafar Mahmood, H.No.E-39, Kohsar Colony, G.T. Road, Texila. CNIC.37406-6201299-5</p> <p>Muhammad Ayub, H.No.55, ST No.82, G-13/1, Islamabad. CNIC.61101-2709821-3.</p>	<p>Ghazala Javed (Pharmacist) Reg.No.8125-A/12 H.No.402/12, B-III, Khurram Colony, Muslim Town, Rawalpindi.</p>	<p>M/s Global Marketing Services, 111 Hali Road, Westridge-I, Cantt. Rawalpindi.</p>	<p>To be evaluated.</p>

32.	M/s B.Braun Pakistan (Pvt) Limited, The Forum, Suite 216, Khayaban-e-Jami, Clifton Block-9m Karachi.  09-11-2016	Dr. Muhammad Zafar Hashmi, H.No.50-A, Khayaban-e-Shaheen, DHA Phase-V, Karachi. CNIC.42301-9668592-5  Wasif Sajjad, H.No.184-A, North Nazimabad Chowk, Karachi. CNIC.42101-2332787-9.	Yawer Imam (Pharmacist) Reg.No.1779, H.No.206-A, Block-3, Gulshan-e-Iqbal, Karachi. CNIC.42202-2906711-3	Plot No.C-153, Sector # 6F, Mehran Town, Korangi Industrial Area, Karachi.	To be evaluated.
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Chairman Medical Device Board informed that 32 applications for grant of establishment licence for import of medical device have been received in this Division out of which 29 applications have been evaluated and found deficient while 03 applications have been received very recently and have not been evaluated yet. The Board discussed about Conformity Assessment Body (CAB) and the QMS status (GDPMD) of these establishments. The Chairman informed the Board that the matter regarding exemption of Conformity Assessment Bodies (CABs) through time based amendment in Medical Devices Rules, 2015 for Conformity assessment of establishments and their medical devices was placed before the Authority in its 38<sup>th</sup> meeting held on 17<sup>th</sup> October, 2016. The decision of the Authority is awaited yet. The Board decided as under:-

**Decision:**        **The Board decided that the applications for establishment licence to import medical devices shall be processed after and in accordance with the notification of the amendments in Medical Devices Rules, 2015 as per decision of the Authority.**

**Item No.V. Checklist for application for grant of Establishment Licence to Import medical devices under Medical Devices Rules,2015.**

Medical Devices and Medicated Cosmetics Division drafted checklist for application for grant of Establishment Licence to Import medical devices on Form -3A of Medical Devices Rules, 2015 for consideration of Medical Device Board.

The Board discussed the checklist point wise in detail. The qualified person i.e. Pharmacist for importer of medical devices under the existing rules was also discussed. It was deliberated that the field of medical devices is very vast including medical equipments and *in-vitro* diagnostic medical devices which need some other professionals as qualified person. The Division informed the MDB that requirement of other qualified persons for importer shall need amendment in Medical Devices Rules, 2015. The Board recommended that the necessary amendments in the Medical Devices Rules, 2015 may be done for induction of relevant professionals as qualified person for import of medical device.

**Decision: The Board approved the checklist as per existing rules as follows:**

1. Application on prescribed Form-3A under Medical Devices Rules, 2015.
  - (a) Each page must be duly signed and stamped by proprietor/ director/managing partner.
  - (b) In case of two or more persons, an affidavit on notarized stamp paper duly signed by each regarding nomination of one person to apply for establishment licence on behalf of others.
  - (c) Provide all information/documents in electronic form as PDF or non editable format on CD.
  
2. **Establishment details:**
  - (d) Establishment name and address including godown address. Provide proof of ownership , lease or rent e.g registry, fard, rent agreement lease agreement etc :
  - (e) Type of ownership i.e. partnership, proprietorship, public limited, private limited, etc: Provide notarized documentary proof.
  - (f) Business registration number as issued by the Registrar of Companies or any other authorized body: Provide notarized documentary proof.
  - (g) Names of partners/proprietors/directors (as per CNIC):
  - (h) Addresses of partners/proprietors/directors (as per CNIC):
  - (i) Date of establishment (as per business registration certificate):
  - (j) Initial investment and details of equity shares: Provide document.
  - (k) Present investment and details of equity shares: Provide document.
  - (l) Profit and loss statement as per audited accounts for last 5 years, if applicable:



- (m) Details of premises including covered area, dimensions, etc. Please provide three copies of clearly visible layout plan and map.
- (n) Details of equipment and machinery for storage and distribution of medical devices (Name, Model, Make and capacity).
- (o) Proof of fee deposited (Deposit slip verified by Statistical Officer, DRAP).
- (p) Name, qualification, registration No, CNIC No. and address of qualified person(s) (Pharmacist) for supervising sale and distribution and other technical staff (Biomedical Engineer , Chemist etc) working. Also provide the following information:
  - i. Three attested copies of the registration certificates issued by the concerned council (attested by concerned Council).
  - ii. Four attested copies of CNIC of each of partners/proprietors/directors and qualified persons.
  - iii. Four attested passport size photographs of each of the partners/proprietors/directors and qualified persons.
  - iv. affidavit binding of the partners/proprietors/directors and qualified persons (on stamp paper duly notarized) mentioning that they:
    - shall comply with the provisions of DRAP Act, 2012 and the rules made there under,
    - have not been convicted of any offence from any court of law,
    - shall inform MDB and the inspector as soon as possible when either of the party ceases to have interest in the licence issued under these rules,
    - Shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the DRAP Act, 2012 and the rules made there under.

**3. Quality management system (Applicability as per existing rules)**

- (a) Has the QMS been certified?
- (b) Provide report and certificate issued by conformity assessment body (CAB):
- (c) Name of CAB:
- (d) CAB registration number:

**4. Post-market surveillance system:**

- (a) Maintenance of distribution records (Summary of procedure/SOP):
- (b) Complaint handling (Summary of procedure/SOP),
- (c) Mandatory problem reporting (Summary of procedure/SOP):
- (d) Recall (Summary of procedure/SOP):
- (e) Field corrective action (Summary of procedure/SOP).

**5. Following details of medical devices intended to be imported:**

- (a) Type of medical device whether it is a general medical device or *in-vitro* diagnostic medical device?
- (b) Classes of medical devices whether Class A, Class B, Class C or Class D:

**6. Declaration** on Stamp Paper duly notarized certifying that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under duly signed and stamped by Owner/Proprietor, Managing Director, CEO.

**7. Any other relevant information that may be required by the MDB.**

**Item No. VI. Checklist for application of Registration of a Medical Device for import under Medical Devices Rules, 2015.**

Medical Devices and Medicated Cosmetics Division drafted checklist for application of registration of a medical device for import on Form 6-A under Medical Devices Rules, 2015 for consideration of Medical Device Board.

**Decision: The Board discussed the checklist point wise in detail and approved the checklist as per existing rules as follow:**

1. Application on prescribed Form-6A under Medical Devices Rules, 2015 (MDR, 2015) for medical devices for import.
  - (i) All information to be provided shall be in English language or notarized copy of English translation.
  - (ii) Each page must be duly signed and stamped by proprietor/director/managing partner.
  - (iii) In case of two or more persons, an affidavit on notarized stamp paper duly signed by each regarding nomination of one person to apply for registration on behalf of others.
  - (iv) Provide all information/documents in electronic form as PDF or non editable format on CD.
2. **Details of Importer:**
  - (i) Name of establishment as per establishment licence (Form-4A).
  - (ii) Complete addresses of establishment as per establishment licence.
  - (iii) Name of responsible persons as per establishment licence.
  - (iv) Establishment licence No., date of issuance and renewal. Attach a copy of valid establishment licence.
  - (v) Telephone number, fax number, email addresses, official websites etc.
3. **General Information:**
  - (i) Medical device brand name.
  - (ii) Does the medical device contain any active ingredients, poison or drug?
  - (iii) Type of medical device whether it is a general medical device or in-vitro diagnostic medical device.
  - (iv) Class of medical device whether Class A, Class B, Class C or Class D.
  - (v) Classification rule, sub-rule and clause that applies to the medical device based on the classification methods of medical device under Chapter-VI of Medical Devices Rules, 2015 to justify the class chosen above.
  - (vi) Medical device category applicable to the device from the medical device technical areas listed in table-4 of the MDR, 2015.
  - (vii) HS code for the medical device, if applicable.
  - (viii) GMDN code for the medical device, if applicable.
  - (ix) Pre-market clearance or approval received from US FDA, TGA Australia, Health Canada, regulatory authorities of EU countries and Japan, if any. Provide certificate of pre-market clearance or approval to show evidence.
  - (x) Name and registration number of conformity assessment body (CAB) by whom conformity assessment of the medical device has been done (**Applicable as per prevailing rules**).

- (xi) Conformity assessment report and certificate for medical device, as applicable. However, if registration of CAB is exempted as per rules, then provide duly notarized & Embassy attested relevant conformity assessment certificates of the medical device.
- (xii) Embassy attested quality management system certificate of manufacturer. If the manufacturing process consists of a number of sub-assembly processes. Quality management system certificate of manufacturing sites where each of these sub-assembly processes are carried out must be provided.
- (xiii) Embassy attested GMP certificate, if any?
- (xiv) Free sale certificate issued by the concerned regulatory authority attested by Embassy of Pakistan in the country of origin.
- (xv) Original Sole agent certificate or agreement with manufacturer abroad with scope of products and validity date, attested by Embassy of Pakistan in the country of origin.
- (xvi) Shelf life as approved in the country of origin. Provide certificate or any document showing regulatory approval of the shelf life in the country of origin.
- (xvii) Complete stability profile to support shelf life.
- (xviii) Unit price of medical device.
- (xix) Storage condition.
- (xx) Attach notarized copy of last inspection report conducted by the concerned regulatory authority or notified body.
- (xxi) Proof of fee deposited (Deposit slip duly verified by Statistical Officer, DRAP).
- (xxii) In case of radiation emitting medical devices/radiological medical devices the applicant shall be required to apply in accordance with Pakistan Nuclear Regulatory Authority (PNRA) guidelines for import.

**4. Information of manufacturer:**

- (i) Provide the details of the manufacturer. The details also include complete address, telephone number, fax number and official website.
- (ii) If the manufacturing process of a medical device consists of a number of sub-assembly processes, the details of all manufacturing sites where each of these sub-assembly processes are carried out must be provided alongwith processes.
- (iii) If multiple sites manufacture the same product, details of each of these sites must be provided incouding design and manufacturing activities?
- (iv) Credentials of the manufacturer abroad (on manufacturer letterhead as per format approved by MDB) attested by Embassy of Pakistan in the country of origin.

**5. Grouping of medical device:**

- (i) Specify medical device grouping that is applicable to the medical device under these rules.
- (ii) Specify whether constituent-components or meical devices that are grouped together are manufactured by the same manufacturer. In case of different manufacturers, specify names and complete addresses of manufacturers alongwith constituent-components or medical devices.
- (iii) List of constituent-components or medical devices that are grouped together.

6. **Information on validation for medical devices with sterile or with measuring function, where applicable.**
7. **Common submission dossier template (CSDT) alongwith supporting documents. CSDT is mandatory for Class C and Class D medical devices and has to be prepared as prescribed under Part-IV of the MDR, 2015.**
8. **Post –market vigilance history:**
  - (i) Please indicate whether the medical device has any history of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies.
  - (ii) Please indicate if the application for registration or the registration of the medical device has been rejected or suspended or cancelled in other countries. Also provide reasons for the rejection, suspension or cancellation of the medical device application or registration.
9. **Declaration of conformity (DoC):** Please attach the complete, signed and notarized DoC alongwith relevant documents. The DoC need to be printed on the manufacturer’s letterhead, filled and signed by the responsible person on the template as specified in MDR, 2015.
10. **This section is applicable only to Class A and Class B medical devices where CSDT is not provided with application.**
  - (i) List all the relevant essential principles applicable to the medical device and rules used to demonstrate conformity to each applicable essential principle. The evidence of conformity shall be provided in tabular form with supporting documentation as required using the format as mentioned under rule 31 of MDR, 2015.
  - (ii) Attach a detailed description of following medical device attributes, as applicable.
    - (a) Complete description of the medical device.
    - (b) Principles of operation or mode of action.
    - (c) Description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device.
    - (d) Description or complete list of various configurations of the medical device to be registered using the format as mentioned in rule 32 of MDR, 2015.
    - (e) Complete description of the key functional elements, its formulation, its composition and its functionality.
    - (f) Explanation of novel features, if any.
    - (g) As appropriate, labelled pictorial representation of the medical device in the form of diagram photographs or drawings with sufficient explanation to understand the drawings and diagram.
    - (h) Intended uses of the medical device.
    - (i) Indications that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended.
    - (j) Instructions for use.
    - (k) Contra-indications.

- (l) Warnings to inform on specific risk or hazard that a user needs to know before using the medical device.
  - (m) Precautions to exercise special care necessary for the safe and effective use of the medical device.
  - (n) Potential adverse effects or side effects.
  - (o) Commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries.
  - (p) List of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in other countries and copies of certificates or approval letters from each country.
  - (q) Specify status of any pending applications in other countries for regulatory approval or marketing clearance.
  - (r) Any other relevant specifications and descriptive information.
- (iii) Report or certificate containing information on the objectives, methodology, results, discussion and conclusions of the biocompatibility tests conducted on materials used in the medical device.
  - (iv) Attach the report or certification containing information on the objectives, methodology, results discussion and conclusion of the pre-clinical physical tests conducted on the medical device.
  - (v) As applicable, attach documentation on software validation studies to verify the correctness of software in medical device. The document shall include the results of all verification, validation and testing performance prior to final release.
  - (vi) As applicable, following information to be provided on medical devices containing biological material:-
    - (a) List of all materials of animals, human, microbial or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin.
    - (b) Detail information concerning the selection of sources or donors.
    - (c) Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances.
    - (d) Process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents.
    - (e) Full description of the system for record keeping allowing traceability from sources to the finished medical device.
  - (vii) As applicable, documentation on clinical evaluation to verify the clinical and performance of the medical device.
  - (viii) Attach documentation on medical device labelling containing the following information:-
    - (a) Sample of labels on the medical device and its packaging;
    - (b) Instructions for installation and maintenance, if applicable;
    - (c) Any information and instructions given to the patient and operator including instructions for any procedure the patient is expected to perform, if applicable, and
    - (d) The promotional material and product brochures.

- (ix) Provide documentaion on risk analysis in the form of a risk management report (RMR).
  - (x) Provide complete documentaion related to the manufactcturing and quality control processes.
12. Any other relevant information that may be required by the MDB.
13. **DECLARATION:** On stamp paper duly notarized certifying that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under duly signed and stamped by director/proprietor/managing partner/owner.

**Item No. VII. CREDENTIAL OF THE MANUFACTURER ABROAD**

For registration of medical devices to be imported, Credentials of manufacturer abroad are required as per form 6-A under Medical Devices Rules, 2015. The Division of MD&MC has drafted following format for the said purpose for consideration of the MDB.

**GENERAL INFORMATION**

*(Each page must be signed and stamped)*

1. Name and address of the applicant (sole agent in Pakistan).
2. Name, address, telephone numbers, fax numbers, email addresses, official website and the status of the manufacturer abroad (private ownership, private limited, public limited, etc).
3. Names and addresses of all manufacturing and processing sites along with activity being performed at each site:-
  - a. Inside country of origin.
  - b. Outside country of origin.
4. Provide a detailed map indicating the location of the site.
5. Provide a site layout plan highlighting all functional areas.
6. Quality Management System (QMS):-
  - a. Has QMS been certified?
  - b. Provide certificate by Conformity Assessment Body.
7. Equipments (Make Model and Capacity) installed for manufacturing of medical devices.
8. Year of Foundation.
9. Which technical personnel are working in different areas and total number of employees.

10. Types of medical devices being manufactured:-
  - a. Are these medical devices totally or partially manufactured by the firm itself?
  - b. If partially manufactured, other processing sites including sterilization sites?
  - c. Research medical devices produced by the firm itself during the last then years.
  - d. Other activities beside medical devices manufacturing.
  - e. Name of countries where products are marketed.
  - f. All these information shall be electronically traceable.
  
11. Do you have research laboratories?
  - a. Numbers of specialized personnel working in these research laboratories (excluding administratives).  
Physicians?  
Pharmacists?  
Chemists?  
Bio medical engineers?  
Others?
  - b. What research activities and trials carried by these laboratories?
  - c. Do you own or have hospitals or medical centers at your disposal for carrying out test and experiments on your products.
  - d. Do you collaborate with universities or scientific centers in research fields; give details.
  
12. Origin of raw materials/components/original equipment manufacturer (OEM) information:-
  - a. Self manufacturing.
  - b. Other sources.
  
13. Do you have quality control laboratories:-
  - a. For testing raw materials.
  - b. For testing final products.
  - c. Types of laboratory tests being performed.
  - d. Number and qualification of personnel working in these laboratories.
  - e. Instruments installed for testing of medical devices.
  
14. Give in details the activities performed by the regulatory authorities or notified bodies for controlling your establishment and its production.
  
15. Name of the products, if any, being exported to Pakistan, which are no more allowed sale or withdrawn in the country of origin.
  
16. Provide a copy of the most recent inspection report or audit report of your establishment attested by the Regulatory Authority (RA) or notarized.
  
17. Photograph of company and of each section.

I, the undersigned (full name of the person responsible for the establishment, hereby declare that all the information, given above is true, and I assume full responsibility for this Declaration with the consequences which might arise from false or erroneous information.

Date.

Name of establishment.

Name, Signature and Stamp.

Legalization of the Pakistani Consulate/ Embassy.

**Decision: The Board approved the above format of Credentials of manufacturer abroad for the purpose of registration of medical devices to be imported.**

Item-VIII. **Guidelines document for Good Distribution Practice for Medical Devices (GDPMD)**

The Medical Device Board in its 2<sup>nd</sup> meeting approved the guidance document on good distribution practice for medical devices (GDPMD). The guidelines document for GDPMD was submitted for the consideration and approval of Authority in its 38<sup>th</sup> meeting is placed at **Annex-A**. The decision of the Authority has not been communicated yet.

**Decision: The MDB approved the guidelines document for GDPMD placed at Annex-A.**

Item No.IX. **Applications for registration of medical devices applied under the Drugs Act, 1976.**

The case for consideration of the applications for registration of medical devices applied as drug under Drugs Act, 1976 before 30-9-2016 (expiry date of Class D medical devices under rule 128 of MDR, 2015) to be dealt under Medical Devices Rules, 2015 has been placed before the Authority in its 38<sup>th</sup> meeting for the policy decision for the consideration of pending applications of medical devices declared as drug under Drug Act, 1976. The decision of the Authority has not been communicated yet.

**Decision: The MDB decided to process such cases in accordance with the decision taken by the Authority in the 38<sup>th</sup> meeting held on 17<sup>th</sup> October, 2016.**



Item-X. **Applications for registration of medical devices (Class D) declared as drug and applied under Drug Act, 1976.**

Following firms have applied for registration of their medical devices (Class D) declared as drug under Drugs Act, 1976. The firms have applied these products on Form 5-A under Drugs (Licensing, registering and advertising) Rules, 1976. Under rule 128 of Medical Devices Rules, 2015 exemption period for Class D medical devices has been expired on 30<sup>th</sup> September, 2016 and these medical devices as per rule 146 of the MDR, 2015 have now to be regulated under MDR, 2015. Under MDR, 2015 establishment (importer or local manufacturer) applying for registration of its medical device shall have relevant establishment license for import or local manufacturing of medical devices. Furthermore, under MDR, 2015 application of medical device shall be applied on Form 6 (for local manufacture) and Form 6-A (for import) along with prescribed documents.

The case for consideration of the applications for registration of medical devices applied as drug under Drugs Act, 1976 before 30-9-2016 (expiry date of Class D medical devices under rule 128 of MDR, 2015) to be dealt under Medical Devices Rules, 2015 notified on 9<sup>th</sup> March, 2015 has been placed before the Authority in its 38<sup>th</sup> meeting for the policy decision for the consideration of pending applications of medical devices declared as drug under Drug Act, 1976.

The decision of the Authority has not been communicated yet.

S.No	Name of Importer and Manufacture/Exporter.	Name of Medical Device (s) Composition & Therapeutic Group.	Demanded price & Pack size	Shelf life
1.	M/s. SES Associates Institutional Distributors & Government Suppliers, Lahore <b>Manufactured by</b> M/s. Kimal Plc. Arundel Road, Uxbridge, Middlesex, UB8, United Kingdom.	Catheter Cardiology Angio FLOW	Decontrolled till policy decision by Policy Board/ Federal Government (all sizes & all types)	02 years
2.	M/s Intek Corporation, # 30,1 <sup>st</sup> Floor, Al-Amin Plaza, The Mall, Rawalpindi. <b>Manufactured by</b>	Heartrail II Guiding Catheter.	Decontrolled till policy decision by Policy Board/ Federal	18 months

	M/s Terumo Corporation, 44-1-2 Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. <b><u>Shipped From (Sales and Marketing Office):</u></b> M/s Terumo Corporation Dubai Branch, Arbift Tower, Dubai, UAE.		Government	
3.	M/s Intek Corporation, # 30,1 <sup>st</sup> Floor, Al-Amin Plaza, The Mall, Rawalpindi. <b>Manufactured by</b> M/s Terumo Corporation, 44-1-2 Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. <b><u>Shipped From (Sales and Marketing Office):</u></b> M/s Terumo Corporation Dubai Branch, Arbift Tower, Dubai, UAE	Radifocus Optitorque Angiographic Catheters.	Decontrolled till policy decision by Policy Board/ Federal Government	18 months
4.	M/s Intek Corporation, # 30,1 <sup>st</sup> Floor, Al-Amin Plaza, The Mall, Rawalpindi. <b>Manufactured by</b> M/s Terumo Corporation, 44-1-2 Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. <b><u>Shipped From (Sales and Marketing Office):</u></b> M/s Terumo Corporation Dubai Branch, Arbift Tower, Dubai, UAE	Ryujin Plus/Ryujin Plus OTW, PTCA Dilatation Catheter.	Decontrolled till policy decision by Policy Board/ Federal Government	18 months
5.	M/s Surgi World, 303 Mohammadia Plaza, College Road, Rawalpindi. <b>Manufactured by</b> M/s Medcomp , 1499 Delp Drive Harleys Villa, USA.	Pro-Picc ® Central Vein Infusion Catheter. (All sizes)	Decontrolled till policy decision by Policy Board/ Federal Government	5 years
6.	M/s Surgi World, 303 Mohammadia Plaza, College Road, Rawalpindi. <b>Manufactured by</b> M/s Medcomp , 1499 Delp Drive Harleys Villa, USA.	Vascu-Picc ® Central Vein Infusion Catheter (All sizes)	Decontrolled till policy decision by Policy Board/ Federal Government	5 years

7.	M/s Surgi World, 303 Mohammadia Plaza, College Road, Rawalpindi. <b>Manufactured by</b> M/s Medcomp , 1499 Delp Drive Harleys Villa, USA.	Pro-Fuse ® CT Ports (Central Vein Infusion Catheter with port) (All sizes)	Decontrolled till policy decision by Policy Board/ Federal Government	5 years
8.	M/s Surgi World, 303 Mohammadia Plaza, College Road, Rawalpindi. <b>Manufactured by</b> M/s Medcomp , 1499 Delp Drive Harleys Villa, USA.	Multi-Cath Central Vein Infusion Catheter (All sizes, Single, Double and Triple Lumen)	Decontrolled till policy decision by Policy Board/ Federal Government	5 years
9.	M/s Johnson & Johnson (Pvt) Ltd, Plot.No.10 & 25, Sector 20, Korangi Industrial Area, Karachi. <b>Legal Manufacturer</b> M/s Codman & Shurtleff, Inc. 325 Paramount Drive Raynham, MA, USA.  <b>Manufacturing Site:</b> M/s Codman & Shurtleff. Calle Cirrcuito Interior Norte No.1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP 32575, Mexico.  <b>Exporting &amp; Releasing Site</b> European Distribution Cente, Johnson & Johnson, Belgium.	Envoy Guiding Catheters - Envoy 5f - Envoy 6f - Envoy-XB	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
10.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway Ireland. <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Sprinter NC/SC RX Balloon Dilatation, Intravascular Catheters.	Decontrolled till policy decision by Policy Board/ Federal Government	24 months
11.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Ireland,	Sprinter Legend RX Balloon Dilatation, Intravascular Catheters.	Decontrolled till policy decision by Policy Board/	24 months

	Parkmore Business Park West, Galway Ireland. <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.		Federal Government	
12.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Mexico s.de R.L.de CV, Mexico <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Sprinter Legend RX Balloon Dilatation, Intravascular Catheters.	Decontrolled till policy decision by Policy Board/ Federal Government	24 months
13.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Mexico s.de R.L.de CV, Mexico <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Catheters.	Decontrolled till policy decision by Policy Board/ Federal Government	24 months
14.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic, Inc, USA <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Catheters.	Decontrolled till policy decision by Policy Board/ Federal Government	36 months
15.	M/s Claris Medical, 54-A, Street 5, Sector F-8/3, Islamabad./ <b>Manufactured by:</b> M/s Biotronic AG Ackerstrasse 6, 8180 Bulach, Switzerland. <b>Contract Medical International GmbH</b> Lauensteiner Strasse 37, 01277 Dresden, Germany.	Pantera Coronary Balloon  Balloon Length (mm) 6,10,15,20,25,30.  Balloon Dia (mm): 1.25, 1.5, 2.0, 2.5,3.0, 3.5, 4.0.	Decontrolled till policy decision by Policy Board/ Federal Government	Not mention ed.

16.	M/s Claris Medical, 54-A, Street 5, Sector F-8/3, Islamabad./ <b>Manufactured by:</b> M/s Biotronic AG Ackerstrasse 6, 8180 Bulach, Switzerland. <b>Contract Medical International GmbH</b> Lauensteiner Strasse 37, 01277 Dresden, Germany.	Pantera Leo- Non- Compliant High Pressure Balloon.  Balloon Length (mm) 8,12,15,20,30.  Balloon Dia (mm): 2.0, 2.25,2.5, 2.75, 3.0, 3.25, 3.5, 3.75, 4.0, 4.50, 5.00.	Decontrolled till policy decision by Policy Board/ Federal Government	Not mention ed.
17.	M/s. SES Associates Distributors & Government Suppliers, Lahore Manufactured by M/s. QualiMed Innovative Medizinproduket GmbH, Winsen, Germany.	Juturna-V <sup>TM</sup> PTA Balloon Catheter  Balloon Length (mm): 20,30,40,50,60,80,100, 120.  Balloon Dia (mm): 3,4,5,6,7,8,9,10,12, 14.  Usable Catheter Length : 50cm, 75cm, 135cm.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
18.	M/s. SES Associates Distributors & Government Suppliers, Lahore <b>Manufactured by</b> M/s. Kimal Plc. Arundel Road, Uxbridge, Middlesex, UB8, 2SA,U.K <b>Manufacturing Site:</b> Sher Wood Road, Aston Fields Industrial Estate, Bromsgrove, Worcesterhire, UK.	Central Venous Catheter Altius. Sizes, types and products codes as per FSC.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
19.	M/s Cardiac Care, 848-C, Shadman-I, Lahore. <b>Manufactured by</b> M/s Vygon-5 rue Adeline - 95440-Ecouen, France.	Leader Cath (CVC) Codes: 115.090, 115.092, 115.094 115.096, 115.11, 115.118	Decontrolled till policy decision by Policy Board/ Federal Government	60 months
20.	M/s Cardiac Care, 848-C, Shadman-I, Lahore. <b>Manufactured by</b> M/s Vygon-5 rue Adeline - 95440-Ecouen, France.	Multicath 2, Multicath 3.  Codes of Multicath 2: 6202.20, 6202.24, 6202.27, 6204.17.  Codes of Multicath 3: 6208.25, 6209.25.	Decontrolled till policy decision by Policy Board/ Federal Government	60 months

21.	M/s. Ontech Corporation, Karachi. <b>Manufactured by</b> M/s. Ameco Medical Industries, Industrial Zone, Ramadan City, Egypt.	Central Venous Catheters	Decontrolled till policy decision by Policy Board/ Federal Government	05 years
22.	M/s. Saru International, Karachi. M/s. Nanchang Biotek Medical Device Co. Ltd., Nanchang City, China.	Healthicon, Central Venous Catheter/ Kit -Single/ Double /Triple Lumen (Infusion Series).	Decontrolled till policy decision by Policy Board/ Federal Government	05 years
23.	M/s. TM Marketing, Karachi. / <b>Manufactured by</b> M/s. ClearStream Technologies Ltd., Moyne Upper, Enniscorthy Co. Wexford, Ireland.	Nimbus Pico U PTCA Catheter (Catheter).	Decontrolled till policy decision by Policy Board/ Federal Government	03 years
24.	M/s. TM Marketing, Karachi. / <b>Manufactured by</b> M/s. ClearStream Technologies Ltd., Moyne Upper, Enniscorthy Co. Wexford, Ireland.	Nimbus Salvo PTCA Catheter (Catheter).	Decontrolled till policy decision by Policy Board/ Federal Government	03 years
25.	M/s. TM Marketing, Karachi. / <b>Manufactured by</b> M/s. Merit Medical Systems, Inc. South Jordan, Utah, U.S.A. <b>Manufacturing location:</b> Merit Medical System, Inc, 1111 South Velasco Angleton, TX 77515 USA.	Concierge Guiding Catheter	Decontrolled till policy decision by Policy Board/ Federal Government	03 years
26.	M/s. TM Marketing, Karachi. / <b>Manufactured by</b> M/s. Merit Medical Systems, Inc. South Jordan, Utah, U.S.A. <b>Manufacturing location:</b> Merit Medical System, Inc, 1111 South Velasco Angleton, TX 77515 USA.	Performa ®, Softouch ® Diagnostic Catheter	Decontrolled till policy decision by Policy Board/ Federal Government	03 years

27.	M/s. Intek Corporation, Rawalpindi. <b>Manufactured by</b> M/s. Lepu Medical Technology (Beijing) Co., Ltd., Xicheng District, Beijing, China.	“Hoper” PTCA Balloon Dilatation Catheter (PTCA Balloon Dilatation Catheter)	Decontrolled till policy decision by Policy Board/ Federal Government	02 years
28.	M/s. Maxims Medical, Lahore. <b>Responsible Manufacturer:</b> M/s. Abbott Vascular Lakeside Drive, California, USA. <b>Manufacturing Site:</b> M/s. Abbott Vascular, Instruments Deutsuhland, Rangendingen, Germany.	Mercury PTCA Balloon Catheter	Decontrolled till policy decision by Policy Board/ Federal Government	02 years
29.	M/s. Maxims Medical, Lahore. <b>Responsible Manufacturer:</b> M/s. TemMed Medical Co. Ltd., Beijing, P.R. China.	Path Maker PTCA Balloon Catheter	Decontrolled till policy decision by Policy Board/ Federal Government	02 years
30.	M/s Intek Corporation, # 30,1 <sup>st</sup> Floor, Al-Amin Plaza, The Mall, Rawalpindi. <b>Manufactured by</b> M/s Terumo Corporation, 44-1-2 Chome, Hatagaya, Shibuya-ku, Tokyo, Japan. <b><u>Shipped From</u></b> <b><u>(Marketing and Sales</u></b> <b><u>Office:</u></b> M/s Terumo Corporation Dubai Branch, Arbift Tower, Dubai, UAE.	Progreat Micro Catheter System  Dia.(mm): 2.0,.2.2, 2.4, 2.7, 2.8.  Length (cm): 110, 130, 150.	Decontrolled till policy decision by Policy Board/ Federal Government	18 months
31.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> M/s.Datascope Corporation, `15 Law Drive, Fairfield, New Jersey 7400, USA. <b>Shipped From</b>	Sensation Plus Intra Aortic Balloon Catheter.  7 FR	Decontrolled till policy decision by Policy Board/ Federal Government 1’s	Not mention ed in form 5- A.

	M/s Maquet Middle East FZ-LLC, G005 Nucleotide Complex, Dubai Biotechnology & Research Park, P.O.Box 214742.			
32.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> M/s.Datascope Corporation, `15 Law Drive, Fairfield, New Jersey 7400, USA. <b>Shipped From</b> M/s Maquet Middle East FZ-LLC, G005 Nucleotide Complex, Dubai Biotechnology & Research Park, P.O.Box 214742.	Linear Intra Aortic Balloon Catheter.  7.5 FR.	Decontrolled till policy decision by Policy Board/ Federal Government 1's	Not mentioned in form 5-A.
33.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> M/s.Datascope Corporation, `15 Law Drive, Fairfield, New Jersey 7400, USA. <b>Shipped From</b> M/s Maquet Middle East FZ-LLC, G005 Nucleotide Complex, Dubai Biotechnology & Research Park, P.O.Box 214742.	Mega Intra Aortic Balloon Catheter.	Decontrolled till policy decision by Policy Board/ Federal Government 1's	Not mentioned in form 5-A.
34.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> 1. M/s.NuMed, Inc 2880 Main Street, Hopkinton, NY, 12965, USA.	Z-Med II Catheter.  Balloon Dia (mm): 23, 25, 26, 28, 30.  Balloon Length (cm): 2, 3, 4, 5,6.	Decontrolled till policy decision by Policy Board/ Federal Government 1's	Not mentioned in form 5-A.



	2. M/s.NuMed Canada, Inc 45 Second Street West, Cornwall, Ontario K6J1G3, Canada.			
35.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> 1. M/s.NuMed, Inc 2880 Main Street, Hopkinton, NY, 12965, USA. 2. M/s.NuMed Canada, Inc 45 Second Street West, Cornwall, Ontario K6J1G3, Canada.	Tyshak II Catheter (GMDN Code 17453).  Balloon Dia (mm): 12, 13, 14, 15, 16, 17, 18, 20, 22, 23, 25, 30.  Balloon Length (cm): 2, 3, 4, 5,6.	Decontrolled till policy decision by Policy Board/ Federal Government 1's	Not mentioned in form 5-A.
36.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> 1. M/s.NuMed, Inc 2880 Main Street, Hopkinton, NY, 12965, USA. 2. M/s.NuMed Canada, Inc 45 Second Street West, Cornwall, Ontario K6J1G3, Canada.	Z-5 Catheter. (GMDN Code 10747). Balloon Dia (mm): 9.5, 13.5. Balloon Length (cm): 0.95, 1.35.	Decontrolled till policy decision by Policy Board/ Federal Government 1's	Not mentioned in form 5-A.
37.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> 1. M/s.NuMed, Inc 2880 Main Street, Hopkinton, NY, 12965, USA. 2. M/s.NuMed Canada, Inc 45 Second Street West, Cornwall, Ontario K6J1G3, Canada.	BIB Stent Placement Catheter  Balloon Length (mm): 12, 14, 15, 16, 18, 20, 22, 24.  Balloon Dia (cm): 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5.	Decontrolled till policy decision by Policy Board/ Federal Government 1's	Not mentioned in form 5-A.

38.	M/s Hakimsons (Pvt) Ltd, Hakimsons House, A/56/S.I.T.E. Manghopir Pir Road, Karachi. <b>Manufactured by:</b> 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.	Xperience Coronary Balloon Dilatation Catheter  Balloon Length (mm): 10, 15, 20, 25,30, 40.  Balloon Dia (cm): 1.50, 2.00, 2.50, 3.00, 3.50, 4.00, 4.50.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years.
39.	M/s Hakimsons (Pvt) Ltd, Hakimsons House, A/56/S.I.T.E. Manghopir Pir Road, Karachi. <b>Manufactured by:</b> 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.	Oceanus 35 PTA Balloon Dilatation Catheter  Balloon Length (mm): 20, 40, 60, 80,120, 150, 200.  Balloon Dia (cm): 5, 6, 7,8, 9, 10, 12.  Catheter Length (cm): 80, 140.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years.
40.	M/s Hakimsons (Pvt) Ltd, Hakimsons House, A/56/S.I.T.E. Manghopir Pir Road, Karachi. <b>Manufactured by:</b> 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.	Oceanus 14 Peripheral Balloon Dilatation Catheter  Balloon Length (mm): 40, 60, 80,120, 150, 200.  Balloon Dia (cm): 1.5, 2.0, 2.5, 3.0, 3.5, 4.0.  Catheter Length (cm): 100, 150.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years.
41.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5,Main Boat Basin, Clifton, Karachi. <b>Legal Manufacturer</b> M/s Cordis Corporation, 14201 North West 60 <sup>th</sup> Avenue,Miami Lakes, FL 33014, USA	ADROIT <sup>TM</sup> Guiding Catheter.  Useable Catheter Length (cm): 55, 90, 100, 125.  Size: 6 F	Decontrolled till policy decision by Policy Board/ Federal Government	3 years

	<p><b>Physical Manufacturer:</b> M/s Cordis de Mexico, S.A. de C.V. Circuito Interior Norte # 1820 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua Mexico 32574.</p>			
42.	<p>M/s. Surgismart, Lahore <b>Manufactured by</b> M/s. Inshitra Medical INC, 9200 Irvine Centre Drive Suit, 200 Irvine CA 92618</p>	<p>Inshitra Ultra IABP Catheter Kit.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>5 years</p>
43.	<p>M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> 1. M/s.NuMed, Inc 2880 Main Street, Hopkinton, NY, 12965, USA.  2. M/s.NuMed Canada, Inc 45 Second Street West, Cornwall, Ontario K6J1G3, Canada.</p>	<p>Bonhoeffer Multi-Track Mitral Dilatation Kit.</p> <p>Balloon Length (mm): 12, 14, 15, 16, 18, 20, 22, 24.</p> <p>Balloon Dia (cm): 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5.</p>	<p>Decontrolled. 1's</p>	<p>Not mention ed in form 5- A.</p>
44.	<p>M/s Johnson &amp; Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5,Main Boat Basin, Clifton, Karachi. <b>Legal Manufacturer:</b> M/s Cordis Cashel, Cahir Road, Cashel, Co. Tipperary, Ireland. <b>Physical Manufacturer:</b> M/s Cordis de Mexico, S.A. de C.V. Circuito Interior Norte # 1820 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua CP 32574 Mexico.</p>	<p>Aviator Plus PTA Balloon Dilatation Catheter</p>	<p>Decontrolled till policy decision by the Federal Government</p>	<p>3 years</p>

45.	<p>M/s Intek Corporation, No.30, 1<sup>st</sup> Floor, Al-Amin Plaza, The Mall, Rawalpindi/ <b>Manufactured by</b> M/s OrbusNeich Medical B.V. Drs. W.Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands.</p>	<p>Sphire II NC Coronary Dilatation Catheter</p> <p>Balloon Length (mm): 8, 10, 12, 15, 18.</p> <p>Balloon Dia (cm): 1.75, 2.00, 2.25, 2.50, 2.75, 3.0, 3.25, 3.50.</p>	<p>Decontrolled till policy decision by the Policy Board/ Federal Government</p>	24 months																																														
46.	<p>M/s Johnson &amp; Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5,Main Boat Basin, Clifton, Karachi. <b>Legal Manufacturer:</b> M/s Cordis Cashel Cahir Road, Cashel Co. Tipperary, Ireland. <b>Physical Manufacturers:</b> M/s Cordis de Mexico, S.A. de C.V. Circuito Interior Norte # 1820 Parque Industrial Salvarcar Ciudad Juarez, Chihuahua CP 32574 Mexico.</p>	<p>Slalom PTA Balloon Dilatation Catheter</p> <table border="1" data-bbox="695 625 1036 1904"> <tr><td>438-3020T</td><td>438-8020S</td></tr> <tr><td>438-3020S</td><td>438-8040S</td></tr> <tr><td>438-3020X</td><td>438-6040M</td></tr> <tr><td>438-3020M</td><td>438-6040MP</td></tr> <tr><td>438-3040T</td><td>438-6040XP</td></tr> <tr><td>438-3040S</td><td>438-7020T</td></tr> <tr><td>438-3040X</td><td>438-7020S</td></tr> <tr><td>438-3040M</td><td>438-7020X</td></tr> <tr><td>438-4020T</td><td>438-7020M</td></tr> <tr><td>438-4020S</td><td>438-7040T</td></tr> <tr><td>438-7040M</td><td>438-7040S</td></tr> <tr><td>438-8020X</td><td>438-7040X</td></tr> <tr><td>438-8040M</td><td>438-8020M</td></tr> <tr><td>438-4020X</td><td>438-8040X</td></tr> <tr><td>438-4020M</td><td>439-3020-T</td></tr> <tr><td>438-4040T</td><td>439-4020-T</td></tr> <tr><td>438-4040S</td><td>439-5020-T</td></tr> <tr><td>438-4040X</td><td>439-6020-T</td></tr> <tr><td>438-4040M</td><td>439-7020-T</td></tr> <tr><td>438-5020T</td><td>439-8020-T</td></tr> <tr><td>438-5020S</td><td>439-3020-</td></tr> <tr><td>438-5020X</td><td></td></tr> <tr><td>438-</td><td></td></tr> </table>	438-3020T	438-8020S	438-3020S	438-8040S	438-3020X	438-6040M	438-3020M	438-6040MP	438-3040T	438-6040XP	438-3040S	438-7020T	438-3040X	438-7020S	438-3040M	438-7020X	438-4020T	438-7020M	438-4020S	438-7040T	438-7040M	438-7040S	438-8020X	438-7040X	438-8040M	438-8020M	438-4020X	438-8040X	438-4020M	439-3020-T	438-4040T	439-4020-T	438-4040S	439-5020-T	438-4040X	439-6020-T	438-4040M	439-7020-T	438-5020T	439-8020-T	438-5020S	439-3020-	438-5020X		438-		<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	3 years
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47.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5,Main Boat Basin, Clifton, Karachi. <b>Manufacturer:</b> M/s Clear Stream Technologies Ltd, Moyne Upper Enniscorthy County Wexford, Ireland.	Sleek PTA Balloon Dilatation Catheter  (Sizes as per Free Sale Certificate).	Decontrolled till policy decision by Policy Board/ Federal Government	3 years	

48.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b>Manufacturer:</b> M/s Clear Stream Technologies Ltd, Moyne Upper Enniscorthy County Wexford, Ireland.	Sleek OTW PTA Balloon Dilatation Catheter  Balloon Length (mm): 20, 40, 80, 100, 120, 150, 220, 280.  Balloon Dia (cm): 1.75, 2.00, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0.	Decontrolled till policy decision by Policy Board/ Federal Govt.	3 years
49.	M/s B.Braun Pakistan (Pvt) Limited, The Forum Suite # 216, Khayaban-e-Jami, Clifton Block-9, Karachi/ <b>Manufacturer:</b> M/s Pendra Care International B.V. Van der Waalspark 22, 9351 VC Leek, The Netherlands.	Serpia Hydorphilic Guiding Catheter.  5Fr, 6Fr, 7Fr, 8Fr.  (Diff. product codes available)	Decontrolled till policy decision by Policy Board/ Federal Govt.	3 years
50.	M/s. Health Tec, 10-B, Street No.24, Valley Road, Westrige-I Rawalpindi. <b>Manufacturer:</b> M/s PendraCare International B.V. Van der Waals Park 22, 9351 VC Leek, The Netherlands.	Pointer Angiographic Catheter.  Sizes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
51.	M/s Genus, 220, D.M.C.H.S, Block-3 Sirajuddaula Road, Karachi. <b>Manufactured By:</b> M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA.	Hawk Non Compliant Coronary Balloon Catheter.  Sizes and codes as per Free Sale Certificate.	Decontrolled till policy decision by the Policy Board/Federal Government	2 years
52.	M/s Genus, 220, D.M.C.H.S, Block-3 Sirajuddaula Road, Karachi. <b>Manufactured By:</b> M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA.	Falcon Guiding Catheter  Sizes and codes as per Free Sale Certificate.	Decontrolled till policy decision by the Policy Board/Federal Government	3 years

53.	M/s Genus, 220, D.M.C.H.S, Block-3 Sirajuddaula Road, Karachi. <b>Manufactured By:</b> M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA.	Hawk Semi Compliant PTCA Coronary Balloon Catheter.  Sizes and codes as per Free Sale Certificate.	Decontrolled till policy decision by the Policy Board/Federal Government	2 years
54.	M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752. USA <b>Manufacturing Site:</b> M/s. Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland.	Flextome™ Cutting Balloon™ Monorail™ Microsurgical Dilatation Device  Balloon Length (mm): 06, 10, 15, 20, 24, 28, 32.  Balloon Dia (mm) 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.76, 4.00.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
55.	M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752. USA <b>Manufacturing Site:</b> M/s. Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland.	NC Emerge™ Monorail™ PTCA Dilatation Catheter  Balloon Length (mm): 6, 8, 12, 15, 20, 30.  Balloon Dia (mm) 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.76, 4.00, 4.50, 5.00,5.50, 6.00.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
56.	M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752. USA <b>Manufacturing Site:</b>	Runway™ Guide Catheter  Product code and sizes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years

	M/s. Availmed S.A de C.V. Av. Paseo Reforma No.8950, C.P.22116 La Mesa, Tijuana Baja California, Mexico.			
57.	M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s Pendra Care International B.V. Van der Waals park 22, 9351 VC Leek, Netherland. <b>Manufacturing Site:</b> M/s Pendra Care International B.V. Van der Waals park 22, 9351 VC Leek, Netherland.	Convey™ Guiding Catheter  Product code and sizes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
58.	M/s ACP System. 13,Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi/ <b>Legal Manufacturer:</b> M/s Medtronic, Inc, 710 Medtronic Parkway N.E., Minneapolis, 55432, USA. <b>Manufacturing Facility:</b> M/s Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah, 10510 El Lago, C.P.22210 Tijuana, Baja California, Mexico. <b>EC Authorized Representative:</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland.	Euphora Rapid Exchange Balloon Dilatation Catheter  Product code and sizes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	2 years
59.	M/s 4S International, Suit No.205, 2 <sup>nd</sup> Floor, Rashid Minhas Road, Block-10-A, Gulshan-e-Iqbal, Karachi/ <b>Manufactured By:</b> M/s Balton Sp. Z o.o. ul. Nowy Swiat 7, m. 14, 00- 496 Warszawa, Poland.	Fryderyk Coronary Angioplasty Catheter  Balloon Length (mm): 10, 15, 20, 25, 30, 35, 40.  Balloon Dia (mm) 1.5, 1.75, 2.0, 2.25, 2.5, 2.75, 3.00, 3.25, 3.5, 3.75, 4.0, 4.5, 5.0.	Decontrolled till policy decision by Policy Board/ Federal Government	4 years & 11 months



60.	M/s. Health Tec, 10-B, Street No.24, Valley Road, Westrige-I Rawalpindi. <b>Manufacturer:</b> M/s PendraCAre International B.V. Vander Waals Park 22, 9351 VC Leek, The Netherlands.	Primum Hydrophilic Guiding Catheter.  Sizes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	3 years
61.	M/s. ACP System, 13-23, Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi. <b>Legal Manufacturer:</b> M/s Medtronic, Inc. 710 Medtronic Parkway NE Minneapolis, MN 55432, USA. <b>Manufacturing Site:</b> M/s Availmed S.A. De C.V. Av. Paseo Reform No. 8950 Interior (B1, C1, E1, E2, F2, G1) (Local A.B.C.G.H) La Mesa, Tijuana, Baja California 22116, Mexico.	Pro-Flo Diagnostic Angiography Catheters  Types, Sizes & Models as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
62.	M/s. ACP System, 13-23, Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi. <b>Legal Manufacturer:</b> M/s Medtronic, Inc. 710 Medtronic Parkway NE Minneapolis, MN 55432, USA. <b>Manufacturing Site:</b> M/s Availmed S.A. De C.V. Av. Paseo Reform No. 8950 Interior (B1, C1, E1, E2, F2, G1) (Local A.B.C.G.H) La Mesa, Tijuana, Baja California 22116, Mexico.	Site Seer Cardiovascular Diagnostic Angiography Catheters  Types, Sizes & Models as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	3 years
63.	M/s. ACP System, 13-23, Naval Fleet Club, Iqbal (S.J) Shaheed Road,	Launcher Guiding Catheters	Decontrolled till policy decision by	2 years

	<p>Karachi.  <b>Legal Manufacturer:</b>  M/s Medtronic, Inc.  710 Medtronic Parkway  NE Minneapolis, MN  55432, USA.  <b>Manufacturing Site:</b>  M/s Availmed S.A. De  C.V. Av. Paseo Reform No.  8950 Interior (B1, C1, E1,  E2, F2, G1) (Local  A.B.C.G.H) La Mesa,  Tijuana, Baja California  22116, Mexico.</p>	Types, Sizes & Models as per Free Sale Certificate.	Policy Board/ Federal Government	
64.	<p>M/s. ACP System,  13-23, Naval Fleet Club,  Iqbal (S.J) Shaheed Road,  Karachi.  <b>Legal Manufacturer:</b>  M/s Medtronic, Inc.  710 Medtronic Parkway  NE Minneapolis, MN  55432, USA.  <b>Manufacturing Site:</b>  M/s Availmed S.A. De  C.V. Av. Paseo Reform No.  8950 Interior (B1, C1, E1,  E2, F2, G1) (Local  A.B.C.G.H) La Mesa,  Tijuana, Baja California  22116, Mexico.</p>	<p>Sherpa NX Guiding  Catheters</p> <p>Types, Sizes &amp; Models as per Free Sale Certificate.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	2 years
65.	<p>M/s. Promed International,  CB-6349 Amarpak Plaza,  Jhelum Road, Rawalpindi.  <b>Legal Manufacturer:</b>  M/s Biosensors Europe SA,  Rue De Lausanne 29, 1110  Morges, Switzerland.  <b>Manufacturing Site:</b>  M/s Biosensors  Interventional  Technologies Pte Ltd, 36  Jalan Tukang, Singapore  619266, Singapore.</p>	<p>Powerline™ PTCA  Catheter</p> <p>Balloon Dia (mm):  1.5, 2.0, 2.5, 2.75, 3.0, 3.5,  4.0.</p> <p>Balloon Length (mm):  10, 15, 20, 25, 30.</p>	Decontrolled till policy decision by Policy Board/ Federal Government  1's	36 months

66.	M/s Hashir Surgical Services (Pvt) Ltd, 1 <sup>st</sup> Floor, House No.16, Street 1, Sector F-2, Phase-6, Hayatabad, Peshawar <b>Manufactured By:</b> M/s Intra Special Catheter GmbH, Oststrasse 2, 66780 Rehlingen-Siersburg, Germany	Venoseld Central Venus Catheter-I Lumen.  <b>Sizes:</b> 14G, 16G, 18G, 20G,24G.  <b>Length (cm):</b> 9, 13, 16, 20, 30.	Decontrolled till policy decision by the Policy Board/Federal Government	5 years
67.	M/s Hashir Surgical Services (Pvt) Ltd, 1 <sup>st</sup> Floor, House No.16, Street 1, Sector F-2, Phase-6, Hayatabad, Peshawar <b>Manufactured By:</b> M/s Intra Special Catheter GmbH, Oststrasse 2, 66780 Rehlingen-Siersburg, Germany	Trilucath Central Venous Catheter-3 Lumen.  <b>Sizes:</b> 5.5F, 7F, 8.5F. <b>Length (cm):</b> 8, 13, 16, 20, 30.	Decontrolled till policy decision by the Policy Board/ Federal Government	5 years
68.	M/s Hashir Surgical Services (Pvt) Ltd, 1 <sup>st</sup> Floor, House No.16, Street 1, Sector F-2, Phase-6, Hayatabad, Peshawar <b>Manufactured By:</b> M/s Intra Special Catheter GmbH, Oststrasse 2, 66780 Rehlingen-Siersburg, Germany	Duocath Central Venus Catheter 2-Lumen.  <b>Sizes:</b> 4F, 5F, 7F, 8F.  <b>Length (cm):</b> 5, 6, 8, 10, 13, 15, 20, 30.	Decontrolled till policy decision by the Policy Board/ Federal Government	5 years
69.	M/s Hashir Surgical Services (Pvt) Ltd, 1 <sup>st</sup> Floor, House No.16, Street 1, Sector F-2, Phase-6, Hayatabad, Peshawar <b>Manufactured By:</b> M/s Intra Special Catheter GmbH, Oststrasse 2, 66780 Rehlingen-Siersburg, Germany	Quadrocath Central Venus Catheter 4-Lumen.  <b>Sizes:</b> 8.5F.  <b>Length (cm):</b> 16, 20, 30.	Decontrolled till policy decision by the Policy Board/ Federal Government	5 years
70.	M/s. Ferozsos Laboratories Limited, P.O. Ferozsos, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way.	Coyote <sup>TM</sup> ES Monorail <sup>TM</sup> PTA Balloon Dilatation Catheter.  Balloon Dia (mm): 1.5, 2.0, 2.5,3.0, 3.5, 4.0.  Balloon Length (mm):	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

	<p>Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN55311, USA</p> <p><b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, RI 02816, USA.</p> <p>M/s Isotron Ireland Limited, IDA Business &amp; Technology Park, Tullamore, County Offaly, Ireland.</p>	40, 60, 80, 100, 120, 150, 220.		
71.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN55311, USA</p> <p><b>Sterilization Sites:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, Rhode Island, USA.</p> <p>M/s Synergy Health Ireland Limited (Tullamore), IDA Business &amp; Technology Park, Tullamore, County Offaly, Ireland.</p> <p>M/s Synergy Health Ede B.V (Venlo) Faunalaan 38, 5928 RZ Vanlo, The Netherlands.</p>	<p>Coyote™ Monorail™ PTA Balloon Dilatation Catheter.</p> <p>Balloon Dia (mm): 1.5, 2.0, 2.5,3.0, 3.5, 4.0.</p> <p>Balloon Length (mm): 20,30, 40.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

72.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA</p> <p><b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, RI 02816, USA.</p> <p>M/s Isotron Ireland Limited, IDA Business &amp; Technology Park, Tullamore, County Offaly, Ireland.</p>	<p>Coyote™ ES Over The Wire™ PTA Balloon Dilatation Catheter.</p> <p>Balloon Dia (mm): 1.5, 2.0, 2.5,3.0, 3.5, 4.0.</p> <p>Balloon Length (mm): 20, 30, 40.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	25 months
73.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Ballybrit Business Park, Galway , Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health Ireland Ltd, (Synergy Health-AST- Ireland), IDA Business and Technology Park, Sragh Tullamore Co. Offaly, Ireland.</p>	<p>Mustang™ Over The Wire™ PTA Balloon Dilatation Catheter.</p> <p>Balloon Dia (mm): 3, 4, 5, 6, 7, 8, 9, 10, 12.</p> <p>Balloon Length (mm): 20, 30, 40, 60, 80, 100, 120, 150, 180, 200.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

	<p>M/s Synergy Health AST, Venlo Faunalaan 38, 5928 RZ Venlo, Netherlands.</p> <p>M/s Boston Scientific Corporation. 8 Industrial Drive Coventry, RI 02816, USA.</p> <p>STERIS Isomedix Services, 3459 South Clinton Avenue, South Plainfield, New Jersey 07080, USA.</p> <p>M/s Synergy Health AST, SRL, B13.1, Street 4, Avenue 1, EI Coyol Free Zone, EL Coyol Alajeula 20102, Costa Rica.</p>			
74.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Business and Technology Park, Model Farm Road, Cork , Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health Ireland Ltd, (Synergy Health-AST- Ireland), IDA Business and Technology Park, Sragh Tullamore Co. Offaly, Irelamabd.</p>	<p>Renegade Fiber Braided Microcatheter.</p> <p>Product codes and sizes as per Free Sale Certificate.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>37 months</p>
75.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b></p>	<p>Imager™ II Angiographic Catheter.</p> <p>Product codes and sizes as per Free Sale Certificate.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal</p>	<p>25 months</p>

	<p>M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Teleflex Medical, Unit 7,8 &amp; 9, Annacotty Business Park, Annacotty Country Limerick, Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health Ireland Ltd, (Synergy Health-AST- Ireland), IDA Business and Technology Park, Sragh Tullamore Co. Offaly, Ireland.</p>		Government	
76.	<p>M/s. Ferozsos Laboratories Limited, P.O. Ferozsos, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN55311, USA</p> <p><b>Sterilization Sites:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, Rhode Island, USA.</p> <p>M/s Synergy Health Ireland Limited (Tullamore), IDA Business &amp; Technology Park, Tullamore, County Offaly, Ireland.</p> <p>M/s Synergy Health Ede B.V (Venlo) Faunalaan 38, 5928 RZ Vanlo, The Netherlands.</p>	<p>Coyote™ Over The Wire PTA Balloon Dilatation Catheter.</p> <p>Balloon Dia (mm): 1.5, 2.0, 2.5,3.0, 3.5, 4.0.</p> <p>Balloon Length (mm): 40, 60, 80,100, 120,150, 220.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

77.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p> <p><b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, Rhode Island, 02816, USA.</p> <p>STERIS Isomedix Services, 3459 South Clinton Avenue, South Plainfield, New Jersey 07080, USA.</p> <p>M/s Synergy Health BV, Faunalaan 38, 5928 RZ Venlo, The Netherland.</p> <p>M/s Synergy Health Ireland Ltd, (Synergy Health-AST- Ireland), IDA Business and Technology Park, Sragh Tullamore Co. Offaly, Irelamabd.</p>	<p>Rubicon™ 14 Support Catheter</p> <p>Product codes and sizes as per Free Sale Certificate.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>37 months</p>
78.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific</p>	<p>Rubicon™ 18 Support Catheter</p> <p>Product codes and sizes as per Free Sale Certificate.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>37 months</p>



	<p>Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p> <p><b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, Rhode Island, 02816, USA.</p> <p>STERIS Isomedix Services, 3459 South Clinton Avenue, South Plainfield, New Jersey 07080, USA.</p> <p>M/s Synergy Health BV, Faunalaan 38, 5928 RZ Venlo, The Netherland.</p> <p>M/s Synergy Health Ireland Ltd, (Synergy Health-AST- Ireland), IDA Business and Technology Park, Sragh Tullamore Co. Offaly, Ireland.</p>			
79.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p> <p><b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, Rhode Island, 02816, USA.</p> <p>STERIS Isomedix Services, 3459 South Clinton Avenue, South Plainfield, New Jersey 07080, USA.</p>	<p>Rubicon™ 35 Support Catheter</p> <p>Product codes and sizes as per Free Sale Certificate.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>37 months</p>

	<p>M/s Synergy Health BV, Faunalaan 38, 5928 RZ Venlo, The Netherland.</p> <p>M/s Synergy Health Ireland Ltd, (Synergy Health- AST- Ireland), IDA Business and Technology Park, Sragh Tullamore Co. Offaly, Irelamabd.</p>			
80.	<p>M/s. Ferozsos Laboratories Limited, P.O. Ferozsos, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p> <p><b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, Rhode Island, 02816, USA.</p> <p>M/s STERIS, NJ, 3459 South Clinton Avenue, South Plainfield, New Jersey 07080, USA.</p> <p>M/s Synergy Health (Venlo), Faunalaan 38, 5928 RZ Venlo, The Netherlands.</p> <p>M/s Synergy Health (Tullamore), IDA Business and Technology Park, Tullamore County Offaly, Ireland.</p>	<p>Sterling™ 14 Monorail ™ PTA Balloon Dilatation Catheter</p> <p>Balloon Dia (mm): 1.5, 2.0, 2.5,3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 8.0.</p> <p>Balloon Length (mm): 10, 15, 20, 30, 40, 60, 100, 150, 200, 220.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>37 months</p>

	M/s Synergy Health (Costa Rica), B13.1, Street 4, Avenue 1, El Coyol Free Zone, EL Coyol Alajeula 20102, Costa Rica.			
81.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Ballybrit Business Park, Galway , Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health (Tullamore), IDA Business and Technology Park, Tullamore County Offaly, Ireland.</p>	XXL Balloon Dilatation Catheter (Esophageal Indication)	Decontrolled till policy decision by Policy Board/ Federal Government	37 months
82.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Ballybrit Business Park, Galway , Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health (Tullamore), IDA Business and Technology Park, Tullamore County Offaly, Ireland.</p>	XXL Balloon Dilatation Catheter (Vascular Indication)	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

83.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Ballybrit Business Park, Galway , Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health (Tullamore), IDA Business and Technology Park, Tullamore County Offaly, Ireland.</p>	Wanda TM Balloon Dilatation Catheter	Decontrolled till policy decision by Policy Board/ Federal Government	30 months
84.	<p>M/s Bio Medics Medical System, F-597, F-Block, Satellite Town, Rawalpindi.</p> <p><b>Manufactured By:</b> M/s Alco Advanced Lightweight Constructions GmbH, Am Borsigturm 50, 13507, Berlin, Germany.</p>	<p>OSIRA PTCA ® Catheter (Rapamycin Eluting Coronary Dilatation Catheter)</p> <p>Stent Dia (mm): 1.5, 2.00, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 4.0.</p> <p>Stent Length (mm): 8, 10, 15, 20, 25, 30, 35, 40.</p>	Decontrolled till policy decision by the Policy Board/ Federal Government	18 months
85.	<p>M/s Intek Corporation, No.30, 1<sup>st</sup> Floor, Al-Amin Plaza, The Mall, Rawalpindi/</p> <p><b>Manufactured by</b> M/s OrbusNeich Medical B.V. Drs. W.Van Royenstraat 5, 3871 AN Hoevelaken, The Netherlands.</p>	<p>Sphire II PRO Coronary Dilatation Catheter</p> <p>Balloon Length (mm): 5, 8, 10, 12, 15, 18, 20, 30.</p> <p>Balloon Dia (cm): 1.0, 1.25, 1.75, 2.0, 2.0, 2.25, 2.50, 2.75, 3.0, 3.25, 3.50, 4.0.</p>	Decontrolled till policy decision by the Policy Board/ Federal Government	24 months
86.	<p>M/s A.H Distributors, Kh-1183, Lane No.5, Peshawar Road, Rawalpindi./</p> <p><b>Legal Manufacturer:</b> M/s Curatia Medical Ltd,</p>	<p>Ursa Angiographic Catheter</p> <p>(product codes and sizes as per Free Sale Certificate)</p>	Decontrolled till policy decision by the Policy Board/ Federal Government	36 months

	<p>198 Xiangjiang road, New District Suzhou 215011, China.</p> <p><b><u>Manufacturing Facility:</u></b> M/s Curatia Medical Ltd, 198 Xiangjiang road, New District Suzhou 215011, China.</p> <p>M/s Curatia Medical Ltd, 9 Peiyuan Road, New District Suzhou 215163, China.</p>			
87.	<p>M/s Johnson &amp; Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi.</p> <p><b><u>Legal Manufacturer</u></b> M/s BioSense Webster, Inc, 15715 Arrowy Hwy, Irwidale, CA USA 91706.</p>	<p>Thermocool Catheters</p> <p>(product codes and sizes as per Free Sale Certificate)</p>	<p>Decontrolled till policy decision by the Policy Board/ Federal Government</p>	3 years
88.	<p>M/s. SES Associates, 61 Bank Square Market, Model town, Lahore</p> <p><b>Manufactured by:</b> M/s. QualiMed Innovative Medizinprodukt GmbH, BoschstraBe 16, D-21423, Winsen, Germany.</p>	<p>Juturna-VQ™ PTA Balloon Catheter</p> <p>Sizes and types as per Free Sale Certificate.</p> <p>Usable Catheter Length: 45cm, 80cm, 120cm, 135cm, 150cm, 160cm,.</p>	<p>Decontrolled till policy decision by the Policy Board/Federal Government</p> <p>1's</p>	3 years
89.	<p>M/s. Ferozsos Laboratories Ltd, P.O. Ferozsos, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN</p>	<p>Emerge Over-The-Wire PTCA Dilatation Catheter</p> <p>Product codes and sizes as per Free Sale Certificate including Emmerge Push OTW.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p> <p>1's</p>	2 years

	<p>55311, USA.</p> <p><b>Sterilization Site:</b> M/s. Boston Scientific Corporation (Coventry), 8 Industrial Drive, Coventry, RI 02816, USA.</p>			
90.	<p>M/s. Ferozsons Laboratories Ltd, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p> <p><b>Sterilization Site:</b> M/s. Boston Scientific Corporation (Coventry), 8 Industrial Drive, Coventry, RI 02816, USA.</p>	<p>Emerge MONORAIL™ PTCA Dilatation Catheter</p> <p>Product codes and sizes as per Free Sale Certificate including Emurge Push Monorail.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p> <p>1's</p>	2 years
91.	<p>M/s. Ferozsons Laboratories Ltd, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN</p>	<p>NC Quantum Apex™ Monorail™ PTCA Dilatation Catheter</p> <p>Product codes and sizes as per Free Sale Certificate.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p> <p>1's</p>	2 years

	55311, USA. <b>Sterilization Site:</b> M/s. Boston Scientific Corporation (Coventry), 8 Industrial Drive, Coventry, RI 02816, USA.			
92.	M/s. Ferozsons Laboratories Ltd, P.O. Ferozsons, Amangarh, Nowshera, <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough MA 01752, USA. <b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA. <b>Sterilization Site:</b> M/s. Boston Scientific Corporation (Coventry), 8 Industrial Drive, Coventry, RI 02816, USA.	Maverick 2™ Monorail™ PTCA Dilatation Catheter  Product codes and sizes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	3 years
93.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway Ireland. <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Resolute Integrity (DES) Coronary Stent  Cobalt Chromium Alloy Stent coated with Zotarolimus (Rapamycin analog)	Decontrolled (Stent length 8mm, 9mm, 12mm, 14mm, 15mm, 18mm, 22mm, 26mm, 30mm, 34mm 38mm)	24 months
94.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway Ireland. <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Integrity BMS Coronary Stent  Cobalt Chromium Alloy Stent	Decontrolled (Stent length 8mm, 9mm, 12mm, 14mm, 15mm, 18mm, 22mm, 26mm, 30mm)	24 months

95.	M/s ACP Systems, Karachi. <b>Manufactured by</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway Ireland. <b>Shipped From:</b> Medtronic Trading NL BV, Earl Bakkenstraat 10, Neatherland.	Endeavor Sprint (DES) Coronary Stent  Cobalt Alloy Stent coated with Zotarolimus (Rapamycin analog)	Decontrolled  (Stent length 8mm, 9mm, 12mm, 14mm, 15mm, 18mm, 24mm, 30mm)	24 months
96.	M/s Claris Medical, 54-A, Street 5, Sector F-8/3, Islamabad./ <b>Manufactured by:</b> M/s Biotronic AG Ackerstrasse 6, 8180 Bulach, Switzerland. <b>Contract Medical International GmbH</b> Lauensteiner Strasse 37, 01277 Dresden, Germany.	Orsiro Drug Eluting Coronary Stent  (Sirolimus)  Stent Length (mm): 9,13,15,18, 22,26, 30.  Stent Dia (mm): 2.0, 2.25, 2.50, 2.75, 3.0, 3.50, 4.00.	Decontrolled	Not mention ed.
97.	M/s Claris Medical, 54-A, Street 5, Sector F-8/3, Islamabad./ <b>Manufactured by:</b> M/s Biotronic AG Ackerstrasse 6, 8180 Bulach, Switzerland. <b>Contract Medical International GmbH</b> Lauensteiner Strasse 37, 01277 Dresden, Germany.	PRO Kinetic Energy Coronary Stents.  Stent Length (mm): 9,13,15,18, 20,22,26,30, 35, 40.  Stent Dia (mm): 2.0, 2.25, 2.50, 2.75, 3.0, 3.50, 4.00, 4.50, 5.00..	Decontrolled	Not mention ed.
98.	M/s. Trans Angio System, Karachi-75400 M/s. Translumina GmbH, Neue Rottenburger Hecingen, Germany.	Yukon <sup>®</sup> CC Stent System	Decontrolled	03 years
99.	M/s. TM Marketing, Karachi. / <b>Manufactured by</b> M/s. ClearStream Technologies Ltd., Moyne Upper, Enniscorthy Co. Wexford, Ireland.	ClearFlex-X Coronary Stent (Drug Eluting Stent).	Decontrolled	03 years



100.	M/s. TM Marketing, Karachi. / <b>Manufactured by</b> M/s. ClearStream Technologies Ltd., Moyne Upper, Enniscorthy Co. Wexford, Ireland.	SatinFlex Coronary Stent	Decontrolled	03 years
101.	M/s. Promed International, Ground Floor, Jamil Mohsin Mansion, G-6 Markaz, Islamabad <b>Legal Manufacturer</b> M/s Biosensors Europe SA, Switzerland. <b>Manufactured by</b> M/s. JW Medical Systems Ltd., 328, Shichang Ave, Weihai, Shandong, P.R. China.	Excel™ Drug Eluting Stent (Medical Device for Angioplasty)	Decontrolled	18 months
102.	M/s. Intek Corporation, Rawalpindi. / <b>Manufactured by</b> M/s. Lepu Medical Technology (Beijing) Co., Ltd., Xicheng District, Beijing, China.	“H-STENT” Coronary Stent Delivery System (Bare Metal Stent)	Decontrolled Dia (mm) 2.5, 3.0, 3.5, and 4.0. Length (mm) 9,12,14, 16, 18, 20, 22, 24.	24 months
103.	M/s. Intek Corporation, Rawalpindi. / <b>Manufactured by</b> M/s. Lepu Medical Technology (Beijing) Co., Ltd., Xicheng District, Beijing, China.	“PARTNER” Sirolimus- Eluting Coronary Stent System (Drug Eluting Stent (DES))	Decontrolled	12 month
104.	M/s. Maxims Medical, Lahore./ <b>Responsible Manufacturer:</b> M/s. Abbott Vascular Lakeside Drive, California, USA. <b>Manufacturing Site:</b> M/s. Abbott Vascular, Belgium.	Multilink 8 Coronary Stent	Decontrolled	02 years
105.	M/s. Maxims Medical, Lahore. / <b>Responsible Manufacturer:</b>	JO Stent Graft Master	Decontrolled	02 years

	M/s. Abbott Vascular Lakeside Drive, California, USA. <b>Manufacturing Site:</b> M/s. Abbott Vascular, Instruments Deutsuhland, Rangendingen, Germany.			
106.	M/s. Maxims Medical, Lahore. / <b>Responsible Manufacturer:</b> M/s. Abbott Vascular Lakeside Drive, California, USA. <b>Manufacturing Site:</b> M/s. Abbott Vascular, Instruments Deutsuhland, Rangendingen, Germany.	Flex Master F1 Coronary Stent	Decontrolled	02 years
107.	M/s. SES Associates Institutional Distributors & Government Suppliers, Lahore <b>Manufactured by</b> M/s. QualiMed GmbH, Winsen, Germany	Nemok TM Drug Eluting Coronary Stent (Sirolimus/Repamycin Eluting Coronary Stent) (All sizes)	De-controlled	2years
108.	M/s. Ferozsos Laboratories, Nowshera, <b>Manufactured by</b> M/s. Boston Scientific Corporation, USA	Omega TM Coronary Stent System  (Bare-Metal Coronary Artery Stent)	De-controlled	12 months
109.	M/s. Stents Specialties 471, Kahuta Triangle, Industrial Area, Islamabad. <b>Manufactured by</b> M/s. Plasmachem GmbH, Germany <b>Supplier</b> M/s. Mack & Co., Bahnhofstrasse, Germany	Bio Diamond Delivery System (Coronary pre- mounted Stent)	Decontrolled	2 years
110.	M/s. Stents Specialties 47, Kahuta Triangle, Industrial Area, Islamabad. <b>Manufactured by</b> M/s. Plasmachem GmbH, Germany <b>Supplier</b> M/s. Mack & Co., Bahnhofstrasse, Germany	Bio Diamond mF12 Stent (12mm)	Decontrolled	2 years

111.	<p>M/s. Surgismart, Lahore  <b>Manufactured by</b>  M/s. Inshitra Medical  INC, 9200 Irvine Centre  Drive Suit, 200 Irvine CA  92618  <b>Contract Manufactured</b>  Fortimedix B.V,  Horselstraat 1 Netherland.</p>	<p>Inshitra Patriot (Cobalt  Chromium Coronary Stent  Delivery System (Bare  Metal Stent)   2.00-4.00mm Stent  Diameter,  9,00-40.00mm Stent  Length</p>	Decontrolled	3 years
112.	<p>M/s Intek Corporation, #  30,1<sup>st</sup> Floor, Al-Amin  Plaza, The Mall,  Rawalpindi.  <b>Manufacturer</b>  M/s Terumo Europe,  Interleuvenlaan 40, 3001  Leuven, Belgium.  <b>Actual Manufacturer:</b>  M/s Ashitaka Factory of  Terumo Corporation, 150,  Maimaigi-cho, Fujinomiya  city, Shizuoka Prefecture  418-0015, Japan.  <b>Shipped From (Marketing  and Sales Office:</b>  M/s Terumo Corporation  Dubai Branch, Arbift  Tower, Dubai, UAE.</p>	<p>Kaname Cobalt  Chromium Coronary Stent  System  Stent Dia (mm): 2.5,  2.75, 3.0, 3.5, 4.0.   Stent Length(mm): 9, 12,  15, 18, 24, 28.</p>	Decontrolled	24 months
113.	<p>M/s Intek Corporation, #  30,1<sup>st</sup> Floor, Al-Amin  Plaza, The Mall,  Rawalpindi.  <b>Manufactured by</b>  M/s Terumo Corporation,  44-1-2 Chome, Hatagaya,  Shibuya-ku, Tokyo, Japan.  <b>Shipped From  (Marketing and Sales  Office:</b>  M/s Terumo Corporation  Dubai Branch, Arbift  Tower, Dubai, UAE.</p>	<p>Tsunami ® Gold  Coronary Stent System   Stent Dia (mm): 2.0, 2.25,  2.5, 3.0, 3.5, 4.0.   Stent Length (mm): 8,  10,13, 15, 18, 20, 23, 25,  30.</p>	Decontrolled	18 months
114.	<p>M/s. Health Tec,  38-B, Nagi Road,  Westrige-I Rawalpindi  Cantt.  <b>Manufacturer:</b>  Blue Medical Device B.V,</p>	<p>Pioneer CoCr Stent  Delivery System on DEB  (Cobalt Chromium Stent  mountain on Paclitaxel  Eluting Balloon Catheter)</p>	Decontrolled (Different codes and sizes available)	3 years

	Netherlands <b>Production plant</b> Panoverweg 7 5708 HR Helmond	Diameter (mm)    Length (mm) 2.50    10,14,18,22, 28 2.75    10,14,18,22,28 3.00    10,14,18,22,28 3..25    10,14,18,22,28 3.50    10,14,18,22,28 4.00    10,14,18, 22,28		
115.	M/s Interex Company, 195 Block 7/8 KMCHS Justice Inamullah Road, Karachi/ <b>Manufactured by</b> 1. M/s.NuMed, Inc 2880 Main Street, Hopkinton, NY, 12965, USA. 2. M/s.NuMed Canada, Inc 45 Second Street West, Cornwall, Ontario K6J1G3, Canada.	CP Stent (Bare & Covered)	Decontrolled. 1's	Not mention ed in form 5- A.
116.	M/s Hakimsons (Pvt) Ltd, Hakimsons House, A/56/S.I.T.E. Manghopir Pir Road, Karachi. <b>Manufactured by:</b> 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.	Architect (CoCr Coronary Stent)  Stent Length (mm): 9, 14, 19, 24, 29, 34, 39.  Stent Dia (cm): 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50.	Decontrolled.	3 years.
117.	M/s. Ferozsos Laboratories Limited, P.O. Ferozsos, Amangarh, Nowshera, <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 017603-1537.USA. <b>Manufacturing Site:</b> M/s. Boston Scientific Ireland Ltd, Ballybrit Business Park, Galway, Ireland.	Synergy <sup>TM</sup> Monorail <sup>TM</sup> Everolius Eluting Platinum Chromium Coronary Stent System  Stent Length (mm): 8, 12, 16,20, 24, 28, 32, 38.  Stent Dia (mm): 2.25, 2.50, 2.75, 3.0, 3.50, 4.0.	Decontrolled till policy decision by Policy Board/ Federal Government	18 month

118.	<p>M/s Digital Imaging Systems, 121, Habitats, Shadman-II, Ghaus-ul-Azam Road, Lahore/  <b>Responsible Manufacturer:</b>  M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  <b>Manufacturing Site:</b>  M/s Abbott Vascular, Cashel Road, Clonmel, Country Tipperary, Ireland.</p>	<p>Xience Xpedition Stent</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>2 years</p>
119.	<p>M/s. Health Tec, 10-B, Street No.24, Valley Road, Westrige-I Rawalpindi.  <b>Manufacturer:</b>  M/s Cardionovum Sp. Z.o.o., Panska Str.73,00-834 Warsaw, Poland</p>	<p>Xlimus Sirolimus Eluting Coronary Stent System</p> <p>Stent Length (mm): 8, 12, 16, 20, 24, 28, 32, 36, 40.</p> <p>Stent Dia (mm): 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50, 5.00.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>2 years</p>
120.	<p>M/s. Ferozsons Laboratories, P.O. Ferozsons, Amangarh, Nowshera,  <b>Legal Manufacturer:</b>  M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, USA 01752.  <b>Manufacturing Site:</b>  M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p>	<p>Rebel<sup>TM</sup> Monorail<sup>TM</sup> PtCr Coronary Stent System</p> <p>Stent Length (mm): 8, 12, 16, 20, 24, 28, 32.</p> <p>Stent Dia (mm) 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	<p>3 years</p>
121.	<p>M/s Genus, 220, D.M.C.H.S, Block-3 Sirajuddaula Road, Karachi.  <b>Manufactured By:</b>  M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA.</p>	<p>Silver Stent-CC BMS Stent.</p> <p>Stent Length (mm): 8, 9, 12, 15, 18, 20, 21, 23, 24, 28, 29, 33, 36.</p> <p>Stent Dia (mm) 2.50, 2.75, 3.00, 3.50, 4.00.</p>	<p>Decontrolled till policy decision by the Policy Board/Federal Government</p>	<p>2 years</p>

122.	M/s Genus, 220, D.M.C.H.S, Block-3 Sirajuddaula Road, Karachi. <b>Manufactured By:</b> M/s Umbra Medical Products, Inc, 8930 East Roan Lane, Inverness, Florida 34450 USA.	Affinity CC Drug Eluting Stent.  Stent Length (mm): 12, 15, 16, 18, 20, 21, 23, 28, 33, 38.  Stent Dia (mm) 3.00, 3.50, 4.00.	Decontrolled till policy decision by the Policy Board/Federal Government	2 years
123.	M/s Digital Imaging Systems, 121, Habitats, Shadman-II, Ghaus-ul- Azam Road, Lahore/ <b>Responsible Manufacturer:</b> M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA. <b>Manufacturing Site:</b> M/s Abbott Vascular, 26351 Ynez Road, Temecula, CA 92591, USA.	Absorb GT1, Bioresorbable Vascular Scaffold.  Scaffold Length (mm): 8, 12, 18, 23, 28  Scaffold Dia (mm): 2.5, 3.0, 3.5.	Decontrolled till policy decision by Policy Board/ Federal Government	01 year
124.	M/s Digital Imaging Systems, 121, Habitats, Shadman-II, Ghaus-ul- Azam Road, Lahore/ <b>Responsible Manufacturer:</b> M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054, USA.  <b>Manufacturing Site:</b> M/s Abbott Vascular, Cashel Road, Clonmel, County Tipperary, Ireland.  M/s Abbott Vascular, Coyol Free Zone, E1 Coyol Alajuela, Costa Rica.	Xience Alpine Stent  Stent Length (mm): 8, 12, 15, 18, 23, 28, 33, 38.  Stent Dia (mm) 2.0, 2.25, 2.50, 2.75, 3.0, 3.25, 3.50, 4.0.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	02 years
125.	M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi/	Resolute Onyx Zotarolimus-Eluting Coronary Stent System	Decontrolled till policy decision by Policy Board/	2 years

	<p><b>Legal Manufacturer:</b> M/s Medtronic, Inc, 710 Medtronic Parkway, Minneapolis, Minnesota 55432, USA.</p> <p><b>Manufacturing Site:</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland.</p> <p><b>EC Authorized Representative:</b> M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland.</p>	<p>Stent Length (mm): 8, 12, 15, 18, 22,26, 30, 34, 38.</p> <p>Stent Dia (mm) 2.0, 2.25, 2.5, 2.75, 3.0, 3.5, 4.0, 4.5, 5.0.</p>	<p>Federal Government</p> <p>1's</p>	
126.	<p>M/s. Promed International, CB-6349 Amarpak Plaza, Jhelum Road, Rawalpindi.</p> <p><b>Legal Manufacturer:</b> M/s Biosensors Europe SA, Rue De Lausanne 29, 1110 Morges, Switzerland.</p> <p><b>Manufacturing Site:</b> M/s Biosensors Interventional Technologies Pte Ltd, 36 Jalan Tukang, Singapore 619266, Singapore.</p> <p><b>Sterilization Sites:</b></p> <ol style="list-style-type: none"> <li>1. BGS-Beta-Gamma- Service GmbH &amp; Co Kg, Fritz-Kotz-Strasse 16, 51674 Wieth, Germany.</li> <li>2. Electron Beam Sdn, Bhd, Lot 7, Jalan Sungai Pinang 4/3, Taman Perindustrian Pulau Indah (Fasa 2), 42920 Port Klang, Selangor, Malaysia.</li> </ol>	<p>BioMatrix Neoflex <sup>TM</sup> Drug Eluting Coronary Stent System.</p> <p>Stent Length (mm): (Unexpanded) 8, 11, 14, 18, 24,28, 33, 36.</p> <p>Nominal Stent Inner Dia (mm) 2.25, 2.5, 2.75, 3.0, 3.5, 4.0.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p> <p>1's</p>	24 months
127.	<p>M/s 4S International, Suit No.205, 2<sup>nd</sup> Floor, Rashid Minhas Road, Block-10-A, Gulshan-e-Iqbal, Karachi/ <b>Manufactured By:</b> M/s Balton Sp. Z o.o. ul. Nowy Swiat 7, m. 14, 00-</p>	<p>Prolim Sirolimus Eluting Coronary Stent with Delivery System RX</p> <p>Stent Length (mm): 8, 10, 12, 15, 18, 22, 25, 29, 34, 36, 38, 40.</p>	<p>Decontrolled till policy decision by Policy Board/ Federal Government</p>	1 years & 11 months

	496 Warszawa, Poland.	Stent Dia (mm) 2.0, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75, 4.00, 4.50.	1's	
128.	M/s 4S International, Suit No.205, 2 <sup>nd</sup> Floor, Rashid Minhas Road, Block-10-A, Gulshan-e-Iqbal, Karachi/ <b>Manufactured By:</b> M/s Balton Sp. Z o.o. ul. Nowy Swiat 7, m. 14, 00-496 Warszawa, Poland.	Coflexus Cobalt Chromium Coronary Stent with Delivery System RX  Stent Length (mm): 8, 10, 12, 15, 18, 22, 25, 29, 34, 36, 38, 40.  Stent Dia (mm) 2.0, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75, 4.00, 4.50.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	1 years & 11 months
129.	M/s 4S International, Suit No.205, 2 <sup>nd</sup> Floor, Rashid Minhas Road, Block-10-A, Gulshan-e-Iqbal, Karachi/ <b>Manufactured By:</b> M/s Balton Sp. Z o.o. ul. Nowy Swiat 7, m. 14, 00-496 Warszawa, Poland.	Alex Cobalt Chromium Sirolimus Eluting Coronary Stent with Delivery System RX  Stent Length (mm): 8, 10, 12, 15, 18, 22, 25, 29, 34, 36, 38, 40.  Stent Dia (mm) 2.0, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75, 4.00, 4.50.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	1 years & 11 months
130.	M/s Cardevo International (Pvt) Ltd, Office No.120, 4 <sup>th</sup> Floor, Main Boulevard Mega Tower, Gulberg-II, Lahore. <b>Manufactured By:</b> M/s Accura Medizintechnik GmbH, Max-Planck-Str.33, 61184, Karben, Germany.	Accura Decent S Sirolimus- Eluting Coronary Stent System  Product codes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	12 months
131.	M/s Digital Imaging Systems, 121, Habitats, Shadman-II, Ghaus-ul-Azam Road, Lahore/ <b>Responsible Manufacturer:</b> M/s Abbott Vascular, 3200 Lakeside Drive, Santa Clara, California 95054,	Multilink 8 Stent	Decontrolled till policy decision by Policy Board/ Federal Government	2 years



	<p>USA.  <b>Having Factory Premises at:</b>  M/s Abbott Vascular,  Cashel Road, Clonmel,  County Tipperary, Ireland.  <b>Manufacturing Site:</b>  M/s Abbott Vascular,  26531 Ynez Road,  Temecula, CA 0259, USA.</p>			
132.	<p>M/s. Life Cares,  M-20 Falaknaz Plaza,  Shahra-e-Faisal, Karachi.  <b>Manufactured by</b>  M/s. Scitech Products  Medicos Ltda, Rua 06  C/Rua 18 c/Rua 19, Qd. 21,  Lts. 01-44, Polo  Empresarial de  Goias, Aparecida de  Goiania City Goias Sate,  Brazil.</p>	<p>Inspiration Drug Eluting  Stents   Stent Length (mm):  13, 16, 19, 23, 29, 33,38.   Stent Dia (mm)  2.5, 2.75, 3.0, 3.5.</p>	<p>Decontrolled  till policy  decision by  Policy Board/  Federal  Government</p>	<p>2 years</p>
133.	<p>M/s. Life Cares,  M-20 Falaknaz Plaza,  Shahra-e-Faisal, Karachi.  <b>Manufactured by</b>  M/s. Scitech Products  Medicos Ltda, Rua 06  C/Rua 18 c/Rua 19, Qd. 21,  Lts. 01-44, Polo  Empresarial de  Goias, Aparecida de  Goiania City Goias Sate,  Brazil.</p>	<p>Bare Metal Stent Cronus  (Chromium Cobalt)   Stent Length (mm):  13, 16, 19, 23, 29, 33,38.   Stent Dia (mm)  2.5, 2.75, 3.0, 3.5.</p>	<p>Decontrolled  till policy  decision by  Policy Board/  Federal  Government</p>	<p>2 years</p>
134.	<p>M/s. Promed International,  CB-6349 Amarpak Plaza,  Jhelum Road, Rawalpindi.  <b>Legal Manufacturer:</b>  M/s Biosensors Europe SA,  Rue De Lausanne 29, 1110  Morges, Switzerland.  <b>Manufacturing Site:</b>  M/s Biosensors  Interventional  Technologies Pte Ltd, 36  Jalan Tukang, Singapore  619266, Singapore.  <b>Sterilization Sites:</b></p>	<p>Axxess <sup>TM</sup> Drug Coated  Coronary Bifurcation  Stent System.   Stent Length (mm):  9, 11, 14.   Maximum Expanded Stent  Dia (mm)  3.75, 4.25, 6.00.</p>	<p>Decontrolled  till policy  decision by  Policy Board/  Federal  Government   1's</p>	<p>24  months</p>

	<p>1. BGS-Beta-Gamma-Service GmbH &amp; Co Kg, Fritz-Kotz-Strasse 16, 51674 Wieth, Germany.</p> <p>2. Electron Beam Sdn, Bhd, Lot 7, Jalan Sungai Pinang 4/3, Taman Perindustrian Pulau Indah (Fasa 2), 42920 Port Klang, Selangor, Malaysia.</p>			
135.	<p>M/s. ACP System, 13-23, Naval Fleet Club, Iqbal (S.J) Shaheed Road, Karachi.</p> <p><b>Legal Manufacturer:</b> M/s Medtronic, Inc. 710 Medtronic Parkway NE Minneapolis, MN 55432, USA.</p> <p><b>Manufacturing Site:</b> M/s Medtronic Ireland, Parkmore Business Park West Galway, Ireland.</p>	<p>Driver Sprint Rapid Exchange Coronary Stent System</p> <p>Product codes as per Free Sale Certificate.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	2 years
136.	<p>M/s. Maxims Medical, 534 H Block, St. No.13, Phase-5,DHA, Lahore.</p> <p><b>Manufactured by:</b> M/s Minvasys, 7, rue du Fosse Blanc-92230, Gennevilliers France.</p>	<p>Amazonia SIR Drug Eluting Stent</p> <p>Stent Length (mm): 8, 12, 16, 20, 24, 28, 32, 36, 40.</p> <p>Stent Dia (mm) 2.25, 2.50, 2.75, 3.00, 3.50, 4.00.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	2 years
137.	<p>M/s. Ferozsos Laboratories, P.O. Ferozsos, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, USA 01752.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed</p>	<p>Express<sup>TM</sup> Vascular SD Monorail<sup>TM</sup> Premounted Stent System</p> <p>Product codes as per Free Sale Certificate.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

	Place, Maple Grove, MN 55311, USA. <b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, RI 02816, USA.			
138.	M/s. Ferozsons Laboratories, P.O. Ferozsons, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, USA 01752. <b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, 5905Nathan Lane, Plymouth, MN 55442, <b>Sterilization Site:</b> M/s BSC Coventry, 8 Industrial Drive Coventry, RI 02816, USA.  M/s Synergy Health Ireland Limited (Tullamore) IDA Business & Technology Park, Tullamore, ?Co, Offaly, Ireland.	Epic™ Over The Wire Self- Expanding Nitinol Stent with Delivery System  Product codes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	37 months
139.	M/s. Ferozsons Laboratories, P.O. Ferozsons, Amangarh, Nowshera. <b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way. Marlborough, MA, USA 01752. <b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Ballybrit Business Park, Galway, Ireland. <b>Sterilization Site:</b> M/s Synergy Health Ireland Limited (Tullamore) IDA	Express™ LD Vascular Over The Wire Premounted Stent System  Product codes as per Free Sale Certificate.	Decontrolled till policy decision by Policy Board/ Federal Government	37 months

	Business & Technology Park, Tullamore, ?Co, Offaly, Ireland., RI 02816, USA.			
140.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Two Scimed Place, Maple Grove, MN 55311, USA.</p> <p><b>Sterilization Site:</b> M/s Synergy Health (Tullamore), IDA Business and Technology Park, Tullamore County Offaly, Ireland.</p>	<p>Wallstent-Uni™ Endoprosthesis Self Expanding Stent</p> <p>Product codes as per Free Sale Certificate.</p>	Decontrolled till policy decision by Policy Board/ Federal Government	25 months
141.	<p>M/s. Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.</p> <p><b>Legal Manufacturer:</b> M/s. Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA, 01752, USA.</p> <p><b>Manufacturing Site:</b> M/s. Boston Scientific Corporation, Ballybrit Business Park, Galway, Ireland.</p> <p><b>Sterilization Site:</b> M/s Synergy Health (Tullamore), IDA Business and Technology Park, Tullamore County Offaly, Ireland.</p>	<p>Wallgraft™ Over The Wire Endoprosthesis with Unistep™ Plus Delivery System</p>	Decontrolled till policy decision by Policy Board/ Federal Government	30 months

142.	M/s Bio Medics Medical System, F-597, F-Block, Satellite Town, Rawalpindi. <b>Manufactured By:</b> M/s Alco Advanced Lightweight Constructions GmbH, Am Borsigturm 50, 13507, Berlin, Germany.	OSIRA CR ® L 605 Cobalt Chromium Rapamycin Eluting Coronary Stent.  Stent Dia (mm): 2.5, 2.75, 3.0, 3.5. Stent Length (mm): 8, 12, 16, 20, 24, 28, 32, 38, 42.	Decontrolled till policy decision by the Policy Board/ Federal Government	18 months
143.	M/s Bio Medics Medical System, F-597, F-Block, Satellite Town, Rawalpindi. <b>Manufactured By:</b> M/s Alco Advanced Lightweight Constructions GmbH, Am Borsigturm 50, 13507, Berlin, Germany.	OSIRA R4 ® 3l6 LVM (Rapamycin Eluting Coronary Stent)  Stent Inner Dia (mm): 2.5, 2.75, 3.0, 3.5, 4.0. Stent Length (mm): 8, 12, 16, 20, 24, 28, 32, 38, 42.	Decontrolled till policy decision by the Policy Board/ Federal Government	18 months
144.	M/s. SES Associates, 61 Bank Square Market, Model town, Lahore <b>Manufactured by</b> M/s. QualiMed Innovative Medizinprodukt GmbH, BoschstraBe 16, D-21423, Winsen, Germany.	UNA™ Stent delivery System (Stainless Steel Coronary Stent)  Stent Length (mm): 10, 14, 18, 24, 28, 34, 38. Balloon Dia (mm): 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 4.00.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	3 years
145.	M/s. SES Associates, 61-Bank Square Market, Model Town, Lahore. <b>Manufactured by</b> M/s. QualiMed Innovative Medizinprodukt GmbH, BoschstraBe 16, D-21423, Winsen, Germany.	SUNA™ Stent delivery System (Cobalt Chromium Coronary Stent)  Stent Length (mm): 8, 10, 12, 14, 16, 18, 19, 24, 28, 34, 38. Balloon Dia (mm): 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 4.00.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	3 years
146.	M/s. SES Associates, 61-Bank Square Market, Model Town, Lahore. <b>Manufactured by</b> M/s. QualiMed Innovative Medizinprodukt GmbH, BoschstraBe 16, D-21423, Winsen, Germany.	Magma Rapamycin Eluting Coronary Stent System  Stent Length (mm): 10, 14, 18, 24, 28, 34, 38. Balloon Dia (mm): 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 4.00.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	1 years

147.	M/s. SES Associates, 61-Bank Square Market, Model Town, Lahore. <b>Manufactured by</b> M/s. QualiMed Innovative Medizinprodukt GmbH, BoschstraBe 16, D-21423, Winsen, Germany.	Navalis Peripheral Vascular Self Expanding Stent System  Stent Length (mm); 20,40, 60, 80, 100, 120, 150.  Stent Dia (mm): 6,7,8,9,10,11.  Usable catheter length: 80cm, 120cm.	Decontrolled till policy decision by Policy Board/ Federal Government  1's	3 years
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**Decision:** The MDB decided to process these applications in accordance with the decision taken by the Authority in its 38<sup>th</sup> meeting held on 17<sup>th</sup> October, 2016

Item-XI. **Applications for registration of medical devices applied on Form 6-A of MDR, 2015.**

Following firms have applied for registration of their medical devices on Form 6-A of MDR, 2015. These applications are not evaluated yet. Under MDR, 2015 establishment (importer or local manufacturer) applying for registration of its medical device shall have relevant establishment license for import or local manufacturing of medical devices. At present, establishment licence has not been issued to any importer or local manufacturer.

S.No	Name and complete addresses of Importer and Manufacturer/manufacturing site(s)	Name of Medical Device	Proposed Class of Medical Device	Demanded Shelf life	Remarks
1.	M/s Care and Cure International, 65-B, Sattelite Town, Rahim Yar Khan. <b>Manufactured by</b> M/s Yangzhou Goldenwell Medical Devices Factory, No.9, Liuqiao Road New District Jiangdu, Jiangsu, P.R.China.	Cure Syringe  5cc	Not mentioned	Not mentioned	<b>Dy. No.786-R&amp;I 18-9-2015</b>  <b>Dy.No.27- DDC(MD) 18-9-2015</b>

2.	M/s M. Yousaf & Co, 131-Tipu Block, Garden Town, Lahore/ <b>Manufactured by</b> M/s Grena Ltd, 1000- great west Road, Brentford, Middlesex, TW8 9HH, United Kingdon.	Disposable Stapler (Surgical Instruments)	Not mentioned	Not mentioned.	Rs.15,000/- <b>Dy. No.1012- R&amp;I 6-10-2015</b>  <b>Dy.No.29- ADC(MD) 12-10-2015</b>
3.	M/s Roche Pakistan Limited, 37-C, Block-6, P.E.C.H.S. Karachi. <b>Manufactured by</b> M/s Roche Diagnostics GmbH. Sandhofer Strasse 116, 68305 Mannheim, Germany.	Cobas Viral Infectious Disease Markers. <b>(dossiers A to K)</b> Anti HBc + Preci Control.  Anti- Hbc + PC.  Anti -HBs + PC.  2xAnti-HCV+PC  HBsAg+Confir- matory+PC.  HBeAg+PC  HIV Ag+PC HIV Ag + Confirmatory  HIV Combi PT +PC  Kit Cobas 6800/ 8800 MPXRMC +96T + 480T +NHP Neg. Cont Kit.  Anti-HBc IgM +PC Cobas AMP/ Cobas TQM HIV- 1, Qualitative Test, v2.0.  (In- vitro test kits)	D	Not mentioned.	RS.15,000/- <b>Dy. No.1089- R&amp;I 26-2-2016</b>  <b>Dy.No.25- ADC(MD) 26-2-2016</b>

4.	M/s Roche Pakistan Limited, 37-C, Block-6, P.E.C.H.S. Karachi. <b>Manufactured by</b> M/s Roche Molecular Systems Inc., 1080- US Highway 202 South Branchburg, NJ 08876, USA.	Cobas Viral Infectious Disease Markers. (dossier L,M) KIT s201 T-SCRN MPX v2.0 96T CE-IVD.  KIT T-SCRN MPX v2.0 Control CE-IVD.  CAP/CTM HCV v2.0 Qualitative CE-IVD.  (In- vitro test kits)	D	Not mentioned	RS.50,000/- <b>Dy. No.1096-R&amp;I</b> <b>26-2-2016</b>  <b>Dy.No.26-ADC(MD)</b> <b>26-2-2016</b>
5.	M/s Abbott Laboratories (Pakistan) Ltd., Opp Radio Pakistan Transmission Center, Hyderabad Road, Landhi Karachi. <b>Legal Manufacturer:</b> M/sAbbott GmbH & Co KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany.	Architect Anti-HBc II Calibrators.  Architect Anti-HBc II Controls  Architect Anti-HBc II Reagent Kit  Architect Anti-HBc II Reagent Kit  Architect Anti-HBc IgM Calibrators  Architect Anti-HBc IgM Controls.  Architect Anti-HBc LgM Reagent Kit	D	Not mentioned	RS.50,000/- <b>Dy. No.1140-R&amp;I</b> <b>2-3-2016</b>  <b>Dy.No.27-ADC(MD)</b> <b>4-3-2016</b>  Form 6-A not provided
6.	M/s Abbott Laboratories (Pakistan) Ltd., Opp Radio Pakistan Transmission Center,	Architect HIV Ag/Ab Combo Calibrators.	D	Not mentioned	RS.50,000/- <b>Dy. No.1141-R&amp;I</b> <b>2-3-2016</b>



	<p>Hyderabad Road, Landhi Karachi.</p> <p><b>Legal Manufacturer:</b> M/s Abbott GmbH &amp; Co KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany.</p>	<p>Architect HIV Ag/Ab Combo Controls</p> <p>Architect HIV Ag/Ab Combo Reagent Kit</p> <p>Architect HIV Ag/Ab Combo Reagent Kit</p> <p>Architect HIV Ag/Ab Combo Reagent Kit</p> <p>Architect rHTLV-I/II Calibrators</p> <p>Architect rHTLV-I/II Controls</p> <p>Architect rHTLV-I/II Reagent Kit</p>			<p><b>Dy.No.28-ADC(MD) 4-3-2016</b></p> <p>Form 6-A not provided</p>
7.	<p>M/s Abbott Laboratories (Pakistan) Ltd., Opp Radio Pakistan Transmission Center, Hyderabad Road, Landhi Karachi.</p> <p><b>Legal Manufacturer:</b> M/s Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo Ireland.</p>	<p>Architect Anti-HBs Calibrators.</p> <p>Architect Anti-HBs Controls</p> <p>Architect Anti-HBs Reagent Kit</p> <p>Architect HBsAg Calibrators.</p> <p>Architect HBsAg Controls</p> <p>Architect HBsAg Reagent Kit</p> <p>Architect HBsAg Qualitative II Calibrators.</p> <p>Architect HBsAg</p>	D	Not mentioned	<p>RS.50,000/- <b>Dy. No.1151-R&amp;I 2-3-2016</b></p> <p><b>Dy.No.29-ADC(MD) 4-3-2016</b></p> <p>Form 6-A not provided</p>

		<p>Qualitative II Controls</p> <p>Architect HBsAg Qualitative II Reagent Kit</p> <p>Architect HBsAG Qualitative II Conformity Reagent Kit</p> <p>Architect HBsAG Qualitative II Conformity Manual Diluent</p>			
8.	<p>M/s Abbott Laboratories (Pakistan) Ltd., Opp Radio Pakistan Transmission Center, Hyderabad Road, Landhi Karachi.</p> <p><b>Legal Manufacturer:</b> M/sAbbott GmbH &amp; Co KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany.</p>	<p>Architect Syphilis TP Calibrators.</p> <p>Architect Syphilis TP Controls.</p> <p>Architect Syphilis TP Reagent Kits</p>	D	Not mentioned	<p>RS.50,000/- <b>Dy. No.1144-R&amp;I</b> <b>2-3-2016</b></p> <p><b>Dy.No.30-ADC(MD)</b> <b>4-3-2016</b></p> <p>Form 6-A not provided</p>
9.	<p>M/s Abbott Laboratories (Pakistan) Ltd., Opp Radio Pakistan Transmission Center, Hyderabad Road, Landhi Karachi.</p> <p><b>Legal Manufacturer:</b> M/sAbbott GmbH &amp; Co KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany.</p>	<p>Architect Anti-HCV Calibrators.</p> <p>Architect Anti-HCV Controls.</p> <p>Architect Anti-HCV Reagent Kits.</p> <p>Architect HCV Ag Controls.</p> <p>Architect HCV Ag Calibrators.</p> <p>Architect HCV Ag Reagent Kit.</p>	D	Not mentioned	<p>RS.50,000/- <b>Dy. No.1143-R&amp;I</b> <b>2-3-2016</b></p> <p><b>Dy.No.31-ADC(MD)</b> <b>4-3-2016</b></p> <p>Form 6-A not provided</p>

10.	M/s Abbott Laboratories (Pakistan) Ltd., Opp Radio Pakistan Transmission Center, Hyderabad Road, Landhi Karachi. <b>Legal Manufacturer:</b> M/s Abbott GmbH & Co KG Max-Planck-Ring 2, 65205 Wiesbaden, Germany.	Architect Chagas Calibrators  Architect Chagas Controls.  Architect Chagas Reagent Kits.	D	Not mentioned	RS.50,000/- <b>Dy. No.1142-R&amp;I</b> <b>2-3-2016</b>  <b>Dy.No.32-ADC(MD)</b> <b>4-3-2016</b>  <b>Form 6-A not provided</b>
11.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b>Legal Manufacturer</b> M/s DePuy (Ireland) Loughberg, Ringaskiddy Co., Cork, Ireland	Attune ® Tibial Insert Fixed Bearing CR Insert.  Attune ® Tibial Insert Rotating Platform CR Insert.  Attune ® Tibial Insert Fixed Bearing PS Insert.	D	Not mentioned	RS.50,000/- <b>Dy. No.1326-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.33-ADC(MD)</b> <b>9-3-2016</b>
12.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b>Legal Manufacturer</b> M/s DePuy France SAS 7, allee Irene Joliot-Curie 69801 Saint Priest Cedex, France.	1. Corail Standard stem. 2. Corail HO stem. 3. Corail Laterized stem. 4. Corail Standard revision stem. 5. Corail High Offset Revision Stem. 6. Corail Standard Cemented Stem 7. Corail High Offset cemented Stem.	D	Not mentioned	RS.50,000/- <b>Dy. No.1325-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.34-ADC(MD)</b> <b>9-3-2016</b>

13.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s DePuy International Limited Trading as DePuy CMW Blackpool, Lancashire FY4 4QQ, United Kingdom.	1. Biostop G 2. Smartset GHV 3. Smartset GMV 4. Depuy CMW 5. VMP + Depuy CMW. 6. Smartmix Cemvav + GHV.	D	Not mentioned	RS.50,000/- <b>Dy. No.1324-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.35-ADC(MD)</b> <b>9-3-2016</b>
14.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Synthes GmbH, Eimattstrasse 3, 4336, Oberdorf, Switzerland.	Rapidsorb ® Resorbable Fixation System	D	Not mentioned	RS.50,000/- <b>Dy. No.1323-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.36-ADC(MD)</b> <b>9-3-2016</b>
15.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ethicon SARL, Puits godet 20, Neuchatel 2000, Switzerland.	Surgicel ®	D	Not mentioned	RS.50,000/- <b>Dy. No.1316-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.37-ADC(MD)</b> <b>9-3-2016</b>
16.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Cordis Corporation, 14201 N.W. 60 <sup>th</sup> Ave., Miami Lakes, FL , USA 33014.	Steerable Guidewires	D	Not mentioned	RS.50,000/- <b>Dy. No.1322-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.38-ADC(MD)</b> <b>9-3-2016</b>
17.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin,	Norian Reinforced <sup>TM</sup> Fast Set Putty <sup>TM</sup>	D	Not mentioned	RS.50,000/- <b>Dy. No.1321-R&amp;I</b> <b>7-3-2016</b>

	Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Synthes GmbH, Eimattstrasse 3, 4336, Oberdorf, Switzerland.				<b>Dy.No.39- ADC(MD) 9-3-2016</b>
18.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Synthes GmbH, Eimattstrasse 3, 4336, Oberdorf, Switzerland.	Intramedullary Nailing System  (Expert Tibial Nail Protect).	D	Not mentioned	<b>RS.50,000/- Dy. No.1330- R&amp;I 7-3-2016</b>  <b>Dy.No.40- ADC(MD) 9-3-2016</b>  <b>Form 6-A not provided</b>
19.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ethicon LLC, Highway 183 KM, San Lorenzo, Puerto Rico, 00754, USA.	Surgicel ® Nu- Knit™.  Surgicel ® Fibrillar™  Surgicel ® Snow ™	D	Not mentioned	<b>RS.50,000/- Dy. No.1329- R&amp;I 7-3-2016</b>  <b>Dy.No.41- ADC(MD) 9-3-2016</b>
20.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Johnson & Johnson International Leonardo Da Vincilaan 15, BE- 1831 Diegem, Belgium	Vicryl™ (Polyglactin 910 Mesh).	D	Not mentioned	<b>RS.50,000/- Dy. No.1313- R&amp;I 7-3-2016</b>  <b>Dy.No.42- ADC(MD) 9-3-2016</b>
21.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Synthes GmbH, Eimattstrasse 3, 4336, Oberdorf, Switzerland.	ChronOS Implants	D	Not mentioned	<b>RS.50,000/- Dy. No.1317- R&amp;I 7-3-2016</b>  <b>Dy.No.43- ADC(MD) 9-3-2016</b>

22.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Synthes GmbH, Eimattstrasse 3, 4336, Oberdorf, Switzerland.	EPOCA Shoulder Prosthesis System	D	Not mentioned	RS.50,000/- <b>Dy. No.1320-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.44-ADC(MD)</b> <b>9-3-2016</b>
23.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ethicon LLC, 475C Street, Los Frailes Industrial Park, Guaynabo PR, USA 00969.	Ethicon Securestrap	D	Not mentioned	RS.50,000/- <b>Dy. No.1318-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.45-ADC(MD)</b> <b>9-3-2016</b>
24.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw Indiana 46582, USA.	DePuy Joint Surgery Family.	D	Not mentioned	RS.50,000/- <b>Dy. No.1327-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.46-ADC(MD)</b> <b>9-3-2016</b>
25.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ferrosan Medical Devices A/S Sydmarken 5, DK 2860, Soeborg, Denmark.	Spongstan TM Absorbable Haemostatic Gelatin Sponge  Spongstan TM Absorbable Haemostatic Gelatin Powder  Surgiflo TM Haemostatic Matrix	D	24 months	RS.50,000/- <b>Dy. No.173-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.47-ADC(MD)</b> <b>9-3-2016</b>

26.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Synthes GmbH, Eimattstrasse 3, 4336, Oberdorf, Switzerland.	Angular Stable Screw Locking System	D	Not mentioned	RS.50,000/- <b>Dy. No.1319-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.48-ADC(MD)</b> <b>9-3-2016</b>
27.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ethicon Inc, Route 22, West Soomeville, NJ, USA08876.	Physiomesht <sup>TM</sup> Flexible Composite MESH	D	Not mentioned m.	RS.50,000/- <b>Dy. No.1732-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.49-ADC(MD)</b> <b>9-3-2016</b>
28.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ethicon Endo-Surgery, LLC 475 CALLE C, Guaynabo, PR USA.  <b>Physical Manufacturer:</b> M/s Ethicon Endo-Surgery, S.A. de C.V, Mexico.	Ethicon Endo Surgery “Family of Linear Cutters Reloads”  1. Echelon. 2. Proximate. 3. Linear Reloads. 4. Endopath.	D	Not mentioned	RS.50,000/- <b>Dy. No.1314-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.50-ADC(MD)</b> <b>9-3-2016</b>
29.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Depuy International, St.Anthony’s Road, Leeds LS 118DT, United Kingdom.	Family of Depuy Joint Surgery	D	Not mentioned	RS.50,000/- <b>Dy. No.1728-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.51-ADC(MD)</b> <b>9-3-2016</b>

30.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Cordis Cashel, Cahir Road, Cashel. Co, Tipperary, Ireland.	Cordis OptEase TM Cordis TrapEase TM  (Family of Vena Cava Filters)	D	Not mentioned	RS.50,000/- <b>Dy. No.1318-R&amp;I</b> <b>7-3-2016</b>  <b>Dy.No.52-ADC(MD)</b> <b>9-3-2016</b>
31.	M/s Johnson & Johnson Pakistan (Pvt) Limited, Fl.19, Sub Plot F-1, Kehkashan Scheme No.5, Main Boat Basin, Clifton, Karachi. <b><u>Legal Manufacturer</u></b> M/s Ethicon LLC, Highway 183KM 8.3, San Lorenzo 00754, Puerto Rico, USA.	Temporary Cardiac Pacing Wires.  Codes & sizes as per Free Sale Certificate.	D	Not mentioned	RS.50,000/- <b>Dy. No.1146-R&amp;I</b> <b>11-4-2016</b>  <b>Dy.No.75-ADC(MD)</b> <b>12-4-2016</b>
32.	M/s Roche Pakistan Limited, 37-C, Block-6, P.E.C.H.S, Karachi.	Accu-Chek Performa Blood Glucose Monitoring System  Accu-Chek Active <b>(Dossier N,O)</b>	C	Not mentioned	RS.50,000/- <b>Dy. No.2574-R&amp;I</b> <b>20-6-2016</b>  <b>Dy.No.99-ADC(MD)</b> <b>20-6-2016</b>
33.	M/s Roche Pakistan Limited, 37-C, Block-6, P.E.C.H.S. Karachi. <b>Manufactured by</b> M/s Roche Molecular Systems Inc., 1080- US Highway 202 South Branchburg, NJ 08876, USA.	Cobas Viral Infectious Disease Markers (Molecular Products)  <b>(Dossiers P &amp; Q)</b>  Cobas®RaqScreen West Nile Virus Test (96-Tests).  Dossiers P & Q Cobas®RaqScreen West Nile Virus Test (6-Sets).  Kit Cobas T-Sern	D	Not mentioned	RS.50,000/- <b>Dy. No.429-R&amp;I</b> <b>25-8-2016</b>  <b>Dy.No.132-ADC(MD)</b> <b>20-9-2016</b>



		<p>Wash RGT (5.1L)</p> <p>Cobas ® Taqscreen Cadaveric Specimen Diluent Kit (96 Tests)</p> <p>Cobas ® TaqScreen DPX Test (96 Tests)</p> <p>Cobas ® TaqScreen DPX Control Kit (12 Sets)</p> <p>Kit Cobas T-Scrn Wash RGT (5.1L)</p>			
34.	<p>M/s Roche Pakistan Limited, 37-C, Block-6, P.E.C.H.S. Karachi. <b>Manufactured by</b> M/s Roche Diagnostics GmbH. Sandhofer Strasse 116, 68305 Mannheim, Germany.</p>	<p>Cobas Viral Infectious Disease Markers <b>(Dossiers R, S &amp; T)</b></p> <p>Elecsys HTLV I/II (100 Tests).</p> <p>Elecsys HTLV I/II (200 Tests).</p> <p>Elecsys HTLV I/II PC (6 x 1 ml) Tests).</p> <p>Elecsys Anti-HBs II (100 Tests)</p> <p>Elecsys Anti-HBs II (200 Tests)</p> <p>Elecsys Anti-HBs PC (16 x 1.3 ml)</p> <p>Elecsys Anti-HBc II (100 Tests)</p>	D	Not mentioned	<p><b>RS.50,000/- Dy. No.423-R&amp;I 25-8-2016</b></p> <p><b>Dy.No.131- ADC(MD) 20-9-2016</b></p>

		Elecsys Anti-HBc II (200 Tests)  Elecsys PreciControl Anti-HBc II.			
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**Decision.** The Board decided to defer these applications for scrutiny/evaluation.

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MDB/GD No.2  
September, 2016



**GUIDELINES ON GOOD DISTRIBUTION PRACTICE FOR  
MEDICAL DEVICES (GDPMD)**

*[Rule 10, Medical Devices Rules, 2015]*

**Regulatory Requirements for Medical Device Safety and Performance**

## **PREFACE**

*Distribution is an important activity in the integrated supply-chain of medical devices. Various personnel and entities are generally responsible for the product sourcing, procurement, transportation, delivery, storage, device tracking, installation, commissioning, service and maintenance and calibration need to be appropriately managed and controlled to ensure the safety and performance of medical devices at the point of use. The Guidelines on Good Distribution Practice for Medical Devices (GDPMD) is developed to elucidate the requirements for an appropriate management and control of these activities. GDPMD specifies the requirements for a quality management system to be established, implemented and maintained by an establishment in carrying out activities in medical device supply-chain to comply with Pakistan medical device regulatory requirements as stipulated in Medical Device Rules, 2015 and DRAP Act, 2012 and to demonstrate its ability to maintain quality, safety and performance of medical devices in compliance with the regulatory requirement throughout the supply-chain. It is the responsibility of the establishment to ensure that they are in compliance with all applicable laws. This document provides general guidance for GDPMD. Although it has been tried that the accurate information be provided, however the authority does not warrant its accuracy and completeness and therefore does not accept any liability for any error or omissions in this document or for any action or decision taken or not taken as a result of using of this document. In the event of any contradiction between the requirements of GDPMD and any written law, the latter shall prevail.*

## **CONTACT INFORMATION**

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Website: [www.dra.gov.pk](http://www.dra.gov.pk)

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## **1. PRELIMINARY**

### **1.1 Objective**

The objective of this document is to ensure the quality, safety and performance of medical device during all aspects of medical device supply-chain, which include, but not limited to procurement, storage, transportation, delivery, installation, commissioning, service and maintenance, calibration and after sale service, tracking, documentation and record-keeping practices.

### **1.2 Scope and Application**

This document is applicable to all parties involved in the supply-chain of medical device, covering authorized representatives of foreign manufacturers, importers or distributors of medical devices in Pakistan .

The design and implementation of GDPMD by an establishment is dependent on the types, categories and classification of medical device, size and structure of the establishment and the processes employed. If any requirement in GDPMD is not applicable due to the type, category and classification of the medical device and supply-chain activities, a justification has to be provided for exclusion from fulfillment of that particular requirement.

## **2. QUALITY MANAGEMENT SYSTEM**

### **2.1 General Requirement:**

The establishment shall establish, document, implement and maintain a quality management system in accordance to the requirements of GDPMD.

Where an establishment chooses to outsource any activity that may affect the quality of medical devices, the establishment shall ensure control over such processes.

The documentation required include:

- (i) a site master file,
- (ii) documented procedures required by the GDPMD,
- (iii) documents needed by the establishment to ensure the effective planning, operation and control of its processes,
- (iv) records required by the GDPMD, and
- (v) any other documentation specified by the regulatory authority.

### **2.2 Control of Documents and Records**

Documents required for GDPMD shall be controlled and records for each purchase and sale, showing the date of purchase and supply, name of medical device, quantity received and supplied and name and address of supplier or consignee shall be established and maintained to provide evidence of conformity to requirements of GDPMD. Record shall be legible, readily identifiable and retrievable.

A documented procedure shall be established for the identification, storage, protection, retrieval, retention time and disposal of record.

The establishment shall retain the record for a period of time:-

- (i) specified by relevant regulatory requirements, or

- (ii) at least equivalent to the lifetime of the medical device as defined by the product owner of the medical devices, whichever is the longest.

All documents shall be prepared, approved, signed and dated by an appropriate authorized person(s).

Documents shall be reviewed regularly and kept up-to-date. If a document has been revised, a control system shall be established to prevent the unintended use of the superseded version.

Where an electronic record system is used in place of a paper-based system, the system utilized should have built-in checks and balances to ensure the integrity of the record and to protect against unauthorized entries and the system should also incorporate audit trails for tracking changes.

Records providing traceability of medical devices from supplier and to the customers shall be maintained.

### **2.3 Complaints**

The establishment shall establish a documented procedure for handling of all written and oral complaints regarding medical devices and record should be established.

The procedure for handling complaints shall ensure that the complaints received are investigated and followed through, and that corrective actions are taken to prevent repeated complaints, and, where a decision is made to recall the medical device, the details of the recall. Any report of adverse event which requires regulatory reporting shall be reported to the regulatory authority as per procedure and regulatory requirements.

Records of the complaint, investigation and any subsequent actions taken shall be maintained.

The investigation should take into consideration the condition and circumstances under which the medical device was distributed, stored and used.

### **2.4 Field Corrective Action (FCA) and Field Safety Notice (FSN)**

**“field corrective action (FCA)”** is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device.

**“field safety notice (FSN)”** means a communication sent out by a manufacturer or its representative to the device users in relation to a FCA.

The establishment shall—

- (i) establish documented procedures for handling of FCA and FSN
- (ii) define the responsibilities for planning, conducting and reporting of corrective actions in the documented procedure;
- (iii) establish in writing a recall or withdrawal procedure in consultation with manufacturer
- (iv) inform the MDB prior to execution of FCA and FSN
- (v) inform all customers to whom the medical device was distributed with the appropriate degree of urgency;

- (vi) inform overseas counterparts on the FCA and FSN if the medical devices are exported;
- (vii) request that the affected medical devices be removed immediately from usable stock and stored separately in a secure area until they are disposed of accordingly; and
- (viii) maintain records of all actions taken in connection with the FCA and FSN

The establishment shall establish documented procedure for incident/problem reporting to comply with the regulatory requirements, which include—

- (i) the identification of the nature of the incident/problem;
- (ii) the investigation;
- (iii) the evaluation and analysis; and
- (iv) the action to be taken.

Corrective actions as applicable shall be taken after final report.

## 2.5 Recall and Return

The establishment shall—

- (i) establish a documented procedure to effectively and promptly recall and return medical device known or suspected to be defective;
- (ii) ensure that the system comply with the regulatory requirements;
- (iii) the manufacturer and/or authorized representative shall be informed in the event of a recall;
- (iv) where a recall is instituted by an entity other than the manufacturer and/or authorized representative, consultation with the manufacturer and/or authorized representative should, where possible, take place before the recall is instituted;
- (v) recall information shall be reported to the MDB.
- (vi) All returned medical devices shall be segregated apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal and treated as nonconforming product.

Some criteria for medical devices to be returned to saleable stock are:-

- (i) The medical devices are in their original unopened containers and in good condition;
- (ii) It is known that the medical devices have been stored and handled under proper conditions;
- (iii) The remaining shelf life period is acceptable; and
- (iv) The medical devices have been examined and assessed by appropriate personnel.

This assessment should take into account the nature of the medical device, any special storage conditions required, and the time that has elapsed since it was distributed. Special attention should be given to thermo-labile medical devices.

Advice should be sought from the product owner as necessary.

The returned medical devices should only be formally released to saleable stock, following a satisfactory quality re-evaluation by a nominated, responsible person.

Medical devices returned to saleable stock should be placed in accordance with the stock rotation system established.



## **2.6 Disposal of Medical Devices**

The establishment shall establish a documented procedure for the disposal of medical devices, keeping in view the regulatory requirements.

If the medical devices have not been immediately sent for disposal, they shall be kept in a clearly segregated area and identified so that they will not be sold inadvertently or contaminate other medical devices.

Control should be established to ensure that:-

- (i) the status is clearly identified;
- (ii) the products cannot re-enter the distribution system, and;
- (iii) it is disposed of safely.

## **2.7 Internal Check System, Management Input and Output Review**

The establishment shall establish internal check system to monitor the implementation of and compliance with the requirements of GDPMD.

Internal checking should normally be conducted once a year.

The result of the checking is usually stated in a written report indicating the nonconformities found. Timely action should be taken to eliminate the nonconformities and their causes. The checking results should be communicated to management for review.

The establishment top management should identify, review and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality system through the use of the quality policy, quality objectives, checking results, analysis of data, corrective and preventive actions and management review. This review shall include assessing opportunities for improvement and the need for changes to the quality management system.

Records from management reviews shall be maintained.

The input to management review may also include information on:

- (i) customer complaints/feedback;
- (ii) surveillance and vigilance activities including field corrective actions, advisory notes, recalls and adverse event /incident reporting;
- (iii) feedback from manufacturer;
- (iv) feedback and directives from the authority;
- (v) status of preventive and corrective actions;
- (vi) changes that could affect the GDPMD regulatory compliance system; and
- (vii) recommendations for compliance.

The output from the management review shall include any decision and action related to:-

- (i) the corrective and preventive actions required; and
- (ii) the effectiveness of the GDPMD regulatory compliance system and its compliance with the regulatory requirements.

Records of the management review should include the identity of those taking part in the review and all points of the review including description of any corrective or preventive action to be taken. For any action determined, the responsibility for such actions, the resources, target dates for completion, etc should be identified.

## **2.8 Corrective and Preventive Action**

For corrective actions, The establishment shall—

- (i) take action to eliminate the cause of nonconformities in order to comply with GDPMD and regulatory requirements; and
- (ii) establish a documented procedure to define requirements for:
  - reviewing nonconformities (including customer complaints);
  - determining the causes of nonconformities;
  - evaluating the need for action to ensure that nonconformities do not recur;
  - determining and implementing action needed, including, if appropriate, updating documentation,
  - recording of the results of any investigation and of action taken; and
  - reviewing the corrective action taken and its compliance with GDPMD and regulatory requirements.

For preventive actions, The establishment shall—

- (i) determine proactive action to eliminate the causes of potential nonconformities in order to comply with GDPMD and regulatory requirements and preventive actions shall be appropriate to the effects of the potential problems; and
- (ii) establish a documented procedure to define requirements for—
  - determining potential nonconformities and their causes;
  - evaluating the need for action to prevent occurrence of nonconformities;
  - determining and implementing action needed;
  - recording of the results of any investigations and of action taken;
  - and reviewing preventive action taken and its effectiveness.

## **3 RESOURCE MANAGEMENT**

### **3.1 Personnel**

Personnel working at the premises shall be sufficient for complying GDPMD. Qualified person shall possess the prescribed qualification.

### **3.2 Training**

The establishment shall

- (i) provide training to key personnel to satisfy needs, and
- (ii) maintain training record.

Training for personnel will be tailored to the person's assignment. Typical training and education should cover the:

- (i) nature of activities,
- (ii) health, safety and environmental regulations and/or regulatory body related requirements,
- (iii) establishment's policies,

- (iv) function of the personnel, and
- (v) procedures and instructions of relevance to personnel.
- (vi) Special training may be necessary for personnel dealing with certain categories of substances/materials such as chemicals, biological, radiation emitting or energy source components and products.

### **3.3 Responsibility and Authority**

The establishment shall ensure that responsibilities and authorities are defined, documented and communicated within the establishment. This should be documented in site master file as well.

### **3.4 Designated person**

The establishment shall appoint designated person who, irrespective of other responsibilities, shall have the ultimate responsibility of:

- (i) Ensuring that processes needed for the quality management system are established, implemented and maintained and reporting to top management on the performance of the quality management system and any need for improvement, and
- (ii) Ensuring the promotion of awareness of regulatory and customer requirements throughout the establishment and liaising with external parties on matters relating to the quality management system and regulatory requirements.

### **3.5 Premises and Facilities.**

The establishment shall ensure that the premises and equipment used are suitable and adequate to ensure proper conservation and distribution of medical devices. Fire extinguishers, smoke detector etc for control of fire shall be available. Storage areas should be cleaned and accumulated waste removed at regular intervals. The frequency and methods of cleaning the premises and areas should be recorded. No smoking, eating and drinking should be permitted in areas used for storage and handling of medical devices.

Buildings should protect medical devices from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.

Premises should be constructed, serviced and maintained regularly to protect stored medical devices from all potentially harmful influences such as undue variations of temperature and humidity.

### **3.6 Cleanliness and Pest Control**

The establishment shall establish documented procedure for cleaning of premises including frequency and methods. Records of cleaning shall be maintained.

The establishment shall document and ensure a pest control mechanism to identify and prevent pest infestation.

Record of pest control mechanism shall be maintained.

### **3.7 Calibration**

The instruments used for measuring and monitoring temperature and humidity shall be calibrated or verified for accuracy from accredited laboratories at defined intervals, or prior to use and the results of such calibrations or verifications shall be recorded and retained.

## **4 AUTHORIZATION**

The establishment shall—

- (i) obtain appropriate authorization to become authorized representative, importer or distributor of medical devices; and
- (ii) establish and maintain written agreement with the relevant party regarding supply of information required for regulatory matters relating to medical devices it deals with.

## **5 SITE MASTER FILE.**

The establishment shall establish and maintain a Site Master File as per format approved by the MDB.

## **6 STORAGE AND STOCK HANDLING, TRACEABILITY AND SUPPLY CHAIN MANAGEMENT**

- The establishment shall provide suitable and adequate storage to ensure proper conservation of the medical devices and shall provide back up for electricity to ensure proper conservation of the medical devices during electric load shedding, wherever required.
- The establishment shall ensure proper receipt of medical devices.
- Medical devices requiring special storage conditions (e.g. temperature and/or humidity or narcotics requiring additional security measures) should be placed in separate areas equipped to provide the desired conditions. A list of such medical devices should be maintained and the medical devices properly identified. Storage conditions shall be monitored and recorded periodically and Records shall be maintained. During transportation special measure should be taken to maintain conditioned required to prevent effect on the integrity and quality of the medical devices.
- There should be adequate storage areas, and where applicable, physically separated zones for the orderly segregation of saleable stock, quarantined, expired, rejected/damaged, recalled and returned medical devices ensured, stored off the ground and suitably spaced having adequate lighting and ventilation.
- Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous materials such as combustible liquids and solids, pressurized gases, highly toxic and radioactive substances.
- Adequate precautions should be taken against spillage or breakage, attack by micro-organisms, contamination and cross-contamination.
- Where controlled environmental storage conditions are required, these conditions should be continuously monitored and documented. The actual storage temperature should be expressed quantitatively. Where the storage temperature is not expressed quantitatively or stated (in terms of a range) on the labels of the registered medical device.

- The establishment shall establish a system to ensure stock rotation with proper label information.
- The expired medical devices shall be disposed of as per procedure in this guidance document.
- Medical devices bearing an expiry date must not be received or supplied close to or after the expiry date such that this date is likely to occur before the consumer uses the medical devices.
- All labels and containers of medical devices should not be altered, tampered or changed.
- The establishment shall establish adequate methods of transportation and deliveries should be made only to authorized wholesalers, distributors or person to achieve safe and secure delivery of all medical devices from their point of collection to their point of delivery.

Medical devices shall be transported in such a way that:-

- (i) their identification is not lost;
- (ii) they do not contaminate, and are not contaminated by, other medical devices or materials/substances;
- (iii) adequate precautions are taken against spillage, breakage or theft;
- (iv) they are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, or to attack by microorganisms and pests.

## **6.1 Installation and Servicing**

The establishment shall where applicable—

- (i) establish and maintain documented procedures, work instructions and reference materials, tools and test equipment and reference measurement procedures, for performing servicing activities including calibration, repair, maintenance and verifying that they meet the regulatory requirements and applicable standards;
- (ii) establish documented requirements which contain acceptance criteria for installation, testing and commissioning of the medical device;
- (iii) establish installation qualification and maintain adequate installation and inspection instructions for medical devices requiring specified installation requirements, and where appropriate, test procedures;
- (iv) ensure proper installation, testing and commissioning;
- (v) ensure equipment used for testing, maintenance and conservation of medical devices are calibrated or verified at specific intervals;
- (vi) ensure the calibration and maintenance of test equipment conforms to the applicable standards; and
- (vii) maintain testing and commissioning, installation, calibration and maintenance service records.

The establishment shall, as appropriate—

- (i) establish an appropriate technical support which include maintenance service, training, calibration, management of spare parts, workshop setup and management;
- (ii) establish maintenance management mechanism to support the customers;

- (iii) ensure the technical and maintenance support services for active medical devices conform to the applicable regulatory requirements.

## **7. SEGREGATION OF COUNTERFEIT, ADULTERATED, MISBRANDED, SPURIOUS AND SUBSTANDARD MEDICAL DEVICES**

Counterfeit, adulterated, misbranded, spurious and substandard medical devices, if found in the distribution network, shall be physically segregated from other medical devices to avoid any confusion. These shall be clearly labelled as “Not for Sale” or in other similar phrases/words.

Appropriate corrective measures should be undertaken for identified counterfeit, adulterate, misbranded, spurious or substandard medical device, which includes but are not limited to the following:-

- (i) Segregation/quarantine of these medical devices,
- (ii) Investigation of supply chain breach.

Communication is required to all affected wholesalers / distributors / retailers / consignees possibly supplied with these medical devices prior to notification to the regulatory authority for such communication

## **8. OUTSOURCE ACTIVITIES**

Where the establishment outsources any process within the scope of the GDPMD, the establishment shall ensure control over such processes. Certain processes such as cleaning, pest control, transportation etc may be outsourced to third party service providers.

The establishment shall establish requirements to ensure that the outsourced activities conform to specified requirements.

**SCOPE OF GDPMD CERTIFICATION**

The GDPMD certificate shall specify the following—

- (i) scope of activities performed by the establishment and category (s) of medical devices dealt by the establishment;
- (ii) outsourced activities, if applicable;
- (iii) any special storage and handling conditions, such as chill room or cold room for cold chain management; and
- (iv) applicable rules of the Medical Device Rules, 2015.
- (v) name, complete address and contact information of the establishment involved in performing activities.
- (vi) issuing date and expiry date of the certificate.
- (vii) particulars of CAB (if applicable) issuing the certificate which include the name and address, logo, registration number where applicable and/or accreditation number issued by Pakistan National Accreditation Council (PNAC) and the name and signature of the certification manager of the CAB; and
- (viii) number, issuing date and expiry date of the certificate.

Scope of activities for establishment to be certified include anyone or combination of the following activities—

- (i) import;
- (ii) storage and warehousing;
- (iii) distribution.
- (iv) installation, testing & commissioning;
- (v) servicing and maintenance; and

List of devices dealt by the establishment—

S.No	*Device Category

**\*List of device categories:**

- 01 Active implantable devices
- 02 Anesthetic and respiratory devices
- 03 Dental devices
- 04 Electro mechanical medical devices
- 05 Hospital hardware
- 06 In vitro diagnostic devices
- 07 Non-active implantable devices
- 08 Ophthalmic and optical devices
- 09 Reusable devices
- 10 Single-use devices
- 11 Assistive products for persons with disability
- 12 Diagnostic and therapeutic radiation devices
- 13 Complementary therapy devices
- 14 Biologically-derived devices
- 15 Healthcare facility products and adaptations
- 16 Laboratory equipment
- 17 Medical software
- 18 Others: Please specify with justification for any additional categories.

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