Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drug Regulatory Authority of Pakistan
****

MINUTES OF THE 13TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 05-08-2019

13th meeting of the Medical Device Board (MDB) was held in the office of Drug Regulatory Authority of Pakistan, TF Complex, G-9/4, Islamabad on 5th August, 2019. The Secretary MDB referred to Sub-rule (9), Rule (59) of Medical Devices Rules, 2017 where in the absence of Chairman MDB, members may elect one of the member to preside over the meeting. The members unanimously elected Dr. Prof. Sajid Bashir, Professor of Pharmaceutics, University of Sargodha,

Sargodha to preside over the meeting as Chairman. Subsequently meeting was chaired by Dr. Prof. Sajid Bashir, Professor of Pharmaceutics, University of Sargodha, Sargodha and was attended by the following:-

S.No.	Name and Designation / Department	Position in the MDB
1.	Dr. Prof. Sajid Bashir, Professor of Pharmaceutics, University of Sargodha, Sargodha.	Member / Chairman
2.	Dr. Abdul Haleem Khan, Associate Professor & Chairperson, Department of Pharmacy, Forman Christian College, Lahore.	Member
3.	Mr. Muhammad Alamgir Rao, Director Procurement, Director General Health Services, Lahore. (Nominee of Director General Health, Punjab).	Member
4.	Mr. Imranullah, Chief Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
5.	Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar.	Member
6.	Dr. Prof. Saqib Shafi Sheikh, Interventional Cardiologist, Mayo Hospital, Lahore.	Member

7.	Prof. Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi.	Member
8.	Mr. Muhammad Asghar, CEO, Cyber Soft Technologies, Lahore.	Member
9.	Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad.	Secretary / Member

The meeting started with the recitation of the Holy Quran. The Secretary MDB welcomed all the participants and presented the agenda of the meeting.

Item No.I. **CONFIRMATION OF MINUTES OF 12TH MEDICAL DEVICE BOARD MEETING**.

Decision: The Board confirmed the minutes of the 12th meeting of MDB.

However member MDB, Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar made an observation that in one of the previous meetings issue of misuse of disposable syringes and hypodermic needles were discussed and how far we have progressed.

Secreatary MDB briefed the Board that a meeting was called inviting Provincial Health Departments, Provincial Healthcare Comissions, Federal Government Hospitals and stakeholders from import and manufacturing side to discuss the matter of misuse of disposable syringes and hypodermic needles but was postponed due to some unavoidable reasons.

It was further briefed that in the wake of HIV-AIDS outbreak in Ratodero, Sindh, WHO team investigated the matter and submitted its report to Government of Sindh, whereby **reuse of syringers** has been found to be one of the leading causes of the outbreak. A meeting was called by the Special Assitant to PM on Health/ Federal Minister, namely, Dr Zafar Mirza in Ministry of National Health Services Regulations & Coordination on 10-07-2019 and leading syringe importers and manufcturers were invited. Dr. Mirza informed that the health care practices in the country were in terrible state. 70% health care is in the hands of private practitioners and 30% is provided by the public sector. However, the quality of health care services is not the best. He further said that in April of this year a serious HIV outbreak occurred in Larkana/Ratodero which has infected more than 700 children and adults. WHO

Rapid Response team investigated the outbreak and reuse of injections and IV drip sets was responsible for majority of infection transmission. He informed that 95% injections in the country are unnecessary and a good majority of them are unsafe. The government, he mentioned, is very concerned on this situation and determined to address the problem of **reuse of injection** equipment. He pointed out that syringe manufacturers and importers are one of the key stakeholders in the national injection safety strategy. It is the responsibility of the government to improve policy and Drug Regulatory Authority of Pakistan (DRAP) has to improve its regulations. WHO injection safety guidelines recommend that to improve injection safety reuse prevention (RUP) syringes or auto disable syringes should be introduced.

The manufacturers and importers share the following view point:-

- It will be difficult to develop market for auto disable syringes on minimum profit margins and huge investment is required to change manufacturing lines and molds.
- The government should focus on educating injection providers and patients.
- Conventional disposable syringes can also be used safely.
- Can patients in Pakistan afford to pay the cost of auto disable syringes.

Special Assitant to PM responded as below:

- The government is willing to provide maximum facilitation to manufacturers to change their molds and lines to produce auto disable syringes in the country.
- Just education and training will change the risky practices of injection providers or the injection demand of patients.
- Economy of scale can bring the prices down for auto disable syringes making it possible for everyone to purchase these syringes.
- The government is determined to introduce auto disable syringes in order to bring down the problem of reuse.
- The offer by M/s Amsons Pharma to manufacturers of syringes to visit their plant was appreciated and Dr Mirza requested DRAP to coordinate the visit of Amsons manufacturing plant so that others can review and learn about manufacturing of auto disable syringes.

The manufacturers visited M/s Amsons Pharma and their feedback in generally was very positive. All are willing to shift their manufacturing lines and moulds to autodisable syringes but they need time.

Special Assistant to PM on Health/ Federal Minister has also constituted a **National Task Force on Injection Safety on 8-07-2019** and the first meeting was held on 11-07-2019. Dr. Arshad Altaf, WHO Consultant presented the draft **National Action Plan to Address Unsafe Injections in Pakistan**. A **Sub-Committee for removal of disposable syringes and replacement with auto-lock syringes -- plan for execution and timelines** was formed and its first meeting was held in ministry of NHSR&C on 06-07-2019.

Secreatary MDB further briefed that the Government of Pakistan is taking this matter very seriously and has attached the highest priority and in coming months positive development will be seen. DRAP has already registered 34 auto-disable / auto-destructive /auto-breakable syringes of 18 importers but their import is very less due to less demand or usage in Public and Private sector.

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

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

S. No	Name of Establishment	Address	Name of Production Inchange	Name of QC Incharge	Inspection panel & date of inspection	Recommendations
1.	**M/s Hafiz Pharma Industry**	44-KM (Ghaniya) Kamoke, District Gujranwala.	Mr. Akhter Hussain (B.Pharm)	Mr. Hassan Ayub (B.Pharm)	Dr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. Dr. Zaka-ur-Rehman, Secretary Pharmacy	Recommended the renewal of Establishment License to manufacture medical devices by way of formulation bearing No.000595 in favour of M/s

					Council, Punjab. Mr. Ajmal Sohail Asif, FID, DRAP, Lahore.	Hafiz Pharma Industry, Kamoke, Gujranwala in respect of following Sections:- (i) Cotton Bandage. (ii) Cotton Crepe Bandage. (iii) Surgical Gauze.

Decision: The MDB approved the renewal of Establishment License to manufacture medical devices in favour of M/s Hafiz Pharma Industry, Kamoke, Gujranwala in respect of following Sections:-

(i) Cotton Bandage.
(ii) Cotton Crepe Bandage.
(iii) Surgical Gauze.

Item No. III . <u>CHANGE OF MANAGEMENT AND ESTABLISHMENT STATUS OF M/S USMAN ENTERPRISES, KARACHI.</u>

M/s Usman Enterprises, Karachi applied for change of management stating that the company was owned by Mr Zafar Usman, but due to death of Mr Zafar Usman the ownership is transferred to his two sons Mr Taimur Usman and Mr Faiz Fasih Zafar Usman. The status of the company changed from sole proprietorship to partnership. Details of management are as under:-

Previous Management	Current Management (Proposed)
1. Mr Zafar Usman (Sole proprietor)	1. Mr Taimur Usman 2. Mr Faiz Fasih Zafar (Partnership)

2. It is submitted that after issuance of notification SRO. 824(I)/2018 dated 26-06-2018, they are now categorized under Medical Devices, hence Medical Devices Rules, 2017 are applicable.

3. The firm submitted partnership deed, undertaking and Rs.50,000/- fee for change of management.

Decision: The MDB approved the change in management of M/s Usman Enterprises, Karachi from Mr. Zafar Usman to Mr. Taimur Usman and Mr. Faiz Fasih Zafar.

Item No.IV. APPLICATIONS FOR GRANT OF ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.

Secretary MDB informed the Board that the following applications for grant of enlistment of medical devices for import on prescribed form 6-A under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s Mira Khan & Co., House No. 12/14, Swati Gate Hakimabad, Peshawar Correspondence Office: Flat No. 414, 4th Floor, Park Tower, F-10/3, Islamabad (ELI-00332) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s RAYS S.p.A., Via Francesco Crispi 26-60027 Osimo (AN), Italy (FSC Italy Issuance Date 07-08-2018)	Vinyl PF Plus Examination Gloves (Powder Free Clear Vinyl Examination Gloves) Class A Shelf Life: ? Rs.5000/-	VINYL Examination Gloves	**Approved** subject to provision of Stability Data to Support 5 Years Shelf Life Claim.
2.	M/s. Digital Imaging Systems, 121-Habitat Apartments, Shadman II, Ghaus -ul-Azam Road, Lahore, Lahore ELI-00094 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Abbott Vascular Inc, 3200 Lakeside drive, Santa Clara, CA 95054- USA **Manufacturing Site:** M/s. Availmed S.A. De C.V.C. Industrial Lt. 001 Mz. 105 No. 20905	**Guide wire Introducer Accessory Kit with Copilot** 1003330 Class A Shelf Life : 02 years Rs.5,000/-	**Torque Device** Facilitates the steering of the guide wire within the vascular anatomy **Guide Wire Introducer** Guides the delicate tip of a guide wire through a hemostasis valve while preserving the preformed tip shape on the guide wire	**Approved.**

		Int.A Col.Cd. Industrial, Tijuana, Baja, California, Mexico 22444. FSC USFDA Valid till 16-05-2020		**CoPilot BBCV** Maintains homeostasis during introduction, withdrawal and use of diagnostic/interventional devices	
3.	**-do-** **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Abbott Vascular Inc, 3200 Lakeside drive, Santa Clara, CA 95054- USA **Manufacturing Site:** M/s. Availmed S.A. De C.V.C. Industrial Lt. 001 Mz. 105 No. 20905 Int.A Col.Cd. Industrial, Tijuana, Baja, California, Mexico 22444. FSC USFDA Valid till 16-05-2020	**Copilot Bleedback control valve** 1003331 Class A Shelf Life : 02 years Rs.5,000/-	The COPILOT Bleedback Control Valve has a.096 (2044mm) inside diameter. This device has two seals that operate independently: the clamp seal and the bleedback control (BBC) seal.	**Approved.**
4.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. ELI-00209	**Legal Manufacturer:** M/s. D-tek s.a. Parc Initialis Rue Rene Descartes, 19 BE-7000 Mons BELGIUM. **Manufacturing Site:** M/s. D-tek s.a. Parc Initialis	**BLUEDIVER1** BlueDiver Instrument Class A Shelf Life : N/A Rs.5,000/-	**Blue Diver Instrument** A machine intended for carrying out invitro diagnosis tests	**Approved.**

	Evaluator: Shahid Muhammad Iqbal	Rue Rene Descartes, 19 BE-7000 Mons BELGIUM. FSC Belgium Issued on 06.02.2019			

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

Secretary MDB informed the Board that the following applications for grant of registration of medical devices for local manufacture on prescribed form 7 under Medical Devices Rules, 2017 were received in the Division. The MDB discussed and decided as mentioned against earch:-

Sr. No.	Name & Address of manufacturer	Name of medical device	Brief description	Decision
1.	M/s Vikor Healthcare (Pvt) Ltd Head office: 159/P, Block 3, Kashmir Road P.E.C.H.S., Karachi. Manufacturing facility: Plot C-126 to C-135, LIEDA, Hub District, Lasbella (ELM-0006) **Evaluator:** Ms. Unum Zia Shamsi	SURGILINE ™ Silk Braided (surgical suture) Codes: STH201 SI110 SR304 ST201 SI204 SI106 SR111 SR301 SR201 ST215 ST216 ST217 SR303 STH202 SI201 SI205 SR101 SS001 SS002 SS008 ST202 ST218 SR302	A sterile braided, non absorbable surgical suture composed of the organic protein fibron.	1. Accelerated stability studies for 6 months at 40°C± 2°C and RH 75% ± 5% provided to support 5 years shelf life claim 2. Long term stability studies for 2 years at 30°C ± 2°C and 65% ± 5% RH provided

		SI101 SI107 SI108 SI109 SI202 SR104 SR202 SR102 SR103 SS004 SS003 SS005 SS009 ST204 ST207 ST219 ST203 ST205 SI102 SI103 SI203 SI301 SR107 SR106 SR105 SL101 SL103 SL102 SS006 SS007 ST212 ST211 ST208 ST210 ST209 ST213 ST101 SI104 SI105 SR108 SR109 SR110 SL201 SL104 SL106 SL105 ST206 ST214 ST220 ST102		

		SI302 S0001 S0002 S0003 S0004 S0005 S0006 S0007 S0008 S0009 S0010 S0011 S0012 S0013 S0014 S0015 S0016 S0017 S0018 Pack size: per dozen Class: D Shelf life: 5 years		
2.	-do- **Evaluator:** Ms. Unum Zia Shamsi	SURGILINE™ SURGIGUT™ Plain (Absorbable catgut suture) Codes: PR201 PC201 PT206 PR301 PT204 PI101 PC202 PT203 PT205 PR302 PI102 PI201 PS001 PC203 PT202 PT207 PR303 PI104 PI103 PI105 PI202 PT201 PT209 PR304 PT208	A sterile monofilament, absorbable surgical suture composed of purified connective tissue (mostly collagen) derived from either the sub mucosal fibrous layer of sheep (ovine) or the serosol layer of beef (bovine) intestine.	1. Accelerated stability studies for 6 months at 40°C± 2°C and RH 75% ± 5% provided to support 5 years shelf life claim 2. Long term stability studies for 2 years at 30°C ± 2°C and 65% ± 5% RH provided

		PI203 PI106 PT101 PT210 PI204 PI107 PT102 PR305 P0003 P0001 P0002 Pack size: per dozen Class: D Shelf life: 5 years		
3.	-do- **Evaluator:** Ms. Unum Zia Shamsi	SURGILINE ™ SURGIGUT ™ Chromic (Absorbable catgut suture) Codes: CR201 CR202 CR205 CCH201 CCH202 CT201 CT202 CT227 CTH201 CTH202 CAH201 CAH202 CB101 CR203 CR204 CR206 CC201 CC202 CCH203 CCH204 CT101 CT203 CT226 CT204 CT205 CT225 CT206 CT207 CTH203 CTH204	A sterile, monofilament absorbable, natural surgical suture composed of purified connective tissue (mostly collagen) derived from either the submucosal fibrous layer of sheep (ovine) or the serosal layer of beef (bovine) intestine. Available in dark brown color	1. Accelerated stability studies for 6 months at 40ºC± 2ºC and RH 75% ± 5% provided to support 5 years shelf life claim 2. Long term stability studies for 2 years at 30ºC ± 2ºC and 65% ± 5% RH provided

		CAH203 CAH204 CAH205 CAH206 CI201 CC203 CC204 CR207 CT001 CT102 CT103 CT104 CT105 CT109 CT110 CT220 CT218 CT215 CT216 CT217 CT219 CT221 CTH206 CC208 CC501 CR209 CT004 CT111 CT232 CT214 CT222 CT223 CT602 CT112 CT224 CT228 CT229 CT230 CT231 CR210 C0001 C0002 C0003 C0004 Pack size: per dozen Class: D Shelf life: 5 years		

Decision: The MDB discussed the matter at length and considering all pros and cons decided to refer the matter to Dr. Abdul Haleem Khan, Member, MDB and Mr. Tahir Aziz, Member MDB along with the submitted stability data and ICH guidelines for their opinion. The Board also authorized the Secretary MDB to issue registration letters if the opinions are in favour of the M/s Vikor Healthcare (Pvt) Ltd.

Item No.VI. CHANGE OF MANAGEMENT AND CONVERSION OF DML OF M/S RENACON PHARMA (PVT) LIMITED.

M/s Renacon Pharma(Pvt) Ltd. applied for conversion of DML (000458) to establishment license to manufacture medical devices. The firm has submitted original DML along with SECP attested Forms 26, 27, 28 and 29. The said firm got renewal of DML-000458 in 247th meeting of CLB for the period of **21-09-2015 to 20-09-2020**. In same meeting the CLB also directed the firm "to shift at new premises after obtaining license within 03 years after fulfillment of legal/Codal formalities". Since the firm possessed area less than 4 Kanals and facing difficulties in maintaining cGMPs. This decision was communicated to firm on 9th of June, 2016. The firm intimated about updated status regarding shifting of their premises to new site and stated that their construction work will be finished by December, 2019 and process of shifting will be completed by January, 2020.

2. The firm also applied for the change of status from private limited to public limited company and also a change in directors where the approval from authority is still pending. The firm has submitted following documents:

(i) Certificate of conversion of private company into public company (SECP)
(ii) Form-29 dated 21-03-2017, 26-05-2017 and 26-12-2017 (SECP)
(iii) Form-A (SECP)
(iv) Memorandum and Article of Association (SECP)
(v) Requisite fee of PKR 50,000/- for change of company status (Challan No. 0591453) and PKR 50,000/- for management change (Challan No. 0610454).
(vi) NIC copies of all directors
(vii) Taxpayer registration certificate

Previous Company Title	New Company Title
RenaconPharma (Pvt) Ltd, 18-Km, Ferozepur Road, OppNishtar Colony, Lahore.	RenaconPharma Ltd, 18-Km, Ferozepur Road, OppNishtar Colony, Lahore.

Previous Management as per Form-29 dated	New Management as per Form-29 dated 26-05-

21-03-2017	2017 and 26-12-2017
i. Dr. Salman Shakoh S/o Muhammad Khurram, CNIC No: 35201-5612172-7	i. Dr. Salman Shakoh S/o Muhammad Khurram, CNIC No: 35201-5612172-7
ii. Mrs. LubnaShakoh W/0 Dr. Salman Shakoh, CNIC No: 35201-6227854-4	ii. Mrs. LubnaShakoh W/0 Dr. Salman Shakoh, CNIC No: 35201-6227854-4
iii. Mr. Jamal Mustafa Siddiqui S/o Abdul Aleem Khan CNIC No: 42201-4450795-1	iii. Mr. Jamal Mustafa Siddiqui S/o Abdul Aleem Khan CNIC No: 42201-4450795-1
iv. Prof. Abdul MajeedChaudhary S/o Ch. Gulzar Muhammad CNIC No: 30202-2715639-5	iv. Prof. Abdul MajeedChaudhary S/o Ch. Gulzar Muhammad CNIC No: 30202-2715639-5
v. Mr. Muhammad ShafiqueAnjum S/o Muhammad Shafi CNIC No: 35202-3698572-7	v. Dr. Salman Faridi S/o Abdul FaizFaridi CNIC No: 42301-8948788-9
vi. Mr. Saulat Said S/o Sheikh Muhammad Said CNIC No: 35202-2452642-9	vi. Syed Shahid Ali Shah S/o Syed Wajid Ali CNIC No: 35202-4892267-5
vii. Mr. Amir Zia S/o Zia Ur Rehman CNIC No: 35202-3036295-7	vii. Syed Sheharyar Ali S/o Syed Shahid Ali CNIC No: 35200-1484648-3

3. The company has also applied for the change in Quality Control Incharge. The previous QC Incharge Mr. Mahmood Ahmed s/o of Barkat Ali has been replaced by Mr. Adeel-ur-Rehman Qureshi s/o Zil-ur-Rehman Qureshi.

4. Keeping in view of described situation, the case is being presented before MDB to consider conversion of DML, change in company status/management and QC Incharge.

Decision: The MDB acceded to the request of M/s Renacon Phama (Pvt) Ltd and approved the change in Company Title, Management and Quality Control Incharge.

Item No.VII **CHANGE OF MANAGEMENT OF M/S FRONTIER PHARMACEUTICAL (PVT) LTD., PESHAWAR.**

M/s Frontier Pharmaceutical (Pvt) Ltd., Peshawar applied for the change of directors along with technical staff (Production and Quality Control Incharge). For the purpose the firm has submitted Rs. 50,000/- and SECP documents of company registration. Detail of management and Technical staff is described as under:

Management Details:

Previous Management	New Management

i. Mr. Mujeeb Alam (Director) ii. Ms. Alliya Amjad (Director) iii. Mr. Imdad Hussain (Director) iv. Mr. Khalid Javed (CEO)	i. Mr. Mujeeb Alam (Director) ii. Ms. Alliya Amjad (Director) iii. Mr. Imdad Hussain (Director) iv. Mr. Mansoor Wazir (CEO)

Technical Staff Details:

Previous Technical Staff	Current Technical Staff
i. Mr. Akhtar Wali (B.Pharm), (Production Incharge) ii. Mr. Faridullah Khan (MSc. Chemistry) (QC Incharge)	i. Mr. Waqar Ahmed (B.Pharm) (Production Incharge) ii. Mr. Ehtisham-ul-Haq (B.S Biotechnology)(QC Incharge)

Decision: The MDB acceded to the request of M/s Frontier Pharmaceutical (Pvt) Ltd., Peshawar and approved the change in Management and Technical Staff.

Item No. VIII. CHANGE OF MANAGEMENT AND COMPANY TITLE OF M/S BSN MEDICAL LIMITED, KARACHI FOR LOCAL MANUFACTURE

M/s BSN Medical Limited, Karachi stated that the company title and managment has have now been changed. The firm have deposited 50,000/- fee for change in particulars of firm and submitted necessary documents. The firm requested to change Title and managment details in their DML No : 000085. The details of previous and current title of Company, Management details and technical staff details are as under:-

Title of Company	
Previous Title	Current Ttile of Company
BSN Medical Limited	Essity Pakistan Limited
Managment details:	
Previous Managment Details	Curerent Managment Details
1. Eric Trock Jansen (Director) 2. Mr Dicter Holst (Director) 3. Mr Rehman Ghani (Director)	1. Mr Khalid Rafiq (Director) 2. Carl Magnus Stennson (Director) 3. Ms Yik-Hing Ping (Director)
Technical staff Details:	
Previous Technical staff	Current Technical staff
1. Mr Iftikhar – ul- Hassan Niazi (B.Pharm) (Production Incharge) 2. Muhammad sadiq Mallik (B. pharmacy) (QC Incharge)	1. Mr Iftikhar – ul- Hassan Niazi (B.Pharm) (Production Incharge) 2. Muhammad Sadiq Mallik (B. pharmacy) (QC Incharge)

Decision: The MDB acceded to the request of M/s BSN Medical Limited, Karachi and approved the change in Company Title, Management and Technical Staff for local manufacturing.

Item No.IX **CHANGE OF MANAGEMENT AND COMPANY TITLE OF M/S NIZAM COTTON PHARMA INDUSTRIES, WAZIRABAD.**

M/s Nizam Cotton Pharma Industries, Wazirabad, District Gujranwala stated that the Company title and Managment has have now been changed. The firm have deposited 50,000/- fee for change in particulars of firm and submitted SECP documents. The firm requested to change Title and managment details in theire DML No: 000355. The details of previous and current title of Comapny, Mangment details and technical staff details are as under:

Title of Company	
Previous Title	Current Ttile of Company
Nizam Cotton Pharma Industries	Nizam Cotton Pharma (Pvt) Ltd
Managment details:	
Previous Managment Details	Curerent Managment Details
1. Mr. Chaudhry Sultan Mehmood	1. Mr. Muhammad Hammad Sethi 2. Mr. Muhammad Fawad Sethi 3. Ms Eisha Asad Shuja 4. Mr Humayoun Khan 5. Mr Chaudhry Sultan Mehmood
Technical Staff Details:	
Previous Technical staff	Current Technical staff
1. Mr Imtiaz Ahmed (Pharm-D) (Production Incharge) 2. Mr Mujtaba Haider (B. pharmacy) (QC Incharge)	1. Mr Tariq Naseem (B. Pharmacy (Production Incharge) 2. Mr Mujtaba Haider (B. pharmacy) (QC Incharge)

Decision: The MDB acceded to the request of M/s Nizam Cotton Pharma Industries, Wazirabad, District Gujranwala and approved the change in Company Tiltle, Management and Technical Staff.

Item No.X. **CHANGE OF MANAGEMENT AND COMPANY OF M/S BSN MEDICAL LIMITED, KARACHI FOR IMPORT**

M/s BSN Medical Limited, Karachi stated that the company title and Managment has have now been changed. The firm have deposited Rs. 10,000/- fee for change in particulars of firm and

submitted necessary documents. The firm requested to change Title and managment details in theirestablisment license to import medical devices ELI No : 00011. The details of previous and current title of Comapny, Mangment details and technical staff details are as under:

Title of Company	
Previous Title	Current Ttile of Company
BSN Medical Limited	Essity Pakistan Limited
Managment details:	
Previous Managment Details	Curerent Managment Details
1. Mr Khalid Rafiq (Director) 2. Eric Troick Jansen (Director) 3. Ms Yik-Hing Ping (Director)	1. Mr Khalid Rafiq (Director) 2. Carl Magnus Stennson (Director) 3. Ms Yik-Hing Ping (Director)

Decision: The MDB acceded to the request of M/s BSN Medical Limited, Karachi and approved the change in Company Tiltle, Management and Technical Staff.

Item No. XI. CHANGE OF TECHNICAL STAFF OF M/S MEDI-CARE DISPOSABLE INDUSTRIES, LAHORE.

M/s Medi-Care Disposable Industries, Lahore applied for approval of Production and QC Incharge and submitted following documents:

(i) Requisite fee of PKR 50,000/-
(ii) Resignation letters of previously approved technical staff
(iii) Appointment letters of proposed technical staff
(iv) NIC copies of proposed technical staff
(v) Acceptance letters of offered job from proposed technical staff
(vi) Degree of PharmD and Pharmacy council registration of proposed technical staff.
(vii) Experience letters of of proposed technical staff
(viii) Undertaking as full time employee from proposed technical staff

The proposed changes in technical staff includes:-

	Previously approved	**Interim**	**Proposed**
Production Incharge	Mr. Hafiz Muhammad NaeemSarwar S/o GhulamSarwar	Mr. Muhammad AwaisAslam	Ms. Sana Hanif D/o Muhammad Hanif

QC Incharge	Mr. QasimYousaf S/o Raja Muhammad Yousaf	Mr. Rashad Mehmood Sadiq	Mr. UmairRafique Khan S/o Rafiq Ahmad Khan

Decision: The MDB acceded to the request of M/s Medi-Care Disposable Industries, Lahore and approved the change in Production and Qualtiy Control Inchage.

Item No. XII. <u>CHANGE OF TECHNICAL PERSON OF M/S ELITE TRADERS, RAWALPINDI.</u>

Case No.1. M/s M/s Elite Traders, House No.B-342, B-Block Satellite Town, Rawalpindi has been granted License to Import Medical Devices on Form 4 vide License No. ELI-00193 dated 20-10-2018. They have requested for approval of proposed change of their technical person in their licence as per detail given below:-

Existing Technical Person as per Establishment License.	**Proposed Technical Person**
Ms. Kanwal Mirza, R/o House No.551, Street No.12, Sector F-15/1, Islamabad. CNIC No.61101-6811444-2.	Ms. Sana Aziz, House No.D-331, Sector-1, Khayaban-e-Sir Syed, Rawalpindi. CNIC No.37405-4165526-2.

2. The firm has submitted following documents:-

(i) Application on Form-2.
(ii) Copy of new Drug Sale License.
(iii) Credentials of qualified person.
(iv) Fee of Rs.10,000/-
(v) Copy of Establishment License.
(vi) Copy of NTN Certificate.
(vii) Undertaking on stamp paper from proprietor and technical person.

Decision: The Board acceeded to the request of the firm /company and approved the change of technical person from Ms. Kanwal Mirza, R/o House No.551, Street No.12, Sector F-15/1, Islamabad CNIC No.61101-6811444-2 to **Ms. Sana Aziz**, House No.D-331, Sector-1, Khayaban-e-Sir Syed, Rawalpindi, CNIC No.37405-4165526-2.

Case No.2. M/s Eastern Medical Care (Pvt) Limited, 7A, Block N, Model Town, Lahore has been granted License to Import Medical Devices on Form 4 vide License No. ELI-00130 dated 17-10-2018. An application has been received from wherein they have requested for change of their technical person in their license as per detail given below:-

Existing Technical Person as per Establishment License.	Proposed Technical Person
Ms. Afshan Fazal R/o 532-A, Faisal Town Lahore. CNIC No.35202-7977038-8.	Ms. Ayesha Shahid, House No.396, Mohallah Nishter Block, Allama Iqbal Town, Lahore. CNIC No.35202-3215485-6.

2. The firm has submitted following documents :-

(i) Application on Form-2.
(ii) Copy of new Drug Sale License.
(iii) Educational documents of qualified person.
(iv) Fee of Rs.10,000/-
(v) Copy of Establishment License.

Decision: The Board acceeded to the request of the firm /company and approved the change of technical person from Ms. Afshan Fazal R/o 532-A, Faisal Town Lahore, CNIC No.35202-7977038-8to **Ms. Ayesha Shahid**, House No.396, Mohallah Nishter Block, Allama Iqbal Town, Lahore, CNIC No.35202-3215485-6.

Case No.3 CHANGE OF QUALIFIED/TECHNICAL PERSON FOR ESTABLISHMENT LICENSE OF M/S GHAZI BROTHERS.

M/s Ghazi Brothers was issued license to import medical devices and Form 4 vide license no. ELI-00002 on 03-08-2018. The qualified person to supervise the import and sale of medical devices Ms. Bushra Aslam resident of House No. 1279, Mehboob Colony, Chishtian, Bhawalnagar CNIC No. 42301-0557650-6.

The firm has applied for change in Qualified/Technical person from Ms. Bushra Aslam to Ms. Romana Pitafi D/o Ghulam Hussain, CNIC No. 42501-6528219-8, Pharmacist, resident of Bin Qasim Town, Mohallah Shah Nawaz, Goth Pipri Malir, Karachi.

The firm has applied on form 2 for change in particulars with the requisite of Rs.10,000/- the matter is placed before the MDB for consideration.

Decision: The Board acceeded to the request of the firm /company and approved the change of technical person from Ms. Bushra Aslam to **Ms. Romana Pitafi** D/o Ghulam

Hussain, CNIC No. 42501-6528219-8, Pharmacist, resident of Bin Qasim Town, Mohallah Shah Nawaz, Goth Pipri Malir, Karachi.

Case No.4. CHANGE OF QUALIFIED/TECHNICAL PERSON ON ESTABLISHMENT LICENSE OF M/S POPULAR INTERNATIONAL (PVT) LTD., KARACHI

M/s Popular International (Pvt) Ltd., has been granted License to import Medical Devices on Form 4 vide License No. ELI-00091 dated 03-08-2018. The qualified person on the said Licence to supervise the import of Medical Devices was Mr. Muhammad Asad Khan, House No B-305, Ashraf Nagar, Nazimabad No. 5, Karachi CNIC 42101-1477546-5.

Now the firm has applied for change in Qualified/Technical person from Mr. Muhammad Asad Khan to Mr. Hafiz Zain ul Abedin, CNIC No. 42101-3606214-7, Pharmacist, resident of Nouman Avenue, Johar Morr, Flat No. A-71, Mohallah Rashid Minhas Road, Karachi and Mr. Muhammad Waqas Khan, CNIC No. 42101-3333864-1, Pharmacist, Resident of House No. R-1160, Sector 15-B, Buffer Zone, North Karachi.

The firm has applied on Form 2 for change in particulars with the requisite fee of Rs.10,000/- .

Decision: The Board acceeded to the request of the firm /company and approved the change of qualified / technical person from from Mr. Muhammad Asad Khan to **Mr. Hafiz Zain ul Abedin**, CNIC No. 42101-3606214-7, Pharmacist, resident of Nouman Avenue, Johar Morr, Flat No. A-71, Mohallah Rashid Minhas Road, Karachi and **Mr. Muhammad Waqas Khan**, CNIC No. 42101-3333864-1, Pharmacist, Resident of House No. R-1160, Sector 15-B, Buffer Zone, North Karachi.

Case No.5. CHANGE OF QUALIFIED/TECHNICAL PERSON FOR ESTABLISHMENT LICENSE OF M/S BIO MEDICS MEDICAL SYSTEM, RAWALPINDI

M/s Bio Medics Medical System has been granted License to Import Medical Devices on Form 4 vide License No. ELI-00022 dated 03-08-2018. The qualified person on the said Licence to supervise the import of Medical Devices was Ms. Mehwish Chohan, House No.B1-1513, Mohallah Jinnah Model Town, Rawalpindi, CNIC No.37405-6094027-8.

The firm has applied for change in qualified/technical person from Ms. Mehwish Chohan to M.s Ayesha Jahan, CNIC No. 13504-4467985-4, Pharmacist, resident of House No. PD-744/C, Street No.13, Mohallah Pindora, Rawalpindi.

The firm has applied on Form 2 for change in particulars with the requisite fee of Rs.10,000/-

Decision: The Board acceeded to the request of the firm /company and approved the change of qualified /technical person from Ms. Mehwish Chohan to **Ms Ayesha Jahan**, CNIC No. 13504-4467985-4, Pharmacist, resident of House No. PD-744/C, Street No.13, Mohallah Pindora, Rawalpindi.

Case No.6. CHANGE OF QUALIFIED/TECHNICAL PERSON FOR ESTABLISHMENT LICENSE OF M/S TECH ZONE, LAHORE.

M/s Tech Zone has granted License to import Medical Devices on Form 4 vide License No. ELI-00040 dated 03-08-2018. The qualified person to supervise the import and sale of Medical Devices Ms. Ambreen Ishaque, E-468, D-I/2-A, Allied Homes, New Iqbal Park, Eden Cottage Road, Lahore CNIC No.36502-0207218-6.

The firm has applied for change in qualified/technical person from Ms. Ambreen Ishaque to Ms. Aysha Wasif, CNIC No. 35201-7247979-0, Pharmacist, Resident of House No. E-23/14-B, Mohallah Islam Nagar, Walton Road, Lahore Cantt.

The firm has applied on form 2 for change in particulars with the requisite of Rs.10,000/- the matter is placed before the MDB for consideration.

Decision: The Board acceeded to the request of the firm /company and approved the change of qualified /technical person from Ms. Ambreen Ishaque to **Ms. Aysha Wasif**, CNIC No. 35201-7247979-0, Pharmacist, Resident of House No. E-23/14-B, Mohallah Islam Nagar, Walton Road, Lahore Cantt.

Case No.7. CHANGE OF QUALIFIED/TECHNICAL PERSON FOR ESTABLISHMENT LICENSE OF M/S GALAXY PHARMA (PRIVATE) LIMITED, KARACHI

M/s Galaxy Pharma (Pvt) Ltd., Karachi was issued license to import medical devices and Form 4 vide license no. ELI-00402 on 29-05-2019. The qualified person to supervise the import and sale of Medical Devices Hafiz Sheikh Faraz uddin Resident of House No. L-14, Mohallah Line 2, Nafees Bunglows, Malir, Karachi CNIC No. 42501-4078457-9.

The firm has applied for change in Qualified/Technical person from Hafiz Sheikh Faraz uddin to Noor Fatima Bhutta D/o Khalid Iqbal Bhutta, CNIC No. 36302-6789366-2, Pharmacist, Resident of 51-Qasim Road, Multan Cantt.

The firm has applied on form 2 for change in particulars with the requisite of Rs.10,000/- the matter is placed before the MDB for consideration

Decision: The Board acceeded to the request of the firm /company and approved the change of qualified /technical person from Hafiz Sheikh Faraz uddin to **Ms.Noor Fatima Bhutta** D/o Khalid Iqbal Bhutta, CNIC No. 36302-6789366-2, Pharmacist, Resident of 51-Qasim Road, Multan Cantt.

Case No.8. CHANGE OF QUALIFIED/TECHNICAL PERSON FOR ESTABLISHMENT LICENSE OF M/S ORGANS PHARMA, KARACHI.

M/s Organs Pharma, Karachi was issued license to import medical devices and Form 4 vide license no. ELI-00403 on 29-05-2019. The qualified person to supervise the import and sale of Medical Devices Ms. Komal Shahbaz Resident of House No. 417, Street No.31, Mohallah Manzoor Colony, Sector C, Karachi CNIC No. 42301-9537352-4.

The firm has applied for change in Qualified/Technical person from Ms. Komal Shahbaz to Rehana Shamsuddin D/o M.Yousaf Atta, CNIC No. 42201-9297496-2.

The firm has applied on form 2 for change in particulars with the requisite of Rs.10,000/- the matter is placed before the MDB for consideration.

Decision: The Board acceeded to the request of the firm /company and approved the change of qualified /technical person from Ms. Komal Shahbaz to Mr. **Rehana Shamsuddin** D/o M.Yousaf Atta, CNIC No. 42201-9297496-2.

Item No.XIII. <u>EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017.</u>

M/s Asto Life Sciences (Pvt) Limited, Lahore have stated that BD Spinal Needles are registered with DRAP vide Registration No.MDIR-0000096 in their name. The quantity of import of BD Spinal Needles is very limited and it is not possible at the manufacturing plant to print the Establishment License Number, Registration number & MRP. Secondly the individual pack is too small to print Establishment License Number, Registration number & MRP.

They have requested for exemption from printing of MRP, Reg. Number and ELI Number on individual pack as this is an institutional product and there is no space for printing due to its smaller size and allow them to print all required information i.e. Establishment License Number, Registration Number and MRP at their warehouse on pack of 25 EA as well as Shelf Pack of 200 of Spinal Needle under Medical Devices Rules, 2017, Chapter-IV under sub-rule (1) & (2) of Rule 38.

Decision: The Board discussed the matter at length and decided to allow M/s Asto Life Sciences (Pvt) Limited, Lahore to print the required information i.e. Establishment License Number, Registration Number and MRP at their warehouse on both the individual spinal needle and its packs for a period of 12 months.

Item No.XIV. <u>SITE VERIFICATION OF FIRMS FOR MANUFACTURING MEDICAL DEVICES</u>

Case No.1. M/s BQ Pharma & Medical Devices (Pvt) Ltd, Plot No.43-A, Main Road, Industrial Estate, Hayatabad, Peshawar has informed that they are interested to install a State of the Art Unit of Blood Collection Tubes, Surgical Sutures, Blood and Urine Bags. The proposed plot for the construction of the Unit is located in Hattar and its size is 100' X 500' = 50000 sq.ft, empty land. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Atiq-ul-Bari, Federal Inspector of Drugs, DRAP, Peshawar was nominated for inspection of site verification. He has recommended that the proposed plot is suitable for establishment of a manufacturing unit as of today. Total area is 22176 sq.ft.

Decision: The Board approved the site of M/s BQ Pharma & Medical Devices (Pvt) Ltd, Plot No.43-A, Main Road, Industrial Estate, Hayatabad, Peshawar for establishment of manufacturing unit of medical devices.

Case No.2. M/s Asian Surgical, Plot No. A/174, Site Area, Nooriabad, Karachi has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Nooriabad, Karachi. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Sajjad Ahmed Abbasi, Federal Inspector of Drugs, DRAP, Karachi was nominated for inspection of site verification. He has recommended the said site was not open plot, there was some construction work already being in progress, the site is located at Nooriabad Industrial Area and the location/surroundings are suitable to establish the manufacturing unit for manufacture of Medical Devices.

Decision: The Board approved the site of M/s Asian Surgical, Plot No. A/174, Site Area, Nooriabad, Karachi for establishment of manufacturing unit of medical devices.

Case No.3. M/s Ali Raza Surgimed (Pvt) Ltd, 1KM, Malikwal Road, Near Motorway, Bhera, Punjab has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Bhera, Punjab. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Hafiz Muhammad Asif Iqbal, Assistant Director (MDMC) ,DRAP, Islamabad was nominated for inspection of site verification.

1.	Location	The plot is located in Agriculture Area at 1 KM, Malikwal Road, Near Motorway, Bhera, Punjab. The subject plot is 1KM away from main G.T. Road
2.	Surrounding	On front of the site there is 4 feet wide open drain/

		nala for delivering water to agriculture land. On the remaining 03 sides i.e. right, left and back, there is open agriculture land. At back side there is some additional area (not included in 4 kanal) which the firm do not want to include in the site. The plot is surrounded by 6 feet wall at front, 5 feet wall on both sides and just a making at the back side. There are 04 rooms constructed inside of the plot and some bases/foundation is on the front sides.
3.	Size	The size of the plot is 04 Kanals. The dimension of the plot is annexed with the report.
4.	Recommendations	The site was located in Agricultural area with Agricultural land almost all around having easy access to the site through a two way carpeted road. Submitted to Medical Devices Board for further consideration.

Decision: The Board discussed the matter at length and decided to defer the case. The Board asked the Medical Devices Division to prepare a check list of their own for site verification. It could be in line with Drugs Licensing Division.

Case No.4. M/s Med Tex Pharma, M/s. Mouza Gopay Ra, Link Sialkot Road, Near Gujranwala Dry Port G.T. Road, Gujranwala Tool Plaza has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Gujranwala Tool Plaza. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Ms. Anam Saeed, Assistant Director, DRAP, Lahore was nominated for inspection of site verification.

1.	Location	The plot was located in Agricultural Area at Mouza

		Gopay Ra, Link Sialkot Road, Near Gujranwala Dry Port Road, Gujranwala. The subject plot was 1KM away from main G.T. Road, with un-metaled / un-paved passage (Katcha Rasta) and there was no easy to the plot.
2.	Surrounding	On the front side of the site there was empty channel to collect rainy water (Barsati Nala) and across the channel there was 20 feet wide un-metaled road. On the remaining 03 sides i.e., right, left and back, there were open agricultural lands.
3.	Size	The size of the plot was 07 Kanals. The dimensions of the plot is annexed with the report
4.	Recommendations	The site was located in Agricultural area with Agricultural land all around and there was no easy access to the plot due to 1 KM un-paved passage between main GT Road, and the plot. Submitted to Medical Devices Board for further consideration.

Decision: The Board discussed the matter at length and decided to defer the case. The Board asked the Medical Devices Division to prepare a check list of their own for site verification. It could be in line with Drugs Licensing Division.

Case No.5. M/s Kamion Pharma has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Karachi. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Dr. Mehwish Tanveer Assistant Director/ Federal Inspector of Drugs-VII, Karachi was nominated for inspection of site verification. She has recommended following observations:-

- The site is situated at Plot No. G/4-C, SITE, Super Highway, Phase II, Karachi and measures half Acre. The plot agreement has also been reviewed.

- The plot is having road on three sides while there are open industrial plots on the back side.
- Currently, the boundary walls are constructed on the plot.
- The plot is observed as per provisions laid down under Rule 6 (1) (a) of S.R.O. 32 (I)/2018 dated 16th January 2018.

In light of observations made during the inspection, the plot is suitable for establishment of manufacturing unit for medical devices.

Decision: The Board approved the site of M/s Kamion Pharma, Plot No. G/4-C, SITE, Super Highway, Phase II, Karachi for establishment of manufacturing unit of medical devices.

Case No.6 M/s Miraj Cotton Textile has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Multan. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Shahid M. Iqbal, Assistant Director (MDMC), Islamabad was nominated for inspection of site verification.

Location:

The site is located at Plot No. 61-C, Industrial Estate Phase-I, Multan. There is no residential or commercial area around this plot.

Size:

Total area / Size of the plot is about 8 Acres (Plot No.61-C) allotted on lease agreement by the Governor of Punjab as per Lease deed issued in favor of M/s. Ehsan Elahi Industries (Pvt) Ltd dated 12.01.1989. M/s. Ehsan Elahi Industries (Pvt) Ltd further rented out a land measuring 7 Kanals to M/s Miraj Cotton Textile for a period of 15 years starting from 01-01-2019, which can be renewed after the said expiry.

Surroundings:

At present, the plot is away from filthy surroundings and is not adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of dust or smoke which may contaminate

Medical Devices being manufactured or adversely affect on quality of Medical Devices. In future the owner of the company will be responsible. At the proposed site there are some existing building structures which include mosque, residential quarters for workers and administration block. The owner of the firm intends to construct a new building facility on 1 Kanal of the proposed site for the manufacture of Gauze and Bandages. A detailed site plan along with undertaking has been submitted.

Recommendations:

The location is in old industrial area and surrounding of the premises complies with the general requirements for establishment to manufacture medical devices. **In view of the above facts the site is suitable for establishment to manufacture medical devices under the Medical Devices Rules, 2017, as of today** documents submitted by the intended manufacturer. All the responsibility lies with the intended manufacturer regarding establishment to manufacture medical devices in the said plot as per GMP compliant facility.

Decision: The Board approved the site of M/s Miraj Cotton Textile, Plot No. 61-C, Industrial Estate Phase-I, Multan for establishment of manufacturing unit of medical devices.

Case No.7 M/s Smile Surgical (Pvt) Limited has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Gadon Amazai, Khyber Pakhtoon Khawa. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Mr. Shahid M. Iqbal, Assistant Director (MDMC), Islamabad was nominated for inspection of site verification

Location:

The site is located at Plot No. 296, Street No. 13 Industrial Estate Gadown Amazai. There is no residential or commercial area around this plot.

Size:

Total area / Size of the plot is about 8 Kanals (Plot No. 296) allotted on lease agreement by the Governor NWFP as per allotment / possession letter issued in favor of Surgeon Jehan Akbar representing M/s. Spectrum Corporation (Pvt) Ltd dated 29.06.2004. Later on Surgeon Jehan Akbar sold the said plot along with constructed building to Mr. Amir Ahmad (partner in M/s Smile Surgical Pvt Limited).

Surroundings:

At present, the plot is away from filthy surroundings and is not adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of dust or smoke which may contaminate Medical Devices being manufactured or adversely affect on quality of Medical Devices. In future the owners of the company will be responsible. At the proposed site a building structure already exists which the firm intends to utilize in production of Medical Devices. The firm management was advised to regularize the building layout plan in order to make it GMP compliant. A detailed site plan along with site verification report has been submitted.

Recommendations:

The location is an old industrial area and surrounding of the premises complies with the general requirements for establishment to manufacture medical devices. In view of the above facts the site is suitable for establishment to manufacture medical devices under the Medical Devices Rules, 2017, as of today. All the responsibility lies with the intended manufacturer regarding establishment to manufacture medical devices in the said plot as per GMP compliant facility.

Decision: The Board approved the site of M/s Smile Surgical (Pvt) Limited, Plot No. 296, Street No. 13 Industrial Estate Gadown Amazai for establishment of manufacturing unit of medical devices.

Case No.8 M/s Farhan Industries, Kasur has informed that they are interested to install Manufacturing Unit for Medical Devices. The proposed plot for the construction of the Unit is located in Kasur, Punjab. They have submitted all relevant documents and requested to depute a team for the verification of plot and for granting NOC to start construction on the proposed site.

Accordingly Ms. Anam Saeed, Assistant Director, DRAP, Lahore was nominated for inspection of site verification.

Location:

The Prosposed site was located at Khewat No.526/542, Khatooni No.15, 9-km Raiwind Road, District Kasur. It was an agricultural area which was now plotted for establishment of industry. The plot was 800 feet away from main kasur-Raiwind Road and access to the plot was provided with 20 ft wide bricked passage. At the start of the passage i.e at the main Kasur-Raiwind Road there was pioneer Factory (Gas Factory).

Size:

The size of plot was 04 kanals and 10 Marlas as per documents provided by the applicant. The dimension of the plot is annexed with the report.

Surroundings:

On the front side of the site there was 20 feet wide bricked passage and on the front side across the passage, there was open agricultural land

On the right side of the site there was open agricultureal land.

On the left side of the site there was a cotton factory.

On the back side of the said there was also agricultural land.

Recommendations:

The above boservations led to the conclusion that the site was suitable for establishment of Medical Devices Manufacturing Unit as per SRO 412 (XXI)/18.

Decision: The Board approved the site of M/s Farhan Industries, Khewat No.526/542, Khatooni No.15, 9-km Raiwind Road, District Kasur for establishment of manufacturing unit of medical devices.

Item No. XV. <u>EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017.</u>

M/s Premier Agencies, Karachi informed that their medical device namely BD Ultra Fine ™ II Insuline Syringe has been registered (Registration No.MDIR-0000001) for import manufactured by M/s Becton Dickinson and Company, USA under sub-rule (2) & (3) of Rule 38 of MDR, 2017.

The firm has stated that after implementation of Medical Devices Rules, 2017 (MDR, 2017) importers are bound to follow the labelling requirement as per MDR, 2017. They have further stated that the relabelling of commercial product is a complex and time consuming job and need ample time to consume the existing labels and initiate the new labelling. From project initiation to production, it involves a number of steps and each step will take around two months, collectively it required almost one and a half year to design and commercialize the new label.

They have further stated that BD Insulin Syringes has been labelled as per Labelling Rules, 1986 hence need revision only at some points which include not limited to Enlistment/Registration number, address of importer etc. It is impracticable for manufacturer to provide the revised labels as per MDR, 2017 due to very small quantities supplying to Pakistan.

M/s premier Agencies, Karachi has also submitted clarification letter from manufacturer which states as under:-

We, Becton Dickinsom Holdings, Singapore on behalf of the Product Owner, Becton Dickinson and Company, US would like to inform you that the above mentioned product is being imported by our authorized distributor, Premier Agencies, Karachi.

Currently, some of the information is missing on labels of BD Insulin Syringes to be fully compliant with the MDR, 2017. For any labeling change, internally at BD will take approximately 12-15 months as it requires review and approval by several functions. Due to the complexity of the process, BD is unable to fulfill the labeling change at our manufacutring site on time to comply with the Pakistan regulatiuons. Rest assure that we may doing our best to make sure no supply disruption to the Pakistan market.

Therefore, in the meantime, in order to comply with the labeling requirements, Premier Agencies, the licence owner will perform the additional labelling activity at their premise unhtil BD is able to supply Pakistan market with products which fulfils the requirements."

It is submitted that Rule 38 and 39 of the MDR, 2017 are reproduced below:-

Rule 38

(1) *No person shall—*

(a) place any medical device in the market unless it has been appropriately labeled including information of establishment-licence's details, enlistment or registration number, MRP; and

(b) use or operate any medical device on another person unless the appropriate label has been provided with the medical device when it is used on the other person for investigational purposes.

(2) Where a medical device has either not been appropriately labeled, or partially labeled as mentioned in sub-rule (1), the importer on his request in this behalf may be allowed by MDB to comply with these rules relating to labelling by printing the information of establishment-licence's details, enlistment or registration number, MRP or any other information which may be required by MDB at establishment's licensed premises.

(3) The importer may, in special cases where the strict application of the labelling requirements is impracticable or may adversely impact the quality and safety of the medical device, obtain exemption from MDB from the labelling requirements as provided in these rules.

(*4) The label of a medical device shall be legible, permanent and prominent.*

Rule 38

Location of labelling of medical devices,— The label shall be appropriately located depending on a particular medical device and its intended use, in accordance with the following manners, namely: —

(a) where it is practicable, the label shall be provided on or it be attached to the medical device itself;

(b) if it is impracticable to provide the label on or to attach the label to the medical device itself, the label shall be provided on the packaging of the individual medical device;

(c) in the case of medical devices that are packaged together because individual packaging of the medical devices is not practical, the label shall be provided as leaflet, packaging insert, document or other media supplied with a single or multiple medical devices; and

(d) if multiple medical devices are supplied to a single user or location or packed together as one package, it may be appropriate to provide only a single copy of the label but more copies shall be supplied upon request.

Submitted for consideration of MDB please.

Decision: The Board discussed the matter at length and decided to allow M/s Premier Agencies, Karachi to print the required information i.e. Establishment License Number, Registration Number and MRP at their warehouse on both the individual and pack of their medical device, namely BD Ultra Fine™ II Insuline Syringe (Registration No.MDIR-0000001) for a period of 12 months.

Item No XVI. **REGISTRATION AS AN INDENTER UNDER RULE 72(1) OF MEDICAL DEVICES RULES, 2017.**

M/s Muller & Phipps Pakistan (Pvt) Limited has a Multinational Distribution Network for National and Multinational Pharmaceutical Manufacturer as well as legal importer of drugs and medical devices. They have broad range of innovative products and solutions in their portfolio and are fully conversant with vast experience to cater import, storage and distribution of medical devices.

The firm has requested for registration as an Indenter for import of medical devices and has referred to the Rule 72 (1) of Medical Devices Rules, 2017 (MDR, 2017) whereby Medical Device Board (MDB) can register an Indenter. The Rule 72 of MDR, 2017 is reproduced as under:-

"Indenting of Medical Devices. *— (1) The medical devices may be imported through an indenter registered by the MDB.*

(2) Where an institute, hospital, a registered charitable trust or institution intends to import medical devices through an indenter, the MDB may allow such indenting subject to the condition that such medical devices imported through indenting shall not be sold for commercial purpose in the open market."

In view of the above, it is submitted that the conditions/pre-requisites for registration of Indenter has not been prescribed in the MDR, 2017. The following conditions for registration of Indenter are proposed for consideration of MDB:-

CONDITIONS FOR REGISTRATION OF INDENTER

DEFINITIONS:-

Indent:

Order of goods (placed trough a local or foreign agent of a foreign supplier) under specified conditions of sale, the acceptance of which by the supplier (or the agent) constitutes a contract of sale.

Indenter:

A person possessing a valid licence to import medical devices (Form-4), representing as an authorized agent of a foreign company, product, and who gets commission or royalty on any transaction which takes place in his home country.

CONDITIONS:

(i) In case of commercial import, the indenter and a person or facilitator to whom an indent be issued shall both possess a valid licence to import medical devices on Form-4.

(ii) In case of an hospital, a registered charitable trust or institution intending to import medical device through an indenter, the person to whom indent is issued shall possess a valid licence to import medical devices on Form-4.

(iii) The indenter shall possess the enlistment or registration certificate of a medical device issued on Form-8 and Form-8A respectively by the MDB as the case may be.

(iv) The indenter shall be solely responsible for the quality, safety and performance of medical devices for which an indent has been issued.

(v) The indenter shall ensure that a person to whom an indent is issued has the specified storage facility for the medical device along with specialized team for the supervision /vigilance of Post Marketing Surveillance (PMS) of the product so that timely recall, return, withdrawal, field safety & corrective action (FSCA), etc., can be taken.

(vi) The indenter shall issue a warranty of an imported medical device as provided in Medical Devices Rules, 2017.

(vii) Both the indenter and to whom an indent has been issued shall ensure that all government taxes and duties are being paid.

(viii) The indenter shall be registered as an indenter for a period of one year on making an application addressed to the Director, Medical Devices &Medicated Cosmetics (MDMC) along with submission of fee challan of Rs.50,000/-.

INDENT # Date:
PROFORMA INVOICE #: Origin:
SELLER : BUYER:

Quantity	Packing	Descriptions	Unit Price C & F	Total Amount
			City BY AIR/SEA	

Payment :

Shipment upto: Negotiation upto: _____

From: Shipping Marks:

CONDITIONS / INSTRUCTIONS

- Please comply Bank contracts conditions, & send one complete set of non-negotiable shipping documents to us and as to opener immediately after shipment.
- Kindly mention product description on each carton.
- Warranty under Medical Device Rules, 2017. Warranty void if packing is altered

I, _____, being a person resident in Pakistan carrying on business (full address) _____under the name_____ holding valid licence No. _____ issued by _____and having authority or being authorized by M/s (full address) _____, authorized vide letter No. _____dated _____, do hereby give this warranty that the medical devices described as sold/indent by me and contained in the bill of sale, invoice, bill of lading or other document describing the medical devices referred to herein do not contravene in any way the provision of the DRAP Act, 2012 and the rules framed there-under.

Signature

BANK DETAILS:

SWIFT CODE:

Buyers Signature For ***Indentor***

Decision: MDB discussed the matter at length. Mr. Abdul Haleem Khan, member MDB asked for time to study the matter in depth and would forward his opinion. The opinion received through email is reproduced as below:

In pursuance of 13th meeting Medical Devices Board held on August 5, 2019, ***I would like reaffirm my comments in respect of Agenda Item XVI titled " Registration as an Indenter under Rule 72 (1) of Medical Devices Rules, 2017*** *and these are detailed below:*

1. The request of the firm has no logical sense as all the Sole Agent / Authorized Distributor of Foreign Manufacturer /Principal in Pakistan are dully entitled to import the medical devices by placing an indent /purchase order to its Foreign Manufacturer / Principal as per laidown procedure, meaning Sole Agents / Authorized Distributors of Foreign Manufacturer /Principal in accordance with true spirit of Medical Devices Rules, 2017

2. Moreover, if any Foreign Manufacturer /Principal is licenced in Pakistan, it should indent/import its products into Pakistan by itself instead of any other firm/commercial party.

Keeping in view the above mentioned facts, I am of the opinion that the request of the firm may be rejected and or deffered for re-consideration in the meeting of MDB afterwards.

Accordingly, the Registration of an Indenter under Rule 72(1) of Medical Device Rules, 2017 is deferred.

Item No.XVII <u>CHANGE OF MANUFACTURER NAME.</u>

M/s Sultansons, Karachi have requested to approve the change of manufacturer name of their following registered imported medical devices from **M/s Zhejiang Quzhou Kangbao Medical Equipment Co. Ltd, No.680 Century Road Quzhou Economic Development Zone, Quzhou City, Zhejiang Province China** to **M/s M/s Zhejiang Quzhou Rongbo Medical Equipment Co. Ltd**. The address of the manufacturer will remain same:-

S.No.	Reg. No.	Name of Medical Device (s)
1.	063928	Classic Disposable Infusion Set

The firm has deposited the fee of Rs.12,500/- for that purpose and submitted following documents:-

(i) Copy of registration letter.
(ii) Copy of Free Sale Certificate with name of manufacturers.
(iii) Copy of Declaration of name change for manufacturer.

(iv) EC Certificate (Production Quality Assurance) with the new company name.
(v) ISO 13485 certificates with the new company name.
(vi) Authorization letter with new manufacturer name.

Decision: The Board acceeded to the request of the firm /company and approved the change of manufacturer name from M/s Zhejiang Quzhou Kangbao Medical Equipment Co. Ltd, No.680 Century Road Quzhou Economic Development Zone, Quzhou City, Zhejiang Province China to **M/s M/s Zhejiang Quzhou Rongbo Medical Equipment Co. Ltd**., No.680 Century Road Quzhou Economic Development Zone, Quzhou City, Zhejiang Province China.

ITEM NO.XVIII ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES OF M/S UDL DISTRIBUTION (PVT) LIMITED, KARACHI

M/s UDL Distribution (Pvt) Ltd., Karachi has requested to grant them additional sizes of their following registered imported medical devices as mentioned below:-

S.No.	Regn.No.	Name of Medical Device	Existing Approved Sizes/Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0000428	Arrow Two Lumen Hemodialysis Catherization Set	CS-12122-E, CS-12122-F, CS-15122-F, CS-15142-F, CV-15122-F, MC-12122-F, MC-15122-F, CS-12142-F, CS-15122-E, CV-12122-F	CV-12122-FX, CV-12122-UF, CV-13122-UF, CV-12142-UF, CV-15142-UF, CV-15122-TS, CS-12122-TS

The firm has deposited fee of Rs.25,000/-. Firm has also submitted a valid and original Free Sale Certificate of country of origin.

The firm has requested for grant of additional sizes/codes of above mentioned medical devices.

Decision: The Board acceeded to the request of the firm /company and approved the additional sizes/codes of above mentioned medical devices.

ITEM NO.XIX **ADDITIONAL SIZES OF ALREADY REGISTERED MEDICAL DEVICES OF M/S DIGITAL IMAGING SYSTEMS, LAHORE**

M/s Digital Imaging Systems, Lahore has requested to grant them additional sizes of their following registered imported medical device as mentioned below:-

S.No.	Regn.No.	Name of Medical Device	Name of Manufacturer	Existing Approved Sizes/Codes	Demanded Additional Sizes/ Codes.
1.	MDIR-0000180	Perclose ProGlide Suture-Medicated Closure System	**Legal Manufacturer:** M/s Abbott Vascular 3200 Lake Side Drive, Santa Clara, CA 95054, USA **Manufacturing Site**: M/s Abbott Vascular Cashel Road Clonmel, Co. Tipperary, Ireland	12673-03 (US Part Number)	12673-05 (CE Part Number) As per Free Sale Certificate Ireland Valid Till 22-03-2024

The firm has deposited fee of Rs.25,000/- and has given application on Form 7-A. Firm has also submitted a valid and original embassy attested Free Sale Certificate of Ireland mentioning the requested additional code.

Decision: The Board acceeded to the request of the firm / company and approved the above mentioned additional sizes of Perclose ProGlide Suture-Medicated Closure System (Reg. No. MDIR-0000180).

Item No.XX **EXTENSION IN SHELF LIFE.**

M/s Digital Imaging Systems, Lahore has requested for extension in shelf life from 2 years to 3 years of their already registered following imported medical device (Registered as Drug):-

Regn. No.	Name of Medical Device	Name of Manufacturer	Approved Shelf Life	Demanded Shelf Life

083404	Xience Alpine RX Everolimus Eluting Coronary Stent System	**Legal Manufacturer:** M/s Abbott Vascular 3200 Lake Side Drive, Santa Clara, CA 95054, USA **Manufacturing Site**: M/s Abbott Vascular Cashel Road Clonmel, Co. Tipperary, Ireland	2 Years	3 Years

The firm has submitted following documents:-

(i) Fee Deposited Rs.25,000/-

(ii) Application on Form 7-A

(iii) Aging Evalution Report supporting 36 Months Shelf Life.

(iv) Registration Certificate issued by India for the above stated Medical Device mentioning 36 Months Shelf Life.

(v) Registration Certificate issued by Srilanka for the above stated Medical Device mentioning 36 Months Shelf Life.

(vi) Report from notified body DEKRA.

Decision: The Board acceeded to the request of the firm /company and approved the shelf of the Xience Alpine RX Everolimus Eluting Coronary Stent System from 2 to 3 years.

Item No.XXI. <u>EXEMPTION FROM INSPECTION ABOARD.</u>

The MDB in its 11th meeting held on 01-02-2018 decided that the following products of M/s the Searle Company Limited, Karachi are approved subject to inspection abroad:-

Sr No.	Name of Importer	Name of Manufacturer	Name of Medical Device	Brief Description	Remarks
1.	M/s Searle Company Limited. 1st Floor, NICL Building, Abbasi Shaheed	**Manufacturer:** Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi,	Medeco Auto Disable Syringe Class B Shelf Life: 5 years 0.5 ml with needle	For administration of medication generally through intra-muscular or intra-venous route. Sterile, single-use.	(1) Sizes or codes not mentioned on Free Sale Certificate

	Road, Karachi.	UAE (FSC valid till 23-01-2019)	size 23 G, length 1" 0.5 ml with needle size 24 G, length 1" 0.5 ml with needle size 24 G, length 3/4" 0.5 ml with needle size 25 G, length 1" 0.5 ml with needle size 25 G, length 5/8" Fee submitted: Rs 100,000/-		
2.	-do-	**Manufacturer:** Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi, UAE (FSC valid till 23-01-2019)	Medeco Inject Insulin Syringe Class B Shelf Life: 3 years 1.0 ml for U-100 with needle 29 G 1.0 ml for U-100 with needle 30 G 1.0 ml for U-100 with needle 31 G Fee submitted: Rs 100,000/-	Sterile, single-use syringe for insulin administration	(1) Sizes or codes not mentioned on Free Sale Certificate
3.	-do-	**Manufacturer:** Abu Dhabhi Medical Devices Co. L.L.C Mussafah City, M43-Block 124, P.O.Box 30485, Abu Dhabi, UAE (FSC valid till 23-01-2019)	Medeco Inject Syringes Class-B Shelf Life: 5 Years Sizes: 2ml, 3ml & 5ml Fee submitted: Rs 100,000/-	Sterile Single Use hypodermic syringe	(1) Sizes or codes not mentioned on Free Sale Certificate

The board decision is reproduced as under:-

Decision: *The MDB cancelled the above products in the name of M/s Vertex Enterprises, Lahore and approved them in the name of M/s Searle Company Limited, Karachi subject to inspection of the manufacturing plant in Abu Dhabi, UAE.*

Similarly in 12th Meeting of MDB the board approved the following product subject to inspection abroad:

1.	-do-	**Manufacturer:** M/s Abu Dhabi Medical Devices Co. L.L.C, Mussafah City M43-Block 124, P.O.Box 30485, Abu Dhabi, U.A.E. (FSC valid till 27-12-2020)	Medeco I.V. Cannula Class B Shelf Life: 5 years Fee submitted: Rs 100,000/-	For the intravenous administration of medication and fluids.	

The board decision is reproduced as under:

Decision: *The Board approved the product subject to inspection of the manufacturer abroad under Rule 71 of Medical Device Rules, 2017. The Board also authorized the Secretary, MDB to issue registration of the product if the manufacturing plant is approved by the panel of experts.*

Meanwhile, the firm has provided the Free Sale Certificate of Belgium for the aforementioned products. Belgium is included in those countries for which inspection is exempted if the product is exported to it.

Decision: The Board considering that the firm has provided the Free Sale Certificate of Belgium for the above four (4) products acceded to the request of the firm for exemption of inpsection of manufacturer abroad. The Board was also informed by Secreatary MDB, that few firms such M/s Nasir Brothers, M/s S. Ejazuddin etc., also submitted their Free Sale Certificate or prove of registration in reference countries to Medical Devices Division later on after Board meetings for exemption of inspection abroad. The Board endorsed the registration certificates issued to such firms.

Item No.XXII. <u>RENEWAL OF DML(ESTABLISHMENT LICENCE) OF M/S NATIONAL ABSORBENT COTTON MILLS, KARACHI.</u>

It is submitted that panel inspection report received from Federal Inspector of Drug –III Karachi of M/s National Absorbent Cotton Mills Co. A-37, S.I.T.E Manghopir Road Karachi for

renewal of Drug Manufacturing License. The panel of following expertsSyed Muied Ahmed (Expert in Production of Drug/Member CLB, Central Licensing Board, DRAP, Islamabad), Mr. Adnan Rizvi (Director, DTL, Karachi), Mr. Muhammad Affaan (Assistant Director, CDL, DRAP, Karachi), Syed Hakim Masood (Area FID-III, Karachi) recommends the renewal of Drug Manufacturing License bearing No: 000137 in favour of M/s National Absorbent Cotton Mills Co. in respect of following sections:

I. Cotton Gauze
II. Crepe Section
III. Cotton Bandage Section

Panel further stated that eye pad section is not recommended as the section did not exist.

It is submitted that after issuance of notification SRO.824(I)/2018 dated 26-06-2018, they are now categorized under Medical Devices, hence Medical Devices Rules, 2017 are applicable.

Submitted for consideration of MDB please.

Decision: The Board renewed the manufacturing licence of the firm on the recommendations of the panel and authorized Secretary MDB to issue Establishment Licence to Manufacture Medical Devices as per Medical Device Rules, 2017.

Item No.XXIII. <u>REGISTRATION OF MEDICAL DEVICES OF M/S MATRIX PHARMA (PVT) LIMITED, KARACHI</u>.

It is submitted that the MDB in its 12th meeting held on 13th May, 2019 approved the following medical devices of M/s Matrix Pharma (Pvt) Ltd., Plot No. 12, Sector 15, Korangi Industrial Area, Karachi subject to foreign inspection and referred the product for expert opinion from Dr. Khalid S. Aslam, whether the product is required in orthopaedic surgery and how effective it is?

1.	**M/s Matrix Pharma** (Pvt) Ltd., Plot No. 12, Sector 15, Korangi Industrial Area, Karachi (ELI-00039)	**Manufacturer:** M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., No. 23, No.8th Street, Hangzhou Econ. &Tech. Development Zone, China **Manufacturing site:** No. 866, Moganshan	Bonisa® Bone Repairing Material (0.5 mg rhBMP-2/vial) Class D Shelf Life: 02 Years Fee Submitted: Rs 50,000/-	Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) with osteoinductive bioactivity, indicated for use in bone	**Approved** subject to foreign inspection abroad. The Board also authorized the Secretary MDB to issue registration of

	Evaluator: Ms. Unum Zia Shamsi	Road (No. 700, Shixiang Road), Hangzhou, China (FSC China Valid Till 17-09-2020)		defect, bone nonunion, bone delayed union or nonunion resulted from various causes, spinal fusion joint fusion and orthopaedic implantation	product if the manufacturing plant is approved by the panel of experts. The Board referred the product for expert opinion from Dr. Khalid S. Aslam, whether the product is required in orthopaedic surgery and how effective it is?
2.	-do-		Bonisa® Bone Repairing Material (2.0 mg rhBMP-2/vial) Class D Shelf Life: 02 Years Fee Submitted: Rs 50,000/-	Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) with osteoinductive bioactivity, indicated for use in bone defect, bone nonunion, bone delayed union or non-union resulted from various causes, spinal fusion joint fusion and orthopaedic implantation	-do-
3.	-do-		Bonisa® Bone Repairing Material (1.0 mg rhBMP-2/vial) Class D Shelf Life: 02 Years Fee Submitted: Rs	Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2) with osteoinductive bioactivity, indicated for	-do-

			50,000/-	use in bone defect, bone nonunion, bone delayed union or non-union resulted from various causes, spinal fusion joint fusion and orthopaedic implantation	

The case was referredfor expert opinion from Dr. Khalid S. Aslam, whether the product is required in orthopaedic surgery and how effective it is? The comments received from Dr. Khalid S. Aslam, Orthopaedic Surgeon, Quaid-e-Azam International Hospital, Islamabad are reproduced as under:-

" I have reviewed the literature, but most of literature is related to how the drug is being manufactured and how it was discovered and how it is prepared. I am sorry, I am not qualified to comment on that, but as the end user, I can tell you about this medical devices, a similar isomer of bone morphogenic protein is available in USA for quite some time and it has giving good results in difficult cases where it works very well. I have no reservations in recommending that this should be availabble here because it is needed in certain cases. My only reservation is that the cost, which they have told me for 1 mg, is Rs. 25,000/- which is a lot of money. I think they should be encouraged to reduce the price and then certainly this will be a valuable addition to our armamentarium to help the patients who are in dire need and have nonunion and gaps in the bone after injury. Please let me know if I can be of further help."

Decision: The MDB considering the expert opinion of Dr. Khalid S. Aslam, Orthopaedic Surgeon, Quaid-e-Azam International Hospital, Islamabad approved the product and authorized the Secretary MDB to issue registration letter subject to fulfillment of other formalities if any.

Item No.XXIV. <u>CANCELLATION/DE-REGISTRATION OF MEDICAL DEVICES BY M/S INTEK CORPORATION, RAWALPINDI</u>

M/s Intek Corporation has applied for cancellation/de-registration of following medical devices with the reason that the products are discontinued by manufacturer and has already registered their advanced version:

Sr No.	Product name	Registration No.(As Drug)	Registration Date
1.	Sapphire Dilatation Catheter	074677	01-01-2014
2.	Scorflex Coronary Dilatation Catheter	074673	01-01-2014
3.	Genous Bio-Engineered CoCr Stent System	074676	01-01-2014
4.	Azule CoCr Alloy Coronary Stent System	074678	01-01-2014
5.	Combo Bio-Engineered Sirolimus Eluting Stent	080003	26-01-2016
6.	Hooper PTCA Balloon Dilatation Catheter	083134	06-03-2017
7.	Nobori Drug Eluting Stent System	080004	26-01-2016

Decision: Board acceded to the request of the the firm and cancelled the above mentioned medical devices of M/s Intek Corporation, Rawalpindi.

Item No.XXV. CANCELLATION /DE-REGISTRATION OF MEDICAL DEVICES BY M/S VIKOR HEALTHCARE (PVT) LTD., KARACHI

M/s Vikor Healthcare (Pvt) Ltd., Karachi has applied for cancellation/de-registration of following Medical Devices (Registered as Drug)with the reason thatsutures have been re classified as Medical Devices through SRO No. 824 (I) 2018 dated June 26th, 2018and since they have surrendered their Drug Manufacturing Licence (DML)and in this context have requested the MDB to cancel their product registration as Drug also.

Sr No.	Product name	Registration No.(As Drug)	Registration Date
1.	Surgiline Surgigut Plain Sutures	086981	26-02-2018
2.	Surgiline Surgigut Chromic Sutures	086982	26-02-2018
3.	Surgiline Silk Braided Sutures	086980	26-02-2018

Decision: The Board has referred the matter of stability studies of above products for fresh registration to Dr. Abdul Haleem Khan, member MDB and Mr. Tahir Aziz, member MDB and authorized the Secretary MDB to cancel the above products if the opinions on stability studies are obtained in favour of the firm / company.

Item No.XXVI. EXTENSION IN SHELF LIFE OF FIREHAWK RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM (REGN.NO.081738)

M/s Otsuka Pakistan Limited, Karachi has requested for extension in shelf life of their already registered imported medical device (registered as drug) namely Firehawk Rapamycin Target Eluting Coronary Stent System (Regn.No.081738) from 12 months to 2 years.

The case was placed before the Medical Device Board (MDB) in its 11TH Meeting 01st Feb, 2019 and the board decided as under:

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

Accordingly the matter was referred to Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist/Cardiovascular Surgeon, Mayo Hospital, Lahore and Maj. (Gen) (R) Dr. Azhar Mahmood Kayani, Executive Director, Rawalpindi Institute of Cardiology, Rawalpindi for their opinion / comments in the matter within 15 days.

In response to our letter, Prof. Dr. Saqib Shafi Sheikh, Interventional Cardiologist/Cardiovascular Surgeon, Mayo Hospital, Lahore has stated ***that the shelf life of next supply of the above stent can be increased to two years. However this cannot be applied to already existing stock in Pakistan imported and stamped as one year shelf life***. The response from Maj. (Gen) (R) Dr. Azhar Mahmood Kayani, Executive Director, Rawalpindi Institute of Cardiology, Rawalpindi was not received.

Then the case was placed before the MDB in its 12th meeting held on 13th May, 2019. The MDB decided as follows:-

> "*The Board decided to refer the matter to Prof. Dr. Ejaz Ahmed, Interventional Cardiologist, Multan Institute of Cardiology, Multan for opinion on extension of shelf life of Firehawk Rapamycin Target Eluting Coronary Stent System. If an opinion is received in favour of extension in shelf life, the approval shall be accorded accordingly."*

Accordingly case was referred to Prof. Dr. Ejaz Ahmed, Interventional Cardiologist, Multan Institute of Cardiology, Multan for opinion on extension of shelf life of Firehawk Rapamycin Target Eluting Coronary Stent System. Prof. Dr. Ejaz Ahmed has stated that:-

> "Extension in shelf life of a particular drug/medical device may be granted on the basis of valid stability studies conducted by individuals/organizations duly recognized and authenticated by a regular authority/board. The provided stability studies in the subject case has been conducted by the manufacturer itself and no documentary proof of recognition/authentication from any regulatory authority/board has been established for the same.
>
> The said studies require to establish certain laboratory and clinical evidences within a specific span of time which is totally a dedicated process over a certain period. Undersigned is of the view that this institute is not fully equipped to evaluate the required parameters of stability studies. In view of above, I would request you to refer the subject case to some other health/testing facility to proceed further in the subject case."

The case has now been referred to Dr. Abdul Haleem Khan, Member, MDB for his view/comments on extension of shelf life of Firehawk Rapamycin Target Eluting Coronary Stent System.

Submitted for ratification of MDB please.

Decision: The Board considered the opinion of Dr. Abdul Haleem Khan, member MDB that he has studied the stability studies and DEKRA report and that he endorsed the extension in shelf life, acceded to the request of the firm and approved the extension in shelf life of Firehawk Rapamycin Target Eluting Coronary Stent System from 12 months to 2 years. The Board also authorized the Secretary MDB to issue letter in this regard after receving formal opinion of Dr. Abdul Haleem Khan, member MDB.

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

Secretary MDB informed the Board that the following applications for grant of registration of medical devices for import on prescribed form 7-A under Medical Devices Rules, 2017 was received in the Division. The MDB discussed and decided as mentioned against earch:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s Eli Lilly Pakistan (Pvt) Ltd., 5-A, 5th Floor, 10th Building, Al-Tijarah Center, 32-1-A, Block 6, PECHS, Karachi (ELI-00265) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Owner Operator:** M/s Eli Lilly and Co, Lilly Corporate Center, Drop Code 1084 Indianpolis, IN 46285, USA **Manufacturer:** M/s Eli Lilly and Company, Pharmaceutical Delivery Systems Lilly Corporate Center Indianpolis, IN 46285, USA **(FSC USFDA Valid Till**	HumaPen Ergo II Class C Shelf Life: 6 Years	Mechanical Pen Injector for Insulin	**Approved.**

		07-09-2019) **Rs.50,000/-**			
2.	M/s. JK Traders, Suit No. 13, 2nd Floor Majeed Plaza, Bank Road, Saddar, Rawalpindi. **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Simeks Tibbi Urunler San ve Tic Ltd Sti, Istanbul Endustri ve Ticaret Serbest Bolgesi, Aydinli SB Mah, 10. Sok, No:5, 34953 Tuzla – Istanbul – Turkey **(FSC Spain Issued on 09th January, 2019)** **Rs.50,000/-**	**SIMPASS PLUS RX PTCA BALLOON DILATATION CATHETER** (PTCA Balloon Dilatation Catheter) Class D Shelf Life : 03 years Codes & Sizes at Annex-A	PTCA Balloon Dilatation Catheter	**Approved.**
3.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Simeks Tibbi Urunler San ve Tic Ltd Sti, Istanbul Endustri ve Ticaret Serbest Bolgesi, Aydinli SB Mah, 10. Sok, No:5, 34953 Tuzla – Istanbul – Turkey **(FSC Spain Issued on 09th January, 2019)** **Rs.50,000/-**	**SIMPASS CTO RX BALLOON DILATATION CATHETER** (PTCA Balloon Dilatation Catheter) Class D Shelf Life : 03 years Codes & Sizes at Annex-A	PTCA Balloon Dilatation Catheter	**Approved.**
4.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal.	**Legal Manufacturer:** M/s. Simeks Tibbi Urunler San ve Tic Ltd Sti, Istanbul Endustri ve Ticaret Serbest Bolgesi, Aydinli SB Mah, 10. Sok, No:5, 34953 Tuzla – Istanbul – Turkey	**SIMPASS HP-NC RX BALLOON DILATION CATHETER** (PTCA Balloon Dilatation Catheter) Class D Shelf Life : 03 years Codes & Sizes at	PTCA Balloon Dilatation Catheter	**Approved.**

		(FSC Spain Issued on 09th January, 2019) **Rs.50,000/-**	Annex-A		
5.	M/s. Digital Imaging Systems, 121- Habitat Apartments, Shadman II, Ghaus -ul-Azam Road, Lahore, Lahore **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. AGA Medical Corporation, 5050 Nathan Lane North, Plymouth, Minnesota, 55442, USA FSC Belgium Issued on 06-12-2018	**Amplatzer TorqVue LP Catheter** 9-TVLPC4F90/080 Class D Shelf Life : 03 years	The AMPLATZER TorqVue Low Profile Delivery System is a general purpose delivery sheath that is an extension of the AMPLATZER TorqVue Delivery System product line. The (TVLP) Delivery System includes a catheter, loader, Tuohy-Borst hemostasis valve, and delivery wire.	**Approved.**
6.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Abbott Vascular, 3200 Lakeside drive, Santa Clara, CA USA 95054 **Manufacturing Site:** M/s. Abbott Vascular, Road No.2, km 58.0, Cruce Davila, Barceloneta, Pueto Rico USA 00617	**Hi-Torque Command Guide Wire** (Peripheral Vascular Guide Wire) Sizes and codes per US FDA FSC No. 6825-3-2019 Class B Shelf Life : 02 years	Intended to facilitate the placement of balloon dilatation catheters during percutaneous trans luminal angioplasty (PTA) in arteries such as the femoral, popliteal, and infra-popliteal arteries. Not	**Approved.**

		FSC USFDA Valid till March 18, 2021		for use in coronary and cerebral vasculature	
7.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Abbott Vascular Inc, 3200 Lakeside drive, Santa Clara, CA 95054- USA **Manufacturing Site:** M/s. Availmed S.A. De C.V.C. Industrial Lt. 001 Mz. 105 No. 20905 Int.A Col.Cd. Industrial, Tijuana, Baja, California, Mexico 22444. FSC USFDA Valid till 16-05-2020	**20/30 Priority Pack with Copilot Bleedback control Valve** 1003327 Class B Shelf Life : 02 years Rs. 25,000	**Torque Device** Facilitates the steering of the guide wire. **Guide Wire Introducer** Guides the delicate tip of a guide wire. **Stopcock** Works with indeflators to inflate and deflate balloons. **0.096 Hemostatic Valve** Maintains homeostasis. **Indeflator 20/30** Inflates and deflates balloons.	**Approved.**
8.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Abbott Vascular Inc, 3200 Lakeside drive, Santa Clara, CA 95054- USA **Manufacturing Site:** M/s. Abbott Vascular, Cashel Road, Clonmel, Tipperary, Ireland. FSC Ireland	**Armada 14 PTA Catheter** **Usable length 90cm** A1015-020 1.5mmx20mm A1015-040 1.5mmx40mm A1015-080 1.5mmx80mm A1015-120 1.5mmx120mm A1020-020	The device is indicated to dilate stenoses in femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis	**Approved.**

		Valid till 09-12-2020	2.0mmx20mm A1020-040 2.0mmx40mm A1020-060 2.0mmx60mm A1020-080 2.0mmx80mm A1020-120 2.0mmx120mm A1020-200 2.0mmx200mm A1025-020 2.5mmx20mm A1025-040 2.5mmx40mm A1025-060 2.5mmx60mm A1025-080 2.5mmx80mm A1025-120 2.5mmx120mm A1025-200 2.5mmx200mm A1030-020 3.0mmx20mm A1030-040 3.0mmx40mm A1030-060 3.0mmx60mm A1030-080 3.0mmx80mm A1030-120 3.0mmx120mm A1030-200 3.0mmx200mm A1040-020 4.0mmx20mm A1040-040 4.0mmx40mm A1040-060 4.0mmx60mm A1040-080 4.0mmx80mm A1040-120 4.0mmx120mm A1040-200 4.0mmx200mm **Usable length 150cm**	fistulae.	

			A2015-020 1.5mmx20mm A2015-040 1.5mmx40mm A2015-080 1.5mmx80mm A2015-120 1.5mmx120mm A2020 020 2.0mmx20mm A2020 040 2.0mmx40mm A2020 060 2.0mmx60mm A2020 080 2.0mmx80mm A2020 120 2.0mmx120mm A2020 200 2.0mmx200mm A2025-020 2.5mmx20mm A2025-040 2.5mmx40mm A2025-060 2.5mmx60mm A2025-080 2.5mmx80mm A2025-120 2.5mmx120mm A2025-200 2.5mmx200mm A2030-020 3.0mmx20mm A2030-040 3.0mmx40mm A2030-060 3.0mmx60mm A2030-080 3.0mmx80mm A2030-120 3.0mmx120mm A2030-200 3.0mmx200mm A2040-020 4.0mmx20mm A2040-040 4.0mmx40mm A2040-060 4.0mmx60mm		

			A2040-080 4.0mmx80mm A2040-120 4.0mmx120mm A2040-200 4.0mmx200mm Class B Shelf Life : 3.5 years Rs. 25,000/-		
9.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. Abbott Vascular Inc, 3200 Lakeside drive, Santa Clara, CA 95054- USA **Manufacturing Site:** M/s. Abbott Vascular, 52 Calle 3, B31, Coyol Free Zone, EI Coyol, Alajuela, Costa Rica. FSC USFDA Valid till 30-01-2021	**Armada 35/35LL Percutaneous Transluminal Angioplasty Catheter** (Peripheral angioplasty balloon catheter) B1030-020 3.0mmx20mm B1030-040 3.0mmx40mm B1040-020 4.0mmx20mm B1040-040 4.0mmx40mm B1040-060 4.0mmx60mm B1040-080 4.0mmX80mm B1040-100 4.0mmx100mm B1040-120 4.0mmx120mm B1040-150 4.0mmx150mm B1040-200 4.0mmx200mm B1040-250 4.0mmx250mm B1050-020 5.0mmx20mm B1050-040 5.0mmx40mm B1050-060 5.0mmx60mm B1050-080 5.0mmx80mm B1050-100	The device is intended for dilation of lesions in the renal, iliac, femoral, popliteal, tibial, and peroneal arteries and for the treatment of obstructive lesions of native or synthetic arteiovenous dialysis fistulae. The device is also indicated for stent post-dilatation in the peripheral vasculature.	**Approved.**

			5.0mmx100mm B1050-120 5.0mmx120mm B1050-150 5.0mmx150mm B1050-200 5.0mmx200mm B1050-250 5.0mmx250mm B1060-020 6.0mmx20mm B1060-040 6.0mmx40mm B1060-060 6.0mmx60mm B1060-080 6.0mmx80mm B1060-100 6.0mmx100mm B1060-120 6.0mmx120mm B1060-150 6.0mmx150mm B1060-200 6.0mmx200mm B1060-250 6.0mmx250mm B1070-020 7.0mmx20mm B1070-040 7.0mmx40mm B1070-060 7.0mmx60mm B1070-080 7.0mmx80mm B1070-100 7.0mmx100mm B1070- 1207.0mmx120mm B1070- 1507.0mmx150mm B1070- 2007.0mmx200mm B1080-020 8.0mmx20mm B1080-040 8.0mmx40mm B1080- 0608.0mmx60mm B1080-080		

			8.0mmx80mm B1090- 0209.0mmx20mm B1090-040 9.0mmx40mm B1090-060 9.0mmx60mm B1090-080 9.0mmx80mm B1100-020 10.0mmx20mm B1100-040 10.0mmx40mm B1100-060 10.0mmx60mm B1100-080 10.0mmx80mm B1120-020 12.0mmx20mm B1120-040 12.0mmx40mm B1120-060 12.0mmx60mm B1120-080 12.0mmx80mm B1140-020 14.0mmx20mm B1140-040 14.0mmx60mm B1140-060 14.0mmx60mm B1140-080 14.0mmx80mm B2030-020 3.0mmx20mm B2030-040 3.0mmx40mm B2040- 0204.0mmx20mm B2040-040 4.0mmx40mm B2040-060 4.0mmx60mm B2040-080 4.0mmx80mm B2040-100 4.0mmx100mm B2040-120 4.0mmx120mm B2040-150		

			4.0mmx150mm B2040-200 4.0mmx200mm B2040-250 4.0mmx250mm B2050-020 5.0mmx20mm B2050-040 5.0mmx40mm B2050-060 5.0mmx60mm B2050-080 5.0mmx80mm B2050-100 5.0mmx100mm B2050-120 5.0mmx120mm B2050-150 5.0mmx150mm B2050-200 5.0mmx200mm B2050-250 5.0mmx250mm B2060-020 6.0mmx20mm B2060-040 6.0mmx40mm B2060-060 6.0mmx60mm B2060-080 6.0mmx80mm B2060-100 6.0mmx100mm B2060-120 6.0mmx120mm B2060-150 6.0mmx150mm B2060-200 6.0mmx200mm B2060-250 6.0mmx250mm B2070-020 7.0mmx20mm B2070-040 7.0mmx40mm B2070-060 7.0mmx60mm B2070-080 7.0mmx80mm B2070-100		

			7.0mmx100mm B2070-120 7.0mmx120mm B2070-150 7.0mmx150mm B2070-200 7.0mmx200mm B2080-020 8.0mmX20mm B2080-040 8.0mmx40mm B2080-060 8.0mmx60mm B2080-080 8.0mmx80mm B2090-020 9.0mmx20mm B2090-040 9.0mmx40mm B2090-060 9.0mmx60mm B2090-080 9.0mmx80mm B2100-020 10.0mmx20mm B2100-040 10.0mmx40mm B2100-060 10.0mmx60mm B2100-080 10.0mmx80mm B2120-020 12.0mmx20mm B2120-040 12.0mmx40mm B2120-060 12.0mmx60mm B2120-080 12.0mmx80mm B2140-020 14.0mmx20mm B2140-040 14.0mmx40mm B2140-060 14.0mmx60mm B2140-080 14.0mmx80mm Class B Shelf Life : 3.5 years		

			Rs. 25,000/-		
10.	M/s Intek Corporation, Office No. 30, Al Amin Plaza, The Mall, Rawalpindi (ELI-00034) **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer/ Manufacturing Site:** M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA **Contract Manufacturer:** (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA (FSC USFDA Valid Till 05-12-2019)	Microplex® Coil System MCS-CS (18) Microplex Cosmos (18 System) Class D Shelf Life: 5 Years Codes and Sizes: As per FSC	Neuro Vascular Embolization Coils	**Approved.**
11.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer/ Manufacturing Site:** M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA **Contract Manufacturer:** (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656	Microplex® Coil System MCS-CSSR (10) Microplex Cosmos (10 System) Class D Shelf Life: 5 Years Codes and Sizes: As per FSC	Neuro Vascular Embolization Coils	**Approved.**

		USA (FSC USFDA Valid Till 05-12-2019)			
12.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer/ Manufacturing Site:** M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA **Contract Manufacturer:** (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA (FSC USFDA Valid Till 05-12-2019)	Microplex® Coil System MCS-CS (18) Microplex Cosmos (18 System) Class D Shelf Life: 5 Years Codes and sizes: As per FSC		**Duplication and already approved at serial no. 10**
13.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer/ Manufacturing Site:** M/s Microvention Inc., 1311 Valencia Avenue Tustin, CA 92780 USA **Contract Manufacturer:** (i) M/s MicroVention Costa Rica S.R.L., Zona Franca Coyol , Alajuela Costa Rica (ii) M/s	Microplex® Coil System MCS-CSSR (10) Microplex Cosmos (10 System) Class D Shelf Life: 5 Years Codes and sizes: As per FSC		**Duplication and already approved at serial no. 11**

		Microvention Inc., 35 Enterprise Aliso Viejo, CA 92656 USA (FSC USFDA Valid Till 05-12-2019)			
14.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal manufacturer** OrbusNeich Medical B.V., Address: Drs. W. Van Royenstraat 5, 3871 AN Hoevelaken, the Netherlands. FSC Netherland Valid until September 20, 2020	**Sapphire II Coronary Dilatation Catheter** (Coronary Dilatation Catheter) **Size Variants:** 234-RL-1005 234-R-1720 234-RL-1008 234-R-2010 234-RL-1010 234-R-2012 234-RL-1015 234-R-2015 234-RL-1205 234-R-2020 234-RL-1208 234-R-2210 234-RL-1210 234-R-2215 234-RL-1215 234-R-2220 234-RL-1510 234-R-2510 234-RL-1515 234-R-2512 234-RL-1520 234-R-2515 234-RL-1710 234-R-2520 234-RL-1715 234-R-2530 234-RL-1720 234-R-2710 234-RL-2010 234-R-2715 234-RL-2015 234-R-2720 234-RL-2020 234-R-	Angioplasty/ Coronary Dilatation Catheter	The product is deferred on account of late application for renewal of product.

			3010 234-R-1005 234-R-3012 234-R-1008 234-R-3015 234-R-1010 234-R-3020 234-R-1015 234-R-3030 234-R-1205 234-R-3210 234-R-1208 234-R-3215 234-R-1210 234-R-3220 234-R-1215 234-R-3510 234-R-1510 234-R-3515 234-R-1512 234-R-3520 234-R-1515 234-R-3530 234-R-1520 234-R-4010 234-R-1710 234-R-4015 234-R-1715 234-R-4020 Class D Shelf Life : 02 years Rs.25,000/-		
15.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA **Manufacturing Sites:** 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA	**Headway 17 Advanced Soft Microcatheter** **Code:** MC172150S Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-	Intended for neurovascular use, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	**Approved**.

		2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica. FSC US FDA Valid till 14 December, 2019.			
16.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA **Manufacturing Sites:** 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica. FSC US FDA Valid till 14 December, 2019.	**Headway 21 Microcatheter** **Codes:** MC212150S MC212156S Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-	Intended for neurovascular use, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	**Approved.**
17.	-do- **<u>Evaluator:</u>** Ms. Unum Zia	**Manufacturer:** M/s. MicroVention, Inc. 1311 Valencia	**Headway 27 Microcatheter** **Codes:**	Intended for neurovascular use, for the infusion of	**Approved.**

	Shamsi	Avenue, tustin, California, 92780 USA **Manufacturing Sites:** 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656 3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica. FSC US FDA Valid till 14 December, 2019.	MC272150S MC272156S Class D Shelf Life : 05 years Fee submitted: Rs. 50,000/-	diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	
18.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA **Manufacturing Sites:** 1. M/s. MicroVention, Inc. 1311 Valencia Avenue, tustin, California, 92780 USA 2. M/s. MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA USA 92656	**Headway 17 Advanced Microcatheter** **Codes:** MC172150STX MC17215045X MC17215090X MC172150AX MC172150BX MC172150CX MC172150DX MC172150WX MC172150JX MC172150SX Class D Shelf Life: 05 years Fee submitted: Rs.	Intended for neurovascular use, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	**Approved.**

		3. MicroVention Costa Rica S.R.L, Edificion B33, Zona Franca Coyol, Alajuela, Costa Rica. FSC US FDA Valid till 14 December, 2019.	50,000/-		
19.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Occlutech GmbH Winzerlaer Straße 2 07745 Jena Germany. **Manufacturing Site:** M/s. Occlutech Tıbbi Urunler San.ve Tic.Ltd.Sti. AHL Serbest Bolgesi, E-5 Blok, 34149, Istanbul Turkey FSC Germany Issued on 2nd January, 2019.	**Occlutech PDA Occluder** **Size Variants:** **Standard Shank:** 42PDA05 42PDA06 42PDA07 42PDA08 42PDA10 42PDA12 42PDA15 42PDA18 **Long Shank:** 43PDA05L 43PDA06L 43PDA07L 43PDA08L 43PDA10L Class D Shelf Life : 05 years	The Occlutech® PDA Occluder is an occlusion system, which is percutaneously implanted through a catheter intervention and intended for the non-surgical occlusion of Patent Ductus Arteriosus (PDA).	**Approved.**
20.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Occlutech GmbH Winzerlaer Straße 2 07745 Jena Germany. **Manufacturing Site:** M/s. Occlutech Tıbbi Urunler San.ve Tic.Ltd.Sti. AHL Serbest Bolgesi, E-5 Blok, 34149,	**Occlutech Muscular VSD Occluder** **Size Variants** 71VSD04 71VSD06 71VSD08 71VSD10 71VSD12 71VSD14 71VSD16 71VSD18 71VSD20 Class D Shelf Life : 05 years	The Occlutech Muscular VSD Occluder is an occlusion system, which is percutaneously implanted through a catheter intervention and intended for the non-surgical occlusion of Muscular	**Approved** subject to provision of stability studies supporting the claimed shelf life.

		Istanbul Turkey FSC Germany Issued on 2nd January, 2019.		Ventricular Septal Defect.	
21.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal manufacturer** M/s. Micro Vention, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA. **Manufacturing Sites:** 1. M/s. MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica. 2. M/s. MicroVention Inc., 35 Enterprise, Aliso Viejo, CA USA 92656 FSC USFDA Valid until December 5, 2019.	**Microplex Platinium Compass Framing Coils (10 System)** (Neuro Vascular Embolization Coils) MCS-CM-FC (10) Platinum Compass Framing Coils-(10 System) 100203CM-V 100203CMSR-V 100254CM-V 100254CMSR-V 100304CM-V 100304 CMSR-V 100355CM-V 100355 CMSR-V 100408CM-V 100408 CMSR-V 100412CM-V 100412 CMSR-V 100510CM-V 100510 CMSR-V 100516CM-V 100516 CMSR-V 100612CM-V 100612 CMSR-V 100618CM-V 100618 CMSR-V 100721 CMSR-V 100824 CMSR-V 100928 CMSR-V 101030 CMSR-V Class D Shelf Life : 05 years Rs.50,000/-	Neuro Vascular Embolization Coils	**Approved** subject to provision of notorized original agency agreement.
22.	-do- **Evaluator:** Shahid Muhammad	**Legal manufacturer** M/s. Micro Vention, Inc. 1311	**Microplex Helical Coils (10 System)** (Neuro Vascular Embolization Coils)	Neuro Vascular Embolization Coils	**Approved** subject to provision of notorized

	Iqbal	Valencia Avenue Tustin, California, 92780 USA. **Manufacturing Sites:** 1. M/s. MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica. 2. M/s. MicroVention Inc., 35 Enterprise, Aliso Viejo, CA USA 92656 FSC USFDA Valid until December 5, 2019.	MCS-HCSR (10) MicroPlex Helical Coils-(10 Systems) 100202HCSR-S-V 100203HCSR-S-V 100204HCSR-S-V 100206HCSR-S-V 100208HCSR-S-V 100303HCSR-S-V 100304HCSR-S-V 100306HCSR-S-V 100308HCSR-S-V 100310HCSR-S-V 100404HCSR-S-V 100406HCSR-S-V 100408HCSR-S-V 100410HCSR-S-V 100515HCSR-R-V 100520HCSR-R-V 100615HCSR-R-V 100620HCSR-R-V 100720HCSR-R-V 100730HCSR-R-V 100820HCSR-R-V 100830HCSR-R-V 100920HCSR-R-V 100930HCSR-R-V 101030HCSR-R-V Class D Shelf Life : 05 years Rs.50,000/-		original agency agreement.
23.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal manufacturer** M/s. Micro Vention, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA. **Manufacturing Sites:** 1. M/s. MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela	**Microplex Platinum Helical Coil (10 System)** (Neuro Vascular Embolization Coils) MCS-HC-S (10) Platinum Helical Coils-Soft (10 System) 100201HC-S-V 100202HC-S-V 100203HC-S-V 100204HC-S-V 100206HC-S-V	Neuro Vascular Embolization Coils	**Approved** subject to provision of notorized original agency agreement.

		Costa Rica. 2. M/s. MicroVention Inc., 35 Enterprise, Aliso Viejo, CA USA 92656 FSC USFDA Valid until December 5, 2019.	100208HC-S-V 100303HC-S-V 100304HC-S-V 100306HC-S-V 100308HC-S-V 100310HC-S-V 100404HC-S-V 100406HC-S-V 100408HC-S-V 100410HC-S-V Class D Shelf Life : 05 years Rs.50,000/-		
24.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal manufacturer** M/s. Micro Vention, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA. **Manufacturing Sites:** 1. M/s. MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica. 2. M/s. MicroVention Inc., 35 Enterprise, Aliso Viejo, CA USA 92656 FSC USFDA Valid until December 5, 2019.	**Platinum Helical Coils Hypersoft (10 System)** (Neuro Vascular Embolization Coils) MCS-HC-HS (10) Platinum Helical Coils-Hypersoft (10 System) 100101HS-V 100102HS-V 100103HS-V 100104HS-V 100105HS-V 100106HS-V 100151HS-V 100152HS-V 100153HS-V 100154HS-V 100155HS-V 100156HS-V 100201HS-V 100202HS-V 100203HS-V 100204HS-V 100206HS-V 100208HS-V 100251HS-V 100252HS-V 100253HS-V 100254HS-V 100256HS-V 100258HS-V 100302HS-V	Neuro Vascular Embolization Coils	**Approved** subject to provision of notorized original agency agreement.

			100303HS-V 100304HS-V 100306HS-V 100308HS-V 100310HS-V 100402HS-V 100403HS-V 100404HS-V 100406HS-V 100408HS-V 100410HS-V 100506HS-V 100508HS-V 100510HS-V 100606HS-V 100608HS-V 100610HS-V 100806HS-V 100808HS-V 100810HS-V Class D Shelf Life : 05 years Rs.50,000/-		
25.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal manufacturer** M/s. Micro Vention, Inc. 1311 Valencia Avenue Tustin, California, 92780 USA. **Manufacturing Sites:** 1. M/s. MicroVention Costa Rica S.R.L., Zona Franca Coyol, Alajuela Costa Rica. 2. M/s. MicroVention Inc., 35 Enterprise, Aliso Viejo, CA USA 92656 FSC USFDA Valid until December 5, 2019.	**Microplex Platinum Helical Coils Regular (10 System)** (Neuro Vascular Embolization Coils) MCS-HC-R (10) Platinum Helical Coils-Regular (10 System) 100515HC-R-V 100520HC-R-V 100615HC-R-V 100620HC-R-V 100720HC-R-V 100730HC-R-V 100820HC-R-V 100830HC-R-V 100920HC-R-V 100930HC-R-V 101030HC-R-V Class D Shelf Life : 05 years Rs.50,000/-	Neuro Vascular Embolization Coils	**Approved** subject to provision of notorized original agency agreement.

26.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Medin Medical Innovations GmbH Adam-Geisler-Str. 1 82140 Olching Deutschland/ Germany (FSC Germany Issuance Date 13-09-2017)	Medin CNO and MEDIN CNO mini Class C Shelf Life: 8 Years REF 3090, REF 3080	The MedinCNO mini is a CPAP driver used for CPAP therapy to premature infants and newborns.	**Approved.**
27.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Medin Medical Innovations GmbH Adam-Geisler-Str. 1 82140 Olching Deutschland/ Germany (FSC Germany Issuance Date 13-09-2017)	Medin Blender (incl. div. flowmeter) Class C Shelf Life: 8 Years REF 1085_easy, 1085_15	The Medin gas blendars enrich breathing gas with oxygen for therapeutic use and measure out the quantity delivered to patients.	**Approved.**
28.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s Top Corporation 19-10 Senju Nakai-Cho, Adachi-KU, Tokyo 120-0035, Japan **Manufacturing site:** M/s Meditop Corporation (Malaysia) SDN BHD No.3, Persiaran Usahawan Tama IKS, Seksyen 9, 43650 Bandar Baru Bangi Selangor Darul Ehsan, Malaysia (FSC Japan Issuance Date 21-11-2018) (FSC Malaysia	Top Infusion Pump.TOP-2300 Class C Estimated life-time: 6 Years Fee submitted: Rs. 50,000/-	A volumetric and drip rate infusion pump which employs a peristaltic finger mechanism for controlling flow, which administers and control infusion fluid as specified. Active medical device	**Approved.**

		expiry date 20-11-2020)			
29.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** TOP Corporation, 19-10 Senju Naki-Cho, Adachi-ku, Tokyo, Japan. (FSC valid 20-11-2020) **Manufacturing Site:** MEDITOP Corporation (Malaysia) SDN . BHD. No. 3 Persiaran Usahawan Taman IKS, SEKSYEN 9 43650 Bandar Baru Bangi Selangor Darul Ehsan Malaysia	TOP-5530 Syringe Pump Class C Shelf Life: 6 years Syringe Pump TOP-5530 Components : Pole Clamp, Drop Sensor, Multiple pump Mount, stand, Nurse call cable, drop sensor holder, Operating Guide, AC Power cable, DC Power cable.	Syringe pump is a micro continuous infusion pump used for nutrition blood transfusion chemotherapeutic agents oxytocic anticoagulants and anesthesia agents in ICU, Critical care and OT wards	**Approved.**
30.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Hoffricheter GmbH mettenheimer Str. 12/14 19601 Schwerin Germany. (FSC issuance 18-12-2018)	CARAT II Pro Respiratory Therapy and Ventilation Class C Shelf Life: Not Applicable. CARAT II Pro Ref: 00004018	The Carat II pro Ventilator may be used for life Sustaining ventilation and, when using a two tube system, provides continuous respiratory support and ventilation of patients without spontaneous respiration. When Using a single tube system, the Carat II pro	**Approved.**

				may also be used for non lifesustaining ventilation and provides intermittent respiratory support and ventilation of patients who demonstrate sufficeicent spontaneous breathing.	
31.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** TOP Corporation, 19-10 Senju Naki-Cho, Adachi-ku, Tokyo, Japan. (FSC valid 20-11-2020) **Manufacturing Site:** MEDITOP Corporation (Malaysia) SDN . BHD. No. 3 Persiaran Usahawan Taman IKS, SEKSYEN 9 43650 Bandar Baru Bangi Selangor Darul Ehsan Malaysia	TOP-5530 Syringe Pump Class C Shelf Life: 6 years Syringe Pump TOP-5530 Components : Pole Clamp, Drop Sensor, Multiple pump Mount, stand, Nurse call cable, drop sensor holder, Operating Guide, AC Power cable, DC Power cable.	Syringe pump is a micro continuous infusion pump used for nutrition blood transfusion chemotherapeu tic agents oxytocic anticoagulants and anesthesia agents in ICU, Critical care and OT wards	**Duplication and already approved at serial 29.**
32.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** TOP Corporation, 19-10 Senju Naki-Cho, Adachi-ku, Tokyo, Japan. **Manufacturing**	TOP-5510 Syringe Pump Class C Shelf Life: 6 years	Pole Clamp, Drop Sensor, Multiple pump Mount, stand, Nurse call cable, drop sensor holder, Operating Guide, AC	**Approved** subject to provision of Stability data and EPSP.

		Site: TOP Corporation Koshigaya Factory 40-34 Noborito-cho, Koshigaya-Shi, Saitama, Japan. (FSC issuance 21-11-2018)		Power cable, DC Power cable.	
33.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland. (FSC valid 10-07-2021)	Hamilton-MR1 Intensive Care Ventilator Class C Shelf Life: not mentioned in form (Sizes & Codes as Per FSC) Hamilton-MR1 161010	The Hamilton-MR1 Ventilator is intended to provide positive pressure ventilator support to adults and pediatrics, and optionally infants and neonates. Intended use: In the MRI department, in the intensive care ward, intermediate care ward, emergency ward, long term acuter care hospital or in the recovery room. During transfer of ventilated patients within the hospital.	**Approved** subject to provision of Stability data**.**
34.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland.	Hamilton-H 900 Respiratory gas humidifier Class C Shelf Life: N/A	The Hamilton-H900 Humidifier is intended for respiratory gas conditioning during invasive	**Approved** subject to provision of Stability data.

		(FSC Switzerland valid 10-07-2021)	Hamilton-H900 950001/ 950004/ 950008	and non-invasive mechanical ventilation. The intended are of use is the intensive care ward or the recovery room. The Hamilton-H900 humidifier is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	
35.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Hamilton Medical AG, Via Crusch 8, 7402 Bonaduz, Switzerland. (FSC Switzerland valid 10-07-2021)	Hamilton –C6 Intensive Care Ventilator Class C Shelf Life: N/A Hamilton –C6 160021 Ventilair 155600 / 155601	The Hamilton – C6 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics, and pediatrics and optionally infants and nenotes. Intended use : Health care facilities During transfer of ventilated patient within health care facilities.	**Approved.**
36.	M/s. Pharma Consultant Pakistan	**Legal Manufacturer:**	**SORIN Paediatric Arterial Cannulae**	Pediatric cannulae are	**Approved** as Class D

	(Pvt) Ltd., Suit NO. 207, 207 A Khan Tower, DHA Square Walton Road, Lahore. **Evaluator:** Hafiz Muhammad Asif Iqbal	M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**Codes:** A272-15N, A272-20N, A272-26N, A272-30N, A272-35N, A272-40N, A272-45N, BA272-15N, BA272-20N, BA272-26N, BA272-30N, BA272-35N, BA272-40N, BA272-45N Class D Shelf Life : 03 years	used in the arterial line of the extra corporeal circuit during cardiopulmonary surgery for periods of up to six hours.	medical device.
37.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**SORIN Venous Femoral Cannulae** **Codes:** BV172-22, BV172-28, V172-22, V172-28 Class D Shelflife : 03 years	Venous Femoral cannulae are intended to be used to cannulate the inferior vena cava and the right atrium via femoral venous access during cardiopulmonary surgery for periods of up to six hours	**Approved** as Class D medical device.
38.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA. FSC USFDA Valid till October 18, 2020	**LivaNova Venous Cardiopulmonary Bypass Cannulae** **Codes:** LRD-61034, LRD-61037, LRD-61040, LRD-61046, LRD-61050, LRD-61134, LRD-61137, LRD-61140, LRD-61146, LRD-61150 NDS-11146, NDS-11150, NDS-21040,	Venous Femoral cannulae are intended to be used to cannulate the inferior vena cava and the right atrium via femoral venous access during cardiopulmonary surgery for periods of up to	**Approved** as Class D medicaldevices.

			NDS-21046, NDS-21050, NDS-21140, NDS-21146, NDS-21150 NV-20020, NV-20024, NV-20028, NV-20032, NV-20034, NV-20036, NV-20040 NV-21020, NV-21028, NV-21032 RDS-61034, RDS-61037, RDS-61040, RDS-61046, RDS-61050, RDS-61134, RDS-61137, RDS-61140, RDS-61146, RDS-61150 RTS-11029, RTS-11129, RTS- 13029, RTS- 13129 RV-40012, RV-40014, RV-40016, RV-40018, RV-40020, RV-40022, RV-40024, RV-40026, RV-40028, RV-40030, RV-40032, RV-40034, RV-40036, RV-40038, RV-40536 RV-41012, RV-41014, RV-41016, RV-41018, RV-41020, RV-41022, RV-41024, RV-41026, RV-41028, RV-41030, RV-41032, RV-41034, RV-41036, RV-41038 Class D Shelflife : 03 years	six hours	
39.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037	**SORIN Arterial Bent Tip Cannula** **Codes:** A212-45C, A212-52A, A212-52B, A212-52C, A212-65A, A212-65B, A212-65C, A212-73A, A212-73B, A212-73C, A212-80A, A212-80B, A212-80C, A221-30B,	Arterial cannulae are intended to be used as perfusion cannulae to return arterial blood from the extracorportal circuit to the patient during cardiopulmona	**Approved** as Class D medical devices.

		Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	A221-30C, A221-38A, A221-38B, A221-38C, A221-45B, A221-45C, A221-65B, A222-30B, A222-30C, A222-38B, A222-38C, A222-45B, A222-45C, A222-52B, A222-52C, A222-65B, A222-65C, A222-80B, A222-80C, A232-30B, A232-30C, A232-38B, A232-38C, A232-45B, A232-45C, A232-52B, A232-52C, A232-65A, A232-65B, A232-65C, A232-80B, A232-80C, A262-65A, A262-65B, A262-65C, A262-80B, A262-80C, A281-70B, A281-70C, A281-80A, A281-80B, A281-80C, A282-70A, A282-70B, A282-70C, A282-80A, A282-80B, A282-80C, A291-70B, A291-70C, A291-80B, A291-80C, A292-70B, A292-70C, A292-80B, A292-80C, A900-23, BA211-30B, BA211-30C, BA211-30N, BA211-38B, BA211-38C, BA211-38N, BA211-45B, BA211-45C, BA211-45N, BA212-30B, BA212-30C, BA212-38B, BA212-38C, BA212-45B, BA212-45C, BA212-52A, BA212-52B, BA212-52C, BA212-65A, BA212-65B, BA212-65C, BA212-73A, BA212-73B, BA212-73C, BA212-80A, BA212-80B, BA212-80C, BA221-30B, BA221-30C, BA221-38A, BA221-38B, BA221-38C, BA221-	rysurgery for periods of up to six hours.	

			45B, BA221-45C, BA221-65B, BA222-30B, BA222-30C, BA222-38B, BA222-38C, BA222-45B, BA222-45C, BA222-52B, BA222-52C, BA222-65B, BA222-65C, BA222-80B, BA222-80C, BA232-30B, BA232-30C, BA232-38B, BA232-38C, BA232-45B, BA232-45C, BA232-52B, BA232-52C, BA232-65A, BA232-65B, BA232-65C, BA232-80B, BA232-80C, BA262-65A, BA262-65B, BA262-65C, BA262-80B, BA262-80C, BA281-70B, BA281-70C, BA281-80A, BA281-80B, BA281-80C, BA282-70A, BA282-70B, BA282-70C, BA282-80A, BA282-80B, BA282-80C, BA291-70B, BA291-70C, BA291-80B, BA291-80C, BA292-70B, BA292-70C, BA292-80B, BA292-80C, BA900-23 Class D Shelflife : 03 years		
40.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037	**SORIN Arterial Femoral Cannulae Codes:** A252-45B, A252-52E, A252-60E, A252-65E, A252-70E, BA252-45B, BA252-52E, BA252-60E, BA252-65E, BA252-70E, A242-55B, A242-75B, BA242-55B, BA242-75B	Arterial Femoral cannulae are used to cannulate the femoral arterial vessels, via access into the arterial femoralis, during cardiopulmona	**Approved** as Class D medical device.

		Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	Class D Shelflife : 03 years	ry surgery for periods of up to six hours	
41.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**SORIN Left Ventricular Vent Catheter** Series: BW-410-62, BW900-171, W410-62, W900-171, BW420-62, BW900-108, W900-108 Class D Shelflife : 03 years	Vent catheters are used to vent blood of left ventricle or the pulmonary aorta during cardiopulmonary surgery for periods of up to six hours.	**Approved** as Class D medical device.
42.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**SORIN Cardioplegia Aortic Root Cannulae** **Codes:** **BR501-15, BR501-20, BR501-26, BR502-15, BR502-20, BR502-26, BR900-05, BR900-06, BR900-07**, **R501-15, R501-20,R501-26, R502-15, R502-20, R502-26, R900-05, R900,06, R900-07** Class D Shelflife : 03 years	Aortic root cannulae are intended for venting the aortic root for delivery of cardioplegic solution and for rapid and secure perfusion into the coronary arteries during cardiopulmonary surgery for periods of up to six hours.	**Approved** as Class D medical device.
43.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA.	LivaNova **Cardioplegia Cannulae AR** **Codes:** AR-11012, AR-11014, AR-11016, AR-11018, AR-11112, AR-11114,	Aortic Root Cannula is designed to deliver cardioplegia solution during cardiopulmonary bypass	**Approved** as Class D medical device.

		FSC USFDA Valid till October 18, 2020	AR-11116 AR-17012, AR-17014, AX-30311, AX-30321 Class D Shelflife : 03 years	surgery and aspirate air from the aorta at the end of the cardiopulmonary bypass procedure.	
44.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA. FSC USFDA Valid till October 18, 2020	LivaNova **Coronary Sinus Cannulae** **Codes:** RCM-14110, RCM-14115, RCM-14215 RCM-14315, RCM-14815, RCM-14510, RCM-14915 RCS-11114, RCS-12114, RCS-13114 RCS-11214, RCS-12214, RCS-13214 RCS-11314, RCS-12314, RCS-13314 Class D Shelflife : 05 years	The Retrograde Cardioplegia Cannula is indicated for use in the infusion of blood or cardioplegia solution into the coronary venous system.	**Approved** as Class D medical device.
45.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**SORIN Paediatric Venous Cannulae** **Codes:** V132-10, BV132-12, BV132-14, BV132-16, BV132-18, BV132-20, BV900-142, BV900-143, BV900-144, BV900-145, V132-10, V132-12, V132-14, V132-16, V132-18, V132-20, V900-142, V900-143, V900-144, V900-145 Class D Shelflife : 03 years	Pediatric cannulae are used in the venous line of the extracorportal circuit during cardiopulmonary surgery for periods of up to six hours.	**Approved** as Class D medical device.
46.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI),	**SORIN Venous two stage Cannulae** **Codes:** OV112-40, BOV112-	Venous cannulae are intended to be used to cannulate the major venous	**Approved** as Class D medical devices.

		Italy **Manufacturing site:** Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	40, BV112-32, BV112-40, BV112-50, V112-32, V112-40, V112-50, V900-11, V900-19, V900-49, V900-99, V900-134, V900-284, BV900-11, BV900-99, BV900-19, BV900-49, BV900-134, BV900-284 Class D Shelf Life : 03 years	vessels during cardiopulmonary surgery for periods of up to six hours.	
47.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA. FSC USFDA Valid till October 18, 2020	LivaNova **Arterial Cardiopulmonary Bypass Cannulae** **Codes:** NA-1116, NA-1117, NA-1118, NA-1126, NA-1127, NA-1128, NA-1136, NA-1137, NA-1138, NA-1206, NA-1207, NA-1208, NA-1316, NA-1317, NA-1318, NA-1326, NA-1327, NA-1328, NA-1336, NA-1337, NA-1338, NA-2116, NA-2117, NA-2118, NA-2126, NA-2127, NA-2128, NA-2136, NA-2137, NA-2138, NA-3416, NA-3417, NA-3418, NA-3426, NA-3427, NA-3428, NA-3436, NA-3437, NA-3438, NA-4516, NA-4517, NA-4518, NA-4526, NA-4527, NA-4528, NA-4536, NA-4537, NA-4538, NA-5516, NA-5517, NA-5518, NA-5526, NA-5527, NA-5528, NA-5536, NA-5537, NA-5538 RA-0138, RA-1116, RA-1117, RA-1118, RA-1126, RA-1127,	The Aortic Arch Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.	**Approved** as Class D medical device.

			RA-1128, RA-1136, RA-1137, RA-1138, RA-1206, RA-1207, RA-1208, RA-2116, RA-2117, RA-2118, RA-2126, RA-2127, RA-2128, RA-2136, RA-2137, RA-2138,AX-10100, AX-10120,AX-20510 Class D Shelf Life : 03 years		
48.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. LivaNova USA, Inc. 14401 West 65th Way Arvada, CO 80004 USA. FSC USFDA Valid till October 18, 2020	LivaNova **Cardioplegia Cannulae VC** Series: VC-11000, VC-11010, VC-11100, VC-11110 Class D Shelflife : 03 years Rs.50,000/-	Vessel Cannula is indicated for use in delivery of cardioplegia solution during cardiopulmonary bypass surgery, or to help check for leaks in a harvested vein which will be used for a graft.	**Approved** as Class D medical devices.
49.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 13.06.2018	SORIN **CSC14** (Heat Exchanger for Cardioplegia) P3740 Class C Shelf Life : 03 years Rs.50,000/-	CSC14 is recommended for use as a heating/cooling device and bubble trap for blood cardioplegia and clear fluid perfusion in exraccorporeal circulation associated with cardiopulmonary bypass.	**Approved.**
50.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17,	**DIDECO CARDIOPLEGIA SETS** (Cardioplegia Perfusion Set)	Set used for the administration of cardioplegic solution containing	**Approved.**

		20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**Codes:** 05471, 05472, 05473, 05474, 05475 Class C Shelf Life : 03 years Rs.50,000/-	blood.	
51.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**DIDECO D905 EOS** (Pediatric small adult oxygenators) **Codes:** 050521,050513,050510,050512,050545,050509,03395,03397,03480,03484,03485,03486 Class C Shelf Life : 03 years Rs.50,000/-	Pediatric small adult oxygenators	**Approved.**
52.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy	**SORIN Perfusion Tubing Systems** (Perfusion Tubing Systems) **Coed:** **As per FSC 69454 P-18-12-2018** Class C Shelf Life : 03 years Rs.50,000/-	Tubing system for cardiopulmonary devices	**Approved.**

		FSC Italy Issued on 18.12.2018			
53.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**Hemoconcentrators** (Infant / Pediatric and Adult Hemoconcentrator) **Codes:** 05009, 05010, 05019, 05020, 05326, 05327, 050179, 050177 Class C Shelf Life : 03 years Rs.50,000/-	Infant / Pediatric and Adult Hemoconcentrator	**Approved.**
54.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**DIDECO PERFUSION TUBING SYSTEMS** (Perfusion Tubing System) **Coed:** **As per FSC 69454 P-18-12-2018** Class C Shelf Life : 03 years Rs.50,000/-	Tubing system for cardiopulmonary devices	**Approved.**
55.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy	**Inspire** (Adult and small Oxygenators) **Codes:** 050700, 050701, 050702, 050703,	Adult and small Oxygenators	**Approved.**

		Manufacturing site: Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	050704, 050705, 050706, 050709, 050710, 050711, 050712, 050713, 050714,050715, 050716, 050717, 050718, 050719, 050720, 050721, 050722 Class C Shelf Life : 03 years Rs.50,000/-		
56.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**DIDECO D902 LILLIPUT 2** (Infant-Newborn Oxygenators) **Codes:** 05324, 050580, 03367,05253, 03388,050502, 03381,05320, 050579, 03378, 03807,050511, 03489, 03811,050581 Class C Shelf Life : 03 years Rs.50,000/-	Infant-Newborn Oxygenators	**Approved.**
57.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy	**DIDECO D901 LILLIPUT 1** (Infant-Newborn Oxygenators) **Codes:** 03354, 05252,03379, 03803,05319, 03380, 03802,050501, 03384,05318, 050578 Class C Shelf Life : 03 years Rs.50,000/-	Infant-Newborn Oxygenators	**Approved.**

		Issued on 18.12.2018			
58.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** Sorin Group Italia S.r.I,Via statale 12 Nored 86, 41037 Mirandola(MO) Italy FSC Italy Issued on 18.12.2018	**DIDECO KIDS** (Infant-Newborn Oxygenators) **Codes:** 03491, 03813,050531, 050582,03493,050535, 050534, 03494,050548, 050549,050540, 050584,03496, 03812,050543, 03673 Class C Shelf Life : 03 years Rs.50,000/-	Infant-Newborn Oxygenators	**Approved.**
59.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** M/s. Sorin Group Italia S.r.I., Via crescentino sn, 13040 Saluggia (VC),Italy FSC Italy Issued on 02.03.2018	Sovering MiniBand (Annuloplasty Ring) ICV0889 / SMN40, ICV0890 / SMN50 Class D Shelf Life : 05 years Rs.50,000/-	Sovering MiniBand device is indicated for the correction of mitral valve insufficiencies.	**Approved.**
60.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** M/s. Sorin Group	Sovering Mitral Band ICV0826 / SB26M, ICV0827 / SB28M, ICV0828 / SB30M, ICV0829 / SB32M, ICV0830 / SB34M, ICV0832 / SB38M, ICV0833 / SB40M Class D	Sovering Mitral Band is used for congenital or acquired insufficiencies characterized by the dilation or deformation of the native annulus.	**Approved.**

		Italia S.r.I., Via crescentino sn, 13040 Saluggia (VC),Italy FSC Italy Issued on 02.03.2018	Shelf Life : 05 years Rs.50,000/-		
61.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** M/s. Sorin Group Italia S.r.I., Via crescentino sn, 13040 Saluggia (VC),Italy FSC Italy Issued on 02.03.2018	Sovering Tricuspid Band ICV0834 / SB28T, ICV0835 / SB30T, ICV0836 / SB32T, ICV0837 / SB34T, ICV0838 / SB36T Class D Shelf Life : 05 years Rs.50,000/-	Sovering device is used for the correction of antrioventricular valve insufficiency or steno-insufficiencies. Tricuspid Band is used for acquired insufficiency, both organic and functional.	**Approved.**
62.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** M/s. Sorin Group Italia S.r.I., Via crescentino sn, 13040 Saluggia (VC),Italy FSC Italy Issued on 02.03.2018	Carbomedics CarboSeal Valsalva (Aortovalvular Prostheses) CP-021, CP-023, CP-025, CP-027, CP-029 Class D Shelf Life : 04 years Rs.50,000/-	Aortovalvular Prostheses are used in open heart surgery for simultaneous replacement of the ascending aorta and the aortic valve in cases of aneurysm, diseection, or other disease conditions of the aorta combined with disease or degeneration of the aortic valve.	**Approved.**

63.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** M/s. Sorin Group Italia S.r.I., Via crescentino sn, 13040 Saluggia (VC),Italy FSC Italy Issued on 02.03.2018	Memo 3D ReChord ICV1330 / MRCS24, ICV1331 / MRCS26, ICV1332 / MRCS28, ICV1333 / MRCS30, ICV1334 / MRCS32, ICV1335 / MRCS34, ICV1336 / MRCs36, ICV1337 / MRCS38 Class D Shelf Life : 05 years Rs.50,000/-	The device is used for correction of mitral insufficiencies or steno-insufficiencies. and used for correction of congenital or acquired mitral insufficiencies with dilation and deformation of the mitral annulus.	**Approved.**
64.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s. Sorin Group M/s. Sorin Group Italia S.r.I., Via Benigno Crespi 17, 20159 Milano (MI), Italy **Manufacturing site:** M/s. Sorin Group Italia S.r.I., Via crescentino sn, 13040 Saluggia (VC),Italy FSC Italy Issued on 02.03.2018	Carbomedics Annuloflex (Annuloplasty Ring) AF-826, AF-828, AF-830, AF-832, AF-834, AF-836 Class D Shelf Life : 05 years Rs.50,000/-	Annuloplasty Ring is used as reinforcement for repair of the human cardiac tricuspid valve damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring.	**Approved.**
65.	M/s The Searle Company Limited, 1st Floor, NICL Building, Abbasi Shaheed Road, Karachi (ELI-00057)	**Manufactured By:** M/s Capsovision, Inc. 18805 Cox Avenue, Suite 250 Saratoga, CA 95070, USA (FSC USFDA	CapsoCam Plus (SV-3) Capsule Endoscope System Class B Shelf Life: 24 Months	The CapsoAccess® Capsule Data Access System enables trained medical personnel to extract in-vivo	**Approved as Class C Medical Device and subject to submission of differential**

	Evaluator: Hafiz Muhammad Asif Iqbal	Valid Till 07-04-2021) Expire		data from the CapsoCam Plus® capsule.	**fee of Rs. 25000/-**
66.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Bain Medical Equipment (Guangzhou) Co., Ltd., No.10, Juncheng Road, Eastern Area, Economic and Technological Development District, Guangzhou 510760, China (FSC China Valid Till 08-01-2020)	Searle Hollow Fiber Dialyzer Class C B-14PF, B-16PF, B-18PF, B-20PF Shelf Life: 36 Months Fee submitted: Rs. 50,000/-	Used for hemodialysis treatment of acute and chronic renal failure	**Deferred** as the same product by the same manufactrurer has been approved in 11th MDB meeting in the name of M/S Dora Enterprises, Lahore.
67.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Bain Medical Equipment (Guangzhou) Co., Ltd., No.10, Juncheng Road, Eastern Area, Economic and Technological Development District, Guangzhou 510760, China (FSC China Valid Till 08-01-2020)	Searle Tubing Set for Hemodialysis Class B Shelf Life: 36 Months BAIN-BL-001, BAIN-BL-002, BAIN-BL-003, BAIN-BL-004, BAIN-BL-005, BAIN-BL-006, BAIN-BL-007, BAIN-BL-008, BAIN-BL-009, BAIN-BL-010, BAIN-BL-011, BAIN-BL-012, BAIN-BL-013, BAIN-BL-014, BAIN-BL-015, BAIN-BL-016, BAIN-BL-017, BAIN-BL-018, BAIN-BL-019, BAIN-BL-020, BAIN-BL-021, BAIN-BL-022, BAIN-BL-023, BAIN-BL-024, BAIN-BL-025, BAIN-BL-026, BAIN-BL-027, BAIN-BL-028,	Intended to connect with the dialyzer to the patient in dialysis treatment	**Deferred** as the same product by the same manufactrurer has been approved in 11th MDB meeting in the name of M/S Dora Enterprises, Lahore.

			BAIN-BL-029, BAIN-BL-030, BAIN-BL-031, BAIN-BL-032, BAIN-BL-033, BAIN-BL-034, BAIN-BL-035, BAIN-BL-036, BAIN-BL-037, BAIN-BL-038, BAIN-BL-039, BAIN-BL-040, BAIN-BL-041, BAIN-BL-042, BAIN-BL-043, BAIN-BL-044, BAIN-BL-045, BAIN-BL-046, BAIN-BL-047, BAIN-BL-048, BAIN-BL-049, BAIN-BL-050, BAIN-BL-051, BAIN-BL-052 Fee submitted: Rs 25,000/-		
68.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Bain Medical Equipment (Guangzhou) Co., Ltd., No.10, Juncheng Road, Eastern Area, Economic and Technological Development District, Guangzhou 510760, China (FSC China Valid Till 08-01-2020)	Searle Disposable A.V. fistula Needle Set Class B Shelf Life: 36 Months BAIN-A.V.F-001, BAIN-A.V.F-002, BAIN-A.V.F-003, BAIN-A.V.F-004, BAIN-A.V.F-005, BAIN-A.V.F-006, BAIN-A.V.F-007, BAIN-A.V.F-008 Fee submitted: Rs 25,000/-	Intended to be used as vein puncture for the hemodialysis treatment	**Deferred** as the same product by the same manufactrurer has been approved in 11th MDB meeting in the name of M/S Dora Enterprises, Lahore.
69.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Manufacture By:** M/s Abu Dhabi Medical Devices Co., LLC, M-43, Plot No. 124, Mussafah Industrial Area, PO Box 30485, Abu Dhabi, UAE	Medeco IV Infusion Set Packing Per Set (Reg No. 062258) Class B Shelf Life: 3 Years Rs.100,000/-	Single Use IV Infusion Set	**Approved as the firm has submitted FSC of Belgium.**

70.	M/s Briogene Private Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Karachi (ELI-00015) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany (FSC Germany Issuance Date 21-02-2018)	Artus EBV RG PCR Kit (24), V1 Artus EBV RG PCR Kit (96), V1 Class C Shelf Life: 23 Months 4501263, 4501265	The EBV PCR Kit is an in vitro nucleic acid amplification test for the quantitation of Epstein-Barr virus (EBV) DNA in human plasma, serum, CSF or Blood cells	**Approved as Class C Medical Device and subject to submission of differential fee of Rs. 25000/-**
71.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Qiagen GmbH Qiafen Str. 1, 40724 Hilden, Germany (FSC Germany Issuance Date 21-02-2018)	Artus® CMV RG PCR Kit (24), CE Artus® CMV RG PCR Kit (96), CE Class C Shelf Life: 23 Months Model: 4503263, 4503265	In vitro nucleic acid amplification test for the quantitation of CcytomigaloVirus DNA in human plasma	**Approved.**
72.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Qiagen GmbH Qiagen Str. 1, 40724 Hilden, Germany **Manufacturing Site:** M/s Qiagen Sciences LLC 19300 Germantown Road, Germantown, MD 20874, Germany (FSC Germany Issuance Date 21-02-2018)	Digene® HC2 High-Risk HPV DNA Test Class C Shelf Life: 18 Months 5197-1330 Rs.25,000/-	An Vitro Nucleic acid hybridization assay for the qualitative detection of 13 high-risk types of HPV DNA in cervical and vaginal specimens	**Approved as Class C Medical Device and subject to submission of differential fee of Rs. 25000/-**

73.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Qiagen GmbH Qiagen Str. 1, 40724 Hilden, Germany (FSC Germany Issuance Date 02-06-2015)	Artus HBV RG PCR Kit (24), Artus HBV RG PCR Kit (96) Class C Shelf Life: 23 Months Codes: 4506263, 4506265 Rs.50,000/-	It is an in vitro nucleic acid amplification test kit for the quantification of Hepatitis Bvirus (HBV) DNA in human plasma.	**Approved.**
74.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Qiagen GmbH Qiagen Str. 1, 40724 Hilden, Germany (FSC Germany Issuance Date 02-06-2015)	Artus® HCV RG RT-PCR Kit (24), Artus® HCV RG RT-PCR Kit (96) Class C Shelf Life: 10 Months Model:4518263, 4518265 Rs.50,000/- Already Submitted on 08-12-16 against Slip No. 0544907	It is an in vitro nucleic acid amplification test kit for the quantification of Hepatitis C virus (HCV) RNA in human plasma.	**Approved.**
75.	M/s BSN Medical (Pvt) Ltd., A/69, SITE Manghopir Road, Karachi (ELI-00011) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s BSN Medical GmbH, Quickbornstrabe 24, 20253 Hamburg, Germany (FSC Germany Issuance Date 23-10-2018)	Leukomed® Control Class C Shelf Life: 3 Years Sizes : As per Free sale Certificate	Leukomed ® Control is a transparent wound dressing with an absorbent hydrogel pad.	**Approved.**
76.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273)	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing**	Ensura DR MRI SureScan Class D Shelf Life: 18 Months (From the date of power source connection)	Dual Chamber Implantable pacemaker, rate-responsive	**Approved.**

	Evaluator: Hafiz Muhammad Asif Iqbal	**Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	EN1DR01		
77.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer/Distributor:** M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico **Contract Manufacturer:** (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA (ii) M/s Vention Medical Costa Rica, S.A. Parque	RETROGATE PERFUSION CANNULAE Gundry® Scilicon RSCP Cannulae with Manual Inflate Cuff Class D Shelf Life: 3 Years 94110, 94113, 94113T, 94115, 94115LK, 94115NPL, 94115T, 94615, 94715	Coronary Sinus Cannula	**Approved.**

		Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica (FSC USFDA Valid Till 11-06-2019)			
78.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer/Distributor:** M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico **Contract Manufacturer:** (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal	DLP® Silicone RCSP Cannulae with Manual Inflate Cuff Class D Shelf Life: 3 Years 94006, 94010, 94015, 94106, 94215, 94215T, 94725, 94725NPL, 94515, 94525, 94625, 94665, 94913, 94913L, 94915, 94965, 94975	Coronary Sinus Cannula	**Approved.**

		DE Heredia, Heredia Costa Rica (FSC USFDA Valid Till 11-06-2019)			
79.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer/Distributor:** M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico **Contract Manufacturer:** (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica	DLP® Malleable Single Stage Venous Cannulae Class D Shelf Life: 3 Years 681112, 68114, 68116, 68118, 68120, 68122, 68124, 68126, 68128, 68130, 68132, 68134, 68136, 68138, 68140	Cardiopulmonary Bypass Cannula Venous	**Approved.**

		(FSC USFDA Valid Till 11-06-2019)			
80.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer/Distributor:** M/s Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN 55428, USA **Manufacturing Facility:** M/s Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago Tijuana, Baja California CP 22210, Mexico **Contract Manufacturer:** (i) M/s Vention Medical Inc., 620 Warson SW GR, MI 49504, USA (ii) M/s Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal DE Heredia, Heredia Costa Rica (FSC USFDA Valid Till 11-06-2019)	MC2® Two Stage Venous Cannulae Class D Shelf Life: 3 Years Codes and sizes: As per FSC	Cardiopulmonary Bypass Cannula, Venous	**Approved.**

81.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA 92705, USA M/s Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 EI Lago Tijuana, Baja California C.P 22210, Mexico (FSC USFDAValid Till 04-03-2020)	Contour 3D™ Annuloplasty Ring 690R Class D Shelf Life: 5 Years Codes and sizes: As per FSC	Mitral/Tricuspid Annuloplasty Ring	**Approved.**
82.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA 92705, USA M/s Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 EI Lago Tijuana, Baja California C.P 22210, Mexico	Duran AnCore™Annuloplasty Band 620B Class D Shelf Life: 5 Years Codes and sizes: As per FSC	Annuloplasty Band	**Approved.**

		(FSC USFDAValid Till 04-03-2020)			
83.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA 92705, USA (FSC USFDAValid Till10-08-2019)	Mosaic™ Bioprosthesis, Model 305 (Aortic) Class D Shelf Life: 5 Years Codes and sizes: As per FSC	Aortic Heart Valve Bioprothesis	**Approved.**
84.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA 92705, USA M/s Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 EI Lago Tijuana, Baja California C.P 22210, Mexico (FSC USFDAValid Till 04-03-2020)	Profile 3D™ Annuloplasty Ring 680R Class D Shelf Life: 5 Years Codes and sizes: As per FSC	Mitral Annuloplasty Ring	**Approved.**

85.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Vascular, 37A Cherry Hill Drive, Danvers, MA 01923, USA. (FSC Ireland Valid Till 24-08-2021)	Export Advance ™ Aspiration Catheters Class D Shelf Life: 2 Years	Aspiration Catheter using stylet tip without coil	**Approved.**
86.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Vascular 37A Cherry Hill Dr Danvers, MA 01923, USA **Contract Manufacturer:** M/s Medplast Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Heredia Costa Rica (FSC USFDA Valid Till 17-08-2019)	InTRAkit Access Kit Class B Shelf Life: 3 Years	Percutaneous Catheter Introducers	**Approved.**

87.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Owner Operator:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Legal Manufacturer:** M/s Medtronic Vascular 37A Cherry Hill Dr Danvers, MA 01923, USA **Contract Manufacturer:** M/s AvailMed S.A. De C.V. C. Industrial Lt. 001 Mz. 105 No. 20905 Int. A. Col. Cd. Industrial Tijuana, Baja California 22444, Mexico (FSC USFDA Valid Till 28-09-2020)	DxTerity Angioplasty Catheters (TRA TRApease) Class D Shelf Life: 3 Years Rs.50,000/-	Diagnostic Catheter	**Approved.**
88.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Protecta ™ XT CRT-D D354TRM Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** D354TRM Rs.50,000/-	Cardiac resynchronization therapy implantable defibrillator (Tripple Chamber, High Power,IS-1/DF4 connector)	**Approved.**

89.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Protecta ™ XT VR D354VRG Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** D354VRG Rs.50,000/-	Single-chamber implantable defibrillator IS-1/DF1 connector	**Approved.**
90.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Protecta XT DR D354DRG Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** D354DRG Rs.50,000/-	Dual-chamber implantable defibrillator (IS-1,DF1 Connector	**Approved.**
91.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing**	Protecta XT DR D354DRM Class D **Shelf Life:** 18 Months from the date of power source	Dual-chamber implantable defibrillator (IS1,DF4 Connector	**Approved.**

		Site: M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	connection. **Model:** D354DRM Rs.50,000/-		
92.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Protecta XT CRT-D D354TRG Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** D354TRG Rs.50,000/-	Cardiac resynchronization therapy implantable defibrillator (Tripple Chamber, High Power,IS-1/DF1 connector)	**Approved.**
93.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland	Protecta XT VR D354VRM Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** D354VRM Rs.50,000/-	Single-chamber implantable defibrillator DF4 connector	**Approved.**

		(FSC Switzerland Valid Till 06-03-2021)			
94.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Evera MRI ™ S VR SureScan DVMC3D1 Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** DVMC3D1 Rs.50,000/-	Single-chamber implantable defibrillator (IS-1,DF1 Connector	**Approved** subject to provision of valid Design Examina-tion certificate.
95.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Evera MRI XT VR SureScan DVMB2D1 Class D **Shelf Life:** 18 Months from the date of power source connection. **Model:** DVMB2D1 Rs.50,000/-	Single-chamber implantable defibrillator (IS-1,DF1 Connector	**Approved** subject to provision of valid Design Examinatio n certificate.
96.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE,	Evera MRI XT DR SureScan DDMB2D4 Class D	Dual-chamber implantable defibrillator (IS-1,DF4 Connector)	**Approved** subject to provision of valid Design Examina-

		Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	**Shelf Life:** 18 Months from the date of power source connection. **Model:** DDMB2D4 Rs.50,000/-		tion certificate.
97.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Evera MRI XT DR SureScan DDMB 2D1 Class D **Shelf Life:** 18 Months from the date of power source connection. **Models:** DDMB 2D1 Rs.50,000/-	Dual Chamber Implantable Defibrillator (IS-1,DF1 Connector)	**Approved** subject to provision of valid Design Examination certificate.
98.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz,	Evera MRI XT VR SureScan DVMB2D4 Class D **Shelf Life:** 18 Months from the date of power source connection. Rs.50,000/-	Single-chamber implantable defibrillator (IS-1,DF4 Connector	**Approved** subject to provision of valid Design Examination certificate.

		Switzerland (FSC Switzerland Valid Till 06-03-2021)			
99.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Relia IPG REVDD01 Class D **Shelf Life:** 18 Months from the date of power source connection. Rs.50,000/-	Dual-chamber sensing ,Ventricular pacing only implantable pacemaker	**Approved.**
100.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Relia ™ IPG RESR01 Class D **Shelf Life:** 18 Months from the date of power source connection Rs.50,000/-	Single-chamber pacemaker, rate-responsive	**Approved.**
101.	-do- **Evaluator:**	**Legal Manufacturer:** M/s Medtronic	Sensia IPG SESR01 Class D	Single-chamber pacemaker, rate-responsive	**Approved.**

	Hafiz Muhammad Asif Iqbal	Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	**Shelf Life:** 18 Months from the date of power source connection Rs.50,000/-	implantable pacemaker	
102.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Brava ™ Quad CRT-D DTBC2QQ Class D **Shelf Life:** 18 Months from the date of power source connection Rs.50,000/-	Cardiac resynchronization therapy implantable defibrillator (Tripple Chamber, High Power,Ventricular Cardioversion & Pacing, DF4 Connector)	**Approved.**
103.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l.,	Brava ™ Quad CRT-D DTBC2Q1 Class D **Shelf Life:** 18 Months from the date of power source connection Rs.50,000/-	Cardiac resynchronization therapy implantable defibrillator (Tripple Chamber,Biventricular), High Power,Ventricular Cardioversion & Pacing,IS-	**Approved.**

		Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)		1/IS-4 DF1 Connector)	
104.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Brava ™ CRT-D DTBC2D4 Class D **Shelf Life:** 18 Months from the date of power source connection Rs.50,000/-	Cardiac resynchronization therapy implantable defibrillator (Tripple Chamber,Biventricular), High Power,Ventricular Cardioversion & Pacing,IS-1 DF4 Connector	**Approved.**
105.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Brava ™ CRT-D DTBC2D1 Class D **Shelf Life:** 18 Months from the date of power source connection Rs.50,000/-	Cardiac resynchronization therapy implantable defibrillator (Tripple Chamber Biventricular, High Power,Ventricular Cardioversion & Pacing,IS-1 DF1 Connector)	**Approved.**

106.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Adapta ™ ADDR01 Class D **Shelf Life:** 18 Months from the date of power source connection **Models:** ADDR03 ADDR06 ADDRL1 ADDRS1 ADSR06 Rs.50,000/-	Dual chamber implantable pacemaker, rate responsive.	**Approved.**
107.	M/s Global Marketing Services, 111, Hali Road Westridge 1, Rawalpindi (ELI-000109) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Cordis Corporation, 14201 N.W. 60th Ave. Miami Lakes, FL 33014, USA **Manufacturing Site:** M/s Cordis de Mexico S.A. de C.V, Calle Circuito Interior Norte # 1820, Parque Industrial Salvarcar, Ciudad Juarez, Chihuahua, CP32574, Mexico (FSC USFDA Valid Till 30-08-2019)	BRITE® Tip Catheter Sheath Introducer Class B Shelf Life: 3 Years Codes and Sizes: As per FSC	Catheter Sheath Introducer	**Approved.**
108.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** M/s. Cepheid AB, Rontgenvagen 5, SE-171 54, Solna, Sweden.	**Xpert ® HBV Viral Load** (HBV VL) GXHBV-VL-CE-10 Class D	The assay is an in vitro nucleic acid amplification test designed for the quantitation of Hepatitis B	**Approved.**

		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA **Warehouse:** Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France FSC Sweden Valid until 22.03.2020	Shelf Life: 10 Months	Virus (HBV) DNA in human serum or plasma (EDTA) from chronically HBV-infected individuals using the automated GeneXpert® Systems.	
109.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** M/s. Sacace Biotechnologies s.r.l. via Scalabrini, 44 2100 Como, Italy. FSC Italy Issued on 25.05.2018	**SaMag Viral Nucleic Acid Extraction Kit** (Viral Nucleic Acid Extraction Kit) Sa-Mag-12 Sa-Mag-24 Class B Shelf Life: Sa-Mag-12 12Months Sa-Mag-24 18 Months	The Kit is designed to be used with SaMag-12/24 automatic nucleic acid extraction system for the extraction of Viral DNA or RNA.	**Approved.**
110.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** M/s. Cepheid AB, Rontgenvagen 5, SE-171 54, Solna, Sweden. Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA **Warehouse:** Cepheid Europe SAS	**Xpert ® HPV** (Expert HPV Assay) GXHPV-CE-10 Class C Shelf Life: 18 Months	Assay is a qualitative in vitro test for the detection of the E6/E7 region of the viral DNA genome .	**Approved.**

		Vira Solelh 81470 Maurens-Scopont France FSC Sweden Valid until 22.03.2020			
111.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** M/s. Cepheid AB, Rontgenvagen 5, SE-171 54, Solna, Sweden. Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA **Warehouse:** Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France FSC Sweden Valid until 12.12.2020	**Xpert ® MTB/RIF Ultra** Class C Shelf Life: 12 Months (Codes /sizes) As per FSC	The test kit is a semi-quantitative, nested real-time polymerase chain reaction (PCR) invitro diagnostic test for the detetction of Mycobacterium tuberculosis (MTB)	**Approved.**
112.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France	**VIDAS anti HEV IgG** (Hepatitis E virus immunoglobulin G (IgG) antibody IVD) **418116 VIDAS® anti HEV IgG** Class C Shelf Life : 18 months Rs.50,000/-	Hepatitis E virus immunoglobulin G (IgG) antibody IVD	**Approved.**

		FSC France Issued on 13th December, 2017			
113.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France FSC France Issued on 13th December, 2017	**Vidas® HCG** (Total Human Chorionic gonadotropin) **30405 VIDAS® HCG** Class C Shelf Life : 12 months Rs.50,000/-	Total Human Chorionic gonadotropin	**Approved.**
114.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France FSC France Issued on 13th December, 2017	**Vidas(R) AFP** (Alpha-fetoprotein) **30413 VIDAS® AFP** Class C Shelf Life : 12 months Rs.50,000/-	Alpha-fetoprotein	**Approved.**
115.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme69280	**API NH(R)** (Multiple Neisseria species culture isolate identification IVD)	Multiple Neisseria species culture isolate identification IVD	**Approved subject to shelf life studies.**

		Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA, 3 route de Port Michaud – 38390 La Balme Les Grottes FSC France Issued on 13th December, 2017	**10400 API NH(R)** Class C Shelf Life : 12 months Rs. 50,000/-		
116.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux Inc. North America Headquarters 100 Rodolphe Street Durham, NC 27712 - USA **Manufacturing Site** M/s. BioMerieux Inc., St. Louis 595 Anglum Rd Hazelwood, MO 63042 USA **Authorized Representative** M/s. BioMerieux SA 376 Chemin de I'Orme 69280 Marcy I'Etoile – France FSC France Issued on 25th July, 2018	**VITEK(R) 2 NH** **21346 NH** Class C Shelf Life : 18 months Rs.50,000/-	Multiple Haemophilus / Neisseria bacteria species culture isolate identification IVD	**Approved to** Full Quality Assurance certificate.
117.	-do- **Evaluator:** Shahid Muhammad	**Legal Manufacturer:** M/s. BioMerieux SA376 Chemin de	**VIDAS TOXO IGG II** (Toxoplasmosis IgG)	Vidas Toxo IgG II is an automated quantitative	**Approved.**

	Iqbal	I'Orme 69280 Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France FSC France Issued on 11th December, 2017	**30210 VIDAS® TOXO IgG II** Class C Shelf Life : 11 months Rs.50,000/-	test for use on the VIDAS family instruments for the quantitative measurement of anti-toxoplasma IgG in human serum or plasma	
118.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. Adaltis S.r.l. Via Durini, 27 – 20122 Milano – Italy **Manufacturing Site:** Via Luigi Einaudi, 7 – 00012 Guidonia Montecelio (Roma) – Italy FSC Italy Issued on 13th March, 2018	EIAgen Detect HIV 4 total Screening Kit 081311 (96 tests) 081312 (192 tests) 081315 (480 tests) Class D Shelf Life : 18 months Rs.50,000/-	The EIAgen Detect HIV 4 Total Screening assay is a 4th generation solid phase ELISA using a mixture of a antigens and antibodies for the in vitro diagnostic screening in human serum or plasma (EDTA, Heparin and Citrate) of antibodies to HIV-1, HIV-2 and HIV-1 p24 antigen.	**Approved** subject to provision of Notorized ISO13485 and Full Quality Assurance Certificate.
119.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France **Manufacturing Site:**	**VIDAS anti HEV IgM** (Hepatitis E virus immunoglobulin M (IgM) antibody IVD) **418115 VIDAS® Anti-HEV IgM** Class C	VIDAS® Anti-HEV IgM (HEVM) is an automated qualitative test for use on the VIDAS® family of instruments for the detection of IgM antibody	**Approved.**

		M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France FSC France Issued on 13th December, 2017	Shelf Life : 18 months Rs.50,000/-	to hepatitis E virus in human serum and plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis of hepatitis E infection in patients with symptoms and/or clinical	
120.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA376 Chemin de I'Orme 69280 Marcy I'Etoile – France FSC France Issued on 13th December, 2017	**VIDAS® D-Dimer Exclusion II** (D-dimer IVD) **30455-02 VIDAS® D-Dimer Exclusion II™ (DEX 2)** Class C Shelf Life : 12 months Rs.50,000/-	VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS® family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate) using the ELFA technique (Enzyme Linked Fluorescent Assay).	**Approved.**
121.	-do- **Evaluator:** Shahid Muhammad	**Legal Manufacturer:** M/s. BioMerieux	**VIDAS® High Sensitive Troponin I** (Troponin I IVD)	VIDAS® High sensitive Troponin I is an automated	**Approved.**

	Iqbal	SA376 Chemin de I'Orme69280 Marcy I'Etoile – France FSC France Issued on 13th December, 2017	**415386 VIDAS® High Sensitive Troponin I** Class C Shelf Life : 15 months Rs.50,000/-	quantitative test for use on the instruments of the VIDAS® family for the determination of human cardiac troponin I in human serum or plasma, using the ELFA technique (Enzyme Linked Fluorescent Assay).	
122.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer :** M/s. BioMerieux SA376 Chemin de I'Orme69280 Marcy I'Etoile – France **Manufacturing Site:** M/s. BioMerieux SA376 Chemin de I'Orme69280 Marcy I'Etoile – France FSC France Issued on 13th December, 2017	**Vidas® AMH** (Anti-Mullerian Hormone) **417011 Vidas® Anti-Mullerian Hormone (AMH)** Class C Shelf Life : 18 months Rs.50,000/-	VIDAS® AMH (AMH) is an automated test for use on the VIDAS® family of instruments, for the quantitative measurement of circulating anti-Müllerian Hormone (AMH) in human serum or plasma.	**Approved.**
123.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019)	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou	HIV 1/2 Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) IHI-402 (Device:40 Tests/Kit) 20163400002 Class D	HIV 1/2 Human Immunodeficiency Virus Rapid Test Device	The Board deliberated the Export only certificate at length and considering that product fulfills the range of

	Evaluator: Hafiz Muhammad Asif Iqbal	Economic & Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	Shelf Life: 25 Months		products required to be registered and approved the product subject to inspection abroad.
124.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic &Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) IHBsb-302 (Device: 40Tests/Kit) 20153401113 Class D Shelf Life: 25 Months	HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma)	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
125.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China	HBsAg One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) IHBsg-302 (Device: 40Tests/Kit) 20153401112 Class D Shelf Life: 25 Months	HBsAg One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma)	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved

		(FSC China Valid Till 04-06-2019) Export only certificate of China			the product subject to inspection abroad.
126.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	HBV One Step Hepatitis B Virus Combo Test Device (Serum/Plasma) IHB-355 (Device: 25Tests/Kit) 20153401111 Class D Shelf Life: 25 Months	HBV One Step Hepatitis B Virus Combo Test Device (Serum/Plasma)	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registeredand approved the product subject to inspection abroad.
127.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood/Serum/Plasma) IHBsg-402 (Device:40 Tests/Kit) 3401639 Class D Shelf Life: 27 Months	HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood/Serum/ Plasma)	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.

128.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) IHC-301 (Strip:50 Tests/Kit) 20143401951 Class D Shelf Life: 27 Months	HBsAg Hepatitis B Surface Antigen Rapid Test Device (Whole Blood/Serum/ Plasma)	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
129.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	HBsAg One Step Hepatitis B Surface Antibody Test Strip (Serum/Plasma) IHBsg-301 (Strip: 50Tests/Kit) 20153401112 Class D Shelf Life: 24 Months	HBsAg One Step Hepatitis B Surface Antibody Test Strip (Serum/Plasm a)	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
130.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Abon Biopharm (Hangzhou) Co.,	HBsAg Hepatitis B Surface Antigen Rapid Test Strip (Whole Blood/Serum/Plasma) IHBsg-401 (Strip: 50Tests/Kit)	HBsAg One Step Hepatitis B Surface Antibody Test Strip (Serum/Plasm a)	The Board deliberated the Export only certificate at length and considering

		Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China (FSC China Valid Till 04-06-2019) Export only certificate of China	(Canister: 100Tests/Kit (25 Tests/Kit*4) 3401639 Class D Shelf Life: 27 Months		that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
131.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer** M/s Abon Biopharm (Hangzhou) Co., Ltd., No. 198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, PR China (FSC China Valid Till 06-04-2019) Export only certificate of China	HCV Hepatitis C Virus Rapid Test Device (serum/plasma) Class D Shelflife: 27 Months IHC-302 40 Test/Kit	HCV Rapid Test	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
132.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** ABON Biopharm (Hangzhou) Co., Ltd # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China **Manufacturing**	Abon Syphilis Ultra Rapid Test Strip (whole blood/serum/plasma) Syphilis Ultra Rapid Test Strip (whole blood/serum/plasma)ISY-U401 Class D Shelf Life 24 Months. Rs.50,000/-	Syphilis Ultra Rapid Test.	**Approved.**

		Site: ABON Biopharm (Hangzhou) Co., Ltd , # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China (FSC China Valid till 04-06-2019) (FSC Germany Issued 21-03-2019)			
133.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China **Manufacturing Site:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China (FSC China Valid till 08-01-2020)	Abon Malaria P.f// Pan Rapid Test Device (whole blood) **ABON Malaria P.f./Pan Rapid Test Device (whole blood) IMA-T402** Class C Shelf Life 24 Months. Rs.50,000/-	Malaria P.f// Pan rapid test	**Approved.**

		(FSC Germany Issued 21-03-2019)			
134.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China **Manufacturing Site:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China (FSC China Valid till 08-01-2020) (FSC Germany Issued 21-03-2019)	Abon TB Tuberclosis Rapid Test Device (Whole blood/ Serum/ Plasma **TB Tuberclosis Rapid Test Device (Whole blood/ Serum/ Plasma** **ITB-402** Class-C Shelf Life 24 Months. Rs.50,000/-	Tuberclosis Test	**Approved.**
135.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China	Syphilis Ultra Rapid Test Device (whole blood/Serum/Plasma) ISY-U402 Class D Shelf life: 24 Months	Syphilis Ultra Rapid Test	**Approved.**

		Manufacturing Site: ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China (FSC China Valid till 04-06-2019) (FSC Germany Issued 21-03-2019)			
136.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic &Technological Development Area, Hangzhou, 310018, P.R China **Manufacturing Site:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China (FSC China Valid till 04-06-2019)	cTnl One Step Troponin I Test Device (Whole Blood/Serum/Plasma) CTI-402 Class C Shelf life: 24 Months Rs.50,000/-	Rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin-I	**Approved.**

		(FSC Germany Issued 21-03-2019)			
137.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China **Manufacturing Site:** ABON Biopharm (Hangzhou) Co., Ltd, # 198 12th Street East , Hangzhou Econonmic & Technological Development Area, Hangzhou, 310018, P.R China (FSC China Valid till 04-06-2019) (FSC Germany Issued 21-03-2019)	Chlamydia Rapid Test Device (Swab/urine) ICH-502 Class C Shelf life: 24 Months Rs.50,000/-	Chlamydia Rapid Test	**Approved.**
138.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea **Manufacturing Site:**	SD BIOLINE Influenza Ag A/B/A (H1N1) Pandemic 19FK31 (10 tests/kit) & 19FK32 (25tests / Kit) Class-C Shelf Life 24 Months.	Invitro diagnostic kit for the differential and qualitative detection of influenza Virus Type A, Type B and A(H1N1) Pandemic antigens directly from	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be

		Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea (FSC Korea issue11-08-2017	Rs.50,000/-	nasal / throat/ nasopharyngeal swab or nasal /nasopharyngeal aspirate specimens.	registered and approved the product subject to inspection abroad.
139.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea. **Manufacturing Site:** Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea (FSC Korea Issuance 11-03-2019)	SD Bioline Chikungunya IgM Class C Shelf Life: 24 Months Product License: 14-2255 Cat.No.46FK10 SD BIOLINE Chikungunya IgM Rs.50,000/-	SD Bioline Chikungunya IgM	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
140.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea. **Manufacturing Site:** Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu,	SD Bioline Salmonella TyphiIgG/Igm Fast SD Bioline Salmonella Typhi IgG/IgM Fast Class C Shelf Life: 24 Months Rs.50,000/-	SD Bioline Salmonella Typhi IgG/IgM Fast	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved

		Yongin-si, Gyeonggi-do, Republic of Korea (FSC Korea Issuance 11-03-2019)			the product subject to inspection abroad.
141.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea. **Manufacturing Site:** Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea (FSC Korea Issuance 11-03-2019)	Panbio Dengue Early Rapid Class C Shelf Life: 24 Months Panbio Dengue Early Rapid 01PF20 Rs.50,000/-	Panbio Dengue Early Rapid	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registeredand approved the product subject to inspection abroad.
142.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea. **Manufacturing Site:** Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea	Panbio Dengue IgM Capture ELISA Class C Shelf Life: 15 Months Panbio Dengue IgM Capture ELISA 01PE20 Rs.50,000/-	Panbio Dengue IgM Capture ELISA	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registeredand approved the product subject to inspection abroad.

		(FSC Korea Issuance 11-03-2019)			
143.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Standard Diagnostics, Inc. 65, Borahaga I-ro, Giheung-gu, Yongin-si, Gyenoggi-do, Korea. **Manufacturing Site:** Standard Diagnostics, Inc 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea (FSC Korea Issuance 11-03-2019)	SD Dengue IgM Caputure ELISA Class C Shelf Life: 18 Months SD Dengue IgM Caputure ELISA Rs.50,000/-	SD Dengue IgMCaputure ELISA	The Board deliberated the Export only certificate at length and considering that product fulfills the range of products required to be registered and approved the product subject to inspection abroad.
144.	M/s Hoora Pharma (Pvt) Ltd., WH-01-20-A7-A8, Korangi Creek Industrial Park, Karachi (ELI-00037) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	IMMULITE 1000 U-Capture Toxoplasma IgM IMMULITE 1000 IgG/IgM (ID1) Sample Diluent Module Class C Shelf Life: 12 Months SMN:10381288 REF:LKTZ1 SMN:10387608 REF:L1KIGW1	IgM Antibodies to Toxoplasma gondii Assay	**Approved.**
145.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare	IMMULITE AFP Sample Diluent IMMULITE 1000 AFP Assay	Alpha-Fetoprotein Assay	**Approved.**

		Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	Class C Shelf Life: 12 Months SMN:10387015 REF:LAPZ SMN:10381162 REF:LKAP1		
146.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	IMMULITE 2000 Toxoplasma Quantitative IgG IMMULITE 2000 IgG/IgM Sample Diluent Class C Shelf Life: 12 Months SMN:10387663 REF:L2IGZ2 SMN:10381323 REF:L2KTXP2	IgG Antibodies to Toxoplasma gondii Assay	**Approved.**
147.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	IMMULITE 2000 U-Capture Toxoplasma IgM IMMULITE 2000 IgG/IgM Sample Diluent Class C Shelf Life: 12 Months SMN:10381298 REF:L2KTZ2 SMN:10387663 REF:L2IGZ2	IgM Antibodies to Toxoplasma gondii Assay	**Approved.**
148.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited,	IMMULITE/IMMULITE 1000 3rd Generation PSA IMMULITE PSA Sample Diluent Class C	Prostate-Specific Antigen Assay	**Approved.**

		Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	Shelf Life: 12 Months SMN:10380956 REF:LKUP1 SMN:10386994 REF:LPSZ		
149.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer/ Manufacturing Site:** M/s Siemens Healthcare Diagnostics Products Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, UK (FSC UK Valid Till 16-10-2020)	IMMULITE 2000 Multi-Diluent 2 Sample Diluent IMMULITE 2000 Multi-Diluent 2 Sample Diluent IMMULITE 2000 AFP IMMULITE 2000 AFP Class C Shelf Life: 12 Months SMN:10283031 REF:L2M2Z SMN:10387058 REF:L2M2Z4 SMN:10381184 REF:L2KAP6 SMN:10381187 REF:L2KAP2	Alpha-Fetprotein Assay	**Approved.**
150.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy, Llanberis,	Free Human Chorionic Gonadotropin Assay 1. Immulite 2000 HCG (SMN 10381194 REF L2KCG6) (SMN 10381206 REF L2KCG2) 2. Immulite HCG Sample Diluent (SMN 10387051 REF L2CGZ) (SMN 10387622	For in vitro diagnostic use with IMMULITE® 2000 Systems Analyzers – for the quantitative measurement of human chorionic gonadotropin (HCG) is serum, and for strictly qualtitative determinations	**Approved.**

		Caernarfon, LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)	REF L2CGZ4) Free Human Chorionic gonadotropin Assay Class C Shelf Life: 12 Months Rs.50,000/-	in urine, as an aid in the detection of Pregnancy.	
151.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)	Siemens Immulite 1000 Un Conjugated Estriol (UE3) assay Immulite 1000 Unconjugated Estriol (UE3) (SMN 10381168 REF LKUE31) Class C Shelf life 12 months Rs.50,000/-	For in vitro diagnostic use with IMMULITE® 1000 Analyzer – for the quantitative measurement of unconjugated (free) estriol in serum, as an aid in monitoring fetal maturity and well –being in the context of high –risk and poorly dated pregnancies.	**Approved.**
152.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy, Llanberis,	Free Human Chorionic gonadotropin assay 1. Siemens Immulite 1000 Free Beta HCG assay (SMN 103891164 REF LKBCG1) 2. Siemens Immulite HCG Sample Diluent (SMN 10386977	For in vitro diagnostic use with IMMULITE and IMMULITE 1000 Analyzers for the quantitative measurement of free β-HCG subunit in serum	**Approved.**

		Caernarfon , LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)	REF LCGZ) 3. Siemens Immulite HCG Sample Diluent (SMN 10386978 REF LCGZ4) Shelf Life : 12 months Class C Rs.50,000/-		
153.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)	Free Human Chorionic gonadotropin assay 1. Immulite 1000 HCG (SMN 10381161 LKCG1) 2. Immulite HCG Sample Diluent (SMN 10386977 LCGZ) (SMN 10386978 LCGZ4) Class C Shelf life: 12 Months Rs.50,000/-	For in vitro diagnostic use with IMMULITE and IMMULITE 1000 Analyzers for the quantitative measurement human chorionic gonadotropin (HCG) in serum, and for strictly qualitative determinations in urine, as an aid in the detection of pregnancy.	**Approved.**
154.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare	Siemens Immulite 2000 Free Beta HCG Assay 1. Immulite 2000 Free Beta HCG (SMN 10381175 L2KFB2) 2. Immulite 2000	For in vitro diagnostic use with IMMULITE 2000 Systems Analyzers –for the quantitative measurement of free β-HCG subunit in serum	**Approved.**

		Diagnostics Product Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)	HCG Sample Diluent (SMN 10387051 L2CGZ) (SMN 10387622 L2CGZ4) Class C Shelf life : 12 Months		
155.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom (FSC valid till 16-10-2020)	Siemens Immulite 1000 PAPP-A assay Immulite 1000 PAPP-A (SMN 10381150 LKPC1) Class C Shelf life: 12 months	For in vitro diagnostic use with IMMULITE and IMMULITE 1000 Analyzers for the quantitative measurement of pregnancy-associated plasma protein A (PAPPA-A) in serum or heparinized plasma.	**Approved.**
156.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Terrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy,	Siemens Immulite 2000 PAPP-A assay Immulite 2000 PAPP-A (SMN 10381213 REF L2KPC2) Class C Shelf life: 12 months Rs.50,000/-	For in vitro diagnostic use with IMMULITE 2000 systems Analyzers for the quantitative measurement of pregnancy-associated plasma protein A (PAPPA-A) in serum or heparinized plasma.	**Approved.**

		Llanberis, Caernarfon, LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)			
157.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Siemens Healthcare Diagnostics Inc., 511 Benedict Avenue, Tarrytown New York, 10591 USA. **Manufacturing Site:** Siemens Healthcare Diagnostics Product Limited, Glyn Rhonwy, Llanberis, Caernarfon, LL55 4EL, United Kingdom (FSC UK valid till 16-10-2020)	Unconjugated Estriol Assay 1. Immulite 2000 Unconjugated Estriol (UE3) (SMN 10381192 REF L2KUE32) (SMN 10381171 REF L2KUE36) Class C Shelf life 12 months Rs.50,000/-	For in vitro diagnostic use with IMMULITE 2000 systems Analyzers for the quantitative measurement of (free) estriol in serum, as an aid in monitoring fetal maturity and well being in the contexst of high rish and poorly dated pregnancies.	**Approved.**
158.	M/s. Physiomed (Pvt) Ltd, 268/3, Kamal Road Saddar Rawalpindi.	i) St. Jude Medical Costa Rica Ltda. Edificio No. 44 Calle 0, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela COSTA RICA 187-4050 ii) St. Jude Medical 14901 DEVEAU PL. MINNETONKA, MN USA 55345 iii) St. Jude Medical 5050 Nathan Lane	BRK® Transseptal Needle 407200, 407202, 407205, 407206, G407208, G407210, G407211 Class D Shelflife : 03 years	The BRK Transseptal Needle is used to puncture the interatrial Septum During a Transseptal catheterization	**Approved.**

		North Plymouth, MN USA 55442			
159.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	i) St. Jude Medical Costa Rica Ltda. Edificio No. 44 Calle 0, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela COSTA RICA 187-4050 ii) St. Jude Medical 14901 DEVEAU PL. MINNETONKA, MN USA 55345 iii) St. Jude Medical 5050 Nathan Lane North Plymouth, MN USA 55442	Response ® Electrophysiology Catheter. 401150, 401152, 401154, 401155, 401156, 401158, 401160, 401206, 401207, 401210, 401211, 401212, 401222, 401223, 401226, 401227, 401228, 401260, 401261, 401271, 401275, 401276, 401278, 401281, 401282, 401305, 401306, 401308, 401309, 401310, 401311, 401312, 401317, 401318, 401360, 401381, 401386, 401392, 401399, 401400, 401415, 401425 Class D Shelflife : 03 years	Response Electrophysiology Catherters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	**Approved.**
160.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	i) St. Jude Medical Costa Rica Ltda. Edificio No. 44 Calle 0, Ave. 2, Zona Franca Coyol, EI Coyol, Alajuela COSTA RICA 187-4050 ii) St. Jude Medical 14901 DEVEAU PL. MINNETONKA, MN USA 55345 iii) St. Jude Medical 5050 Nathan Lane	Supreme ® Electrophysiology Catheter. 401430, 401433, 401434, 401435, 401436, 401438, 401441, 401442, 401443, 401444, 401448, 401449, 401450, 401451, 401453, 401466, 401468, 401470, 401474, 401475, 401859, 401860, 401862, 401863, 401864, 401865, 401871, 401872,	Response Electrophysiology Catherters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.	**Approved.**

		North Plymouth, MN USA 55442	401876, 401877, 401878, 401890, 401891, 401892, 401893, 401950, 401952, 401956, 401957, 401960, 401966, 401967, 401968, 401969, 401978, 401979, 401993, 401994, 401996, 402003, 402004, 402008, 402009, 402010, 402011, 402012, 402020, 402033, 402034, 402046 Class D Shelflife : 03 years		
161.	M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Near Hill Park, Karachi (ELI-00091) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Polysorb™ (Braided Absorbable Suture) Class D Shelf Life: 5 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Synthetic Braided Absorbable Suture	**Approved subject to provision of Valid FSC.**
162.	-do- **Evaluator:** Hafiz Muhammad	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire	Surgidac ™ (Uncoated Braided Polyester) Class D	Braided Polyester Non-Absorbable Sutures	**Approved subject to provision of fresh**

	Asif Iqbal	Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Shelf Life: 5 years **Sizes:** As per Free Sale Certificate Rs.50,000/-		**FSC.**
163.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Caprosyn ™ (Monofilament Absorbable Suture) Class D Shelf Life: 3 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Synthetic Monofilament Absorbable Sutures	**Approved subject to provision of fresh FSC.**
164.	-do- **Evaluator:**	**Legal Manufacturer:** M/s Coviden LLC,	Surgipro ™ (Monofilament Polypropylene)	Monofilament, Non-Absorbable,	**Approved subject to provision**

	Hafiz Muhammad Asif Iqbal	15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Class D Shelf Life: 5 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Polypropylene and Polythylene Sutures	**of fresh FSC.**
165.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Biosyn ™ Monofilament Absorbable Suture Class D Shelf Life: 5 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Monofilament Absorbable Suture	**Approved subject to provision of fresh FSC.**

166.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Maxon ™ (Monofilament Absorbable Suture) Class D Shelf Life: 5 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Synthetic Absorbable Suture	**Approved subject to provision of fresh FSC.**
167.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic	Flexon ™ (Multifilament Temporary Cardiac Pacing Lead) Class D Shelf Life: 5 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Multifilament Temporary Cardiac Pacing Lead	**Approved subject to provision of fresh FSC.**

		(FSC USFDA Valid Till 16-08-2019)			
168.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	V-LOC ™ 180 (Absorbable Wound Closure Device) Class D Shelf Life: 3 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Absorbable Wound Closure Device	**Approved subject to provision of fresh FSC and DOC.**
169.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo	V-LOC ™ PBT (Non-Absorbable Wound Closure Device) Class C Shelf Life: 3 years **Sizes:** As per Free Sale Certificate Rs.50,000/-	Non Absorbable Wound Closure Device	**Approved subject to provision of fresh FSC.**

		Dominican Republic (FSC USFDA Valid Till 16-08-2019)			
170.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	SOFSILK ™ (Wax Coated Braided Silk Silicone Coated Braided Silk) Class D Shelf Life: 5 Years Rs.50,000/- **Codes/ Sisez:** CS100, GS92M, GS823, S1373 S197, S403, SS5677G, CS10M , CS93M, GS824, S1732K, S199 , S404, SS5678, CS1193M, CS9M GS831, S1733K, S204, S405, SS5679, CS16M, ES439, GS832, S1734K, S205, S583, SS5679G, CS17M, GS299, GS833, S1735, S206, S805, SS5684, CS210, GS30M, GS834, S1740K S2176K, S606, SS5684G, CS211, GS33M, GS835, S1746K, 8243, S607, SS5684GE, CS390 GS34M, GSJ33M, S1750K, S244 S608, SS5685G, CS423, GS43M, GSJ34M, S176, S245, S610, SS591,CS424, GS44M, GSJ36M, S1765K, S246, SS1639G, SS621, CS425, GS451,	Braided Silk Non Absorbable Sutures	**Approved subject to provision of fresh FSC.**

			GSJ37M,S1766K S254, SS1694G, SS622, CS434 GS452, GSJ46M, S1768K, S255, SS1775G, SS623, CS482, GS453 GSJ47M, S1769K, S2752K, SS1925G, SS623G, CS485, GS45M, GSJ63M, S1780K, S2767K, SS1984G, SS624, CS490, GS46M, GSJ64M, S1783K, S2780K, SS522, SS629, CS562, GS47M, LS636, S1789K, S2782K, SS523, SS631,CS575 GS61M, LS637, S182, S2792K, SS525, SS632,CS744, GS62M , LS638, S183, S282, SS5639, SS633, CS745, GS63M, LS639 S184, S303, SS5640, SS6330G, CS748, GS64M, LS640, S185 S304, SS5640G, SS645, CS791 GS65M, S1172, S187, S305, SS5641, SS646, CS792, GS66M S1173, S193, S316, SS5641G , SS647,CS793, GS67M, S1174 S194, S317, SS5649G, SS648, CS794, GS68M, S1272, S195, S318, SS5676, SS649, CS85M GS822, S1274, S196, S346, SS5677, SS651, SS653, SS70M VS870, SS654 SS722, VS871, SS655, SS723, VS872, SS656, SS732, VS873, SS673,		

			SS733 VS880, SS675, SS734, VS881, SS677, SS745, VS882, SS677G SS746, VS889, SS678, SS783, VS890, SS678G, SS784, VS891, SS679, VS671, SS82M, SS680, VS706M, VS533, SS681, VS709 VS552, SS682, VS766G, VS581, SS682G, VS802, VS964, SS683 VS806, SS683G, VS809, SS684 VS810, SS684G, VS823, SS685 VS842, SS685G, VS843, SS686 VS844, SS689, VS845, SS694 VS846, SS695, VS863		
171.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	CHROMIC GUT (Absorbable Suture) Class D Shelf Life: 4 Years Rs.50,000/- **Codes/ Sisez:** 3CG802, G637C, 3CG811, CG824L, CG982, G253, LG111, SG675, 3CG813, CG825L, CG983, G254, LG112, SG676, CG100M, CG865, G13, G2745K LG113, UG202,CG101M, CG866 G14, G2797K, LG114, UG203, CG10M, CG882, G15, G82, LG115, UG204, CG11M, CG883 G1744, G83, SG1816G, UG205, CG36, CG884, G1751G, G84,	Absorbable Surgical suture	**Approved subject to provision of fresh FSC.**

			SG1929, UG245, CG38M, CG885, G1751GK, G85, SG197 UG246, CG415, CG904, G1752GK, GG121, SG5163G, UG256, CG47, CG905, G1758K, GG122, SG535, UG777, CG48 CG912, G1766K, GG123, SG5637, UG778, CG49, CG913, G1780K, GG124, SG5637G, UG789, CG589M, CG914, G1790K, GG125 SG5638 CG800 CG915 G1791K GG126 SG5644 CG801 CG922 G1792K GG127 SG5644G CG802 CG923 G1793K GG128 SG5687 CG803 CG924 G1794 GG129 SG5687G CG804 CG925 G1794K GG130 SG634 CG810 CG933 G1798K GG181 SG634G CG817 CG977 6216 60523S CG811 CG943 G211 GGI 82 SG635 CG812 CG962 G212 GG185 SG635G CG813 CG963 G213 GG191 SG636 CG815 CG964 G214 GG377 SG636G CG816 CG975M G215 GG522 SG63		
172.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA	NOVAFIL ™ (Monofilament Polybutester) Class D Shelf Life: 5 Years	Monofilament Polybutester Nonabsorbable Sutures	**Approved subject to provision of fresh FSC.**

		Manufacturing Site: (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Rs.50,000/- **Codes/ Sisez:** 8886440013 440013 8886442233 442233 8886445951 448951 PB67 13K XC490 8886440023 440023 8886442243 442243 8886445961 445961 P86723K XC822 8886440113 440113 8886442253 442253 8886445971 445971 PB749K 8886440123 440123 8886442263 442263 8886446063 446063 PB7740K 8886440133 440133 8886442431 442431 8886446361 446361 SPB1213G 66440223 440223 8886442441 442441 8886446371 446371 SPB1233G 3886440233 440233 8886442451 442451 8886448473 446473 SPB1623G XNF 1965 8886440243 440243 8886442461 442461 8886446571 446571 SPB1643G XNF 1966 8886440333 440333 8886442531 442531 8886446581 446581 SPB1945G XNF1993 8886440343 440343 8886442641 442641 8886446681 446681 SPBS142G XNF1994 8886440861 440861 8886442651 442851 8886446961 446961 SPB5142GE XNF1995 8886441003 441003 8886442661 442661 8886446971 446971		

			SPB5143G XNF697 8886441013 441013 8886443371 443371 8886447071 447071 SPB5223G 8886442033 8886441023 441023 8886443671 443671 8886447081 447081 SPB5413G 8886441431 441431 8886445041 445041 8886449041 449041 SPB5423G 9886441543 441543 8886445241 445241 8886449051 449051 SPB5433G 8886441853 441853 8886445251 445251 8886452218 452218 SPB5633G 8886441913 441913 8886445261 445261 8886453863 453863 SPB5833G 8886441923 441923 8886445463 445463 8886455441 455441 SPB5843G 8886441933 441933 8886442023 442023 8886442033 442033 8886442043 442043 8886400963 400963 8886445853 445853 8886445863 445863 8886461951 461951 8886445473 445473 8886445561 445561 8886445571 445571 XNF1964		
173.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA	Ticron ™ Coated Braided Polyester Class D Shelf Life: 5 Years Rs.50,000/-	Silicone Coated Braided Polyester Non-Absorbable Sutures	**Approved subject to provision of fresh FSC.**

		Manufacturing Site: (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	**Codes/ Sisez:** 8886262741, 262741, 8886287756, 287756, 8886301751, 301751, 8886305051, 305051, 8886262751, 262751, 8886287956, 287956, 8886301761, 301761, 8886305061, 305061, 8886263151, 263151, 8886288041, 288041, 8886302341, 302341, 8886305256, 305256, 8886263451, 263451, 8886288051, 288051, 888302351 302351, 8886305451, 305451, 8886263656, 263656, 8886291451, 291451, 8886302361, 302361, 8886305461, 305461, 8888264051, 264051, 8886291461, 291461, 8886302371, 302371, 8886305471 305471 8886264451 264451, 8886294753 294753, 8886302551 302551, 8886305431 305481, 8886264551 264551, 8886295351 295351, 8886302671 302671, 8886305541 305541, 8886265856 265856, 8886296283 296283, 8886302681 302681, 8886305689 305689, 8886276851 276851, 8886297851 297851, 8886302779 302779, 8886305953 305953, 8886277521 277521, 8886298156 298156, 8886302871 302871, 8886306241 306241, 8886277531 277531, 8886300141 300141, 8886302881 302881,		

			8886306251 306251, 8886277541 277541, 8886300162 300162, 8886303352 303352, 8886306261 306261, 8886280121 280121, 8886300172 300172, 8886303541 303541, 8886306551, 8886280851 280851, 8886300262 300262, 8886303551 303551, 888630 306551, 6561 306561, 6281151 281151, 8886300332 300332 8886303756, 303756 8886306941 306941, 8886281551 281551, 8886300342 300342, 8886304056 304056, 8886307051 307051, 8886281889 281889, 8886300352 300352, 8886304321 304321, 8886308251 308251, 8886283951 283951, 8886300821 300821, 8886304521 304521, 8886308261 308261, 8886284051 284051, 8886300831 300831, 8886304531 304531, 8886308356 308356, 8886285156 285156, 8886300841 300841, 8886304631 304631, 8886308446 308446, 8886285256 285256, 8886300851 300851, 8886304731 304731, 8886308456 308456, 8886285433 285433, 8886301151 301151, 8886304741 304741, 8886308656 308656, 8886285551 285551, 8886301261 301261, 8886304851 304851, 8886308731 308731,		

			8886286234 286234, 8886301561 301561, 8886305041 305041, 8886308741 308741 8886308751 308751, 8886311961 311961, 8886316361 316361, 8886320261 320261, 8886308841 308841, 8886312331 312331, 8886316371 316371, 8886320356 320356, 312341 8886316551, 316551 8886320451 320451, 08851 8886312341, 8886309051 309051, 8886312551 312551, 8886316731 316731, 8886320541 320541, 8886309061 309061, 8886312779 312779, 8886316741 316741, 8886320551 320551, 8886309071 309071, 8886312879 312879, 8886316751 316751, 8886320561 320561, 8886309081 309081, 8886312882 312882, 8886316761 316761, 8886320951 320951, 8886309156 309156, 8886312951 312951, 8886316851 316851, 8886321156 321156, 8886309261 309261, 8886313156 313156, 8886318231 318231, 8886321251 321251, 8886309271 309271, 8886313461 313461, 8886318241 318241, 8886321356 321356, 8886309351 309351, 8886313921 313921, 8886318251 318251, 8886321366 321366, 8886309361 309361, 8886314681 314681,		

			8886318531 318531, 8886321836 321836, 8886309761 309761, 8886314783 314783, 8886318541 318541, 8886321856 321856, 8888309771 309771, 8886314789 314789, 8886318551 318551, 8886321956 32195, 886310371 310371, 8886315409 315409, 8886318561 318561, 8886322056 322056, 8886310421 310421, 8886315581 315581, 8886318571 318571, 8886322156 322156, 86310631 310631, 8886315751 315751, 8886318621 318621, 8886322256 322256, 8886310731 310731, 8886315931 315931, 8886318631 318631, 8886322621 322621, 8886310943 310943, 8886315941 315941, 8886318641 318641, 8886322631 322631, 8886322641 322641, 886316021 316021, 8886319061 319061, 8886322741 322741, 8886311371 311371, 8886316031 316031, 8886319071 319071, 8886322751 322751, 8886311381 311381, 8886316041 316041, 8886319151 319151, 8886322856 322856, 8886311761 311761, 8886316051 316051, 8886319351 319351, 8886322931 322931, 8886311771 311771, 8886316351 316351, 8886320251 320251, 8886322941 322941,		

			8886311179 311179 , 8886315951 315951, 8886318651 31, 8886311361 311361		
174.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	V-LOC ™ 90 Absorbable Wound Closure Device Class D Shelf Life: 3 Years Rs.50,000/- **Codes/ Sisez:** VLOCM0003 VLOCM0314 VLOCM1413 VLOCM0004 VLOCM0315 VLOCM1423 VLOCM0005 VLOCM0316 VLOCM1544 VLOCM0013 VLOCM0324 VLOCM 1549 VLOCM0014 VLOCM0336 VLOCM 1623 VLOCM0015 VLOCM0344 VLOCM 1624 VLOCM0023 VLOCM0345 VLOCM1704 VLOCM0024 VLOCM0346 VLOCM1744 VLOCM0025 VLOCM0603 VLOCM1824 VLOCM0033 VLOCMO604 VLOCM1904 VLOCM0034 VLOCM0613 VLOCM1944 VLOCM0035 VLOCM0614	Absorbable Wound Closure Device	**Approved subject to provision of fresh FSC.**

			VLOCM2004 VLOCM0113 VLOCM0623 VLOCM2044 VLOCM0114 VLOCM0624 VLOCM2105 VLOCM0115 VLOCM0625 VLOCM2106 VLOCM0123 VLOCM0644 VLOCM2115 VLOCMO124 VLOCM0804 VLOCM2116 VLOCMO125 VLOCM0813 VLOCM2145 VLOCM0133 VLOCMO814 VLOCM2146 VLOCM0134 VLOCM0823 VLOCM2205 VLOCMO135 VOCM0824 VLOCM2245 VLOCM0223 VLOCM0843 VLOCM2744 VLOCM0224 VLOCM0844 VLOCM3225 VLOCMO305 VLOCM1203 VLOCM3226 VLOCM0306 VLOCM1204 VLOCM3244		
175.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60	PTFE Polymer Pledgets ™ (Non-Absorbable Pre-Punched Pledgets) Class D Shelf Life: 5 Years Rs.50,000/-	Non-Absorbable Pre-Punched Pledgets	**Approved subject to provision of fresh FSC.**

		Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	**Codes/ Sisez:** 8886867501, 8886867701, 8886867801, 8886867901, 8886868201, XX5169		
176.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing Site:** (i) M/s Coviden 60 Middletown Ave North Haven, CT 06473, USA (ii) M/s Coviden Zona Franca DE San Isidro Carretera San Isidro, Km 17, Santo Domingo Dominican Republic (FSC USFDA Valid Till 16-08-2019)	Vascufil ™ Coated Monofilament Polybutester Class D Shelf Life: 5 Years Rs.50,000/- **Codes/ Sisez:** 8886470105V 470105V 8886472211V 472211V 8886479401V 479401v 8886470205V 470205V 8886472221V 472221V 8886479505V 479505V 8886470301V 470301V 8886472641V 472641V 8888470311 8886470401V 470401V 8886473051V 473051V 8886470411V 470411V 8886473131V 473131V	Monofilament Polybutester Nonabsorbable Sutures	**Approved subject to provision of fresh FSC.**

			8886470501V 470501V 8886473141V 473141V 8886470511V 470511V 8886473151V 473151V 8886470711V 470711V 8886473411V 473411V 8886470901V 470901V 8886473421V 473421V 8886470911V 470911V 8886473511V 473511V 478647 86470921V 470921V 888473611V 473611V 86471011V 471011V 888473621v 473821V 8886471021V 471021V 8886473921V 473921V 8886471121V 471121V 8886473931V 473931V 8886471401V 471401V 8886474111V 474111V 8886471411V 471411V 8886474121V 474121V 8886471621V 471621V 8886474215V 474215V 8886471631V 471631V 8886475031V 475031V 8886471641V		

			471641V 8886475041V 475041V 8886471831V 471831V 8886475051V 475051V 8886471921V 471921V 8886475611V 475811V 8886471931V 471931V 8886475931V 475931V 8886471941V 471941V 8886478417V 47B417V 8886472141V 472141V 8886478805V 478805V		
177.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** Covidien AG, Victorvon Bruns-Strasse 19, 8212 Neuhausen am Rheinfall, Switzerland (Medtronic Company) **Manufacturing Site** Sofradim Production, 116 avenue du Formans, 01600 Trevoux, France (Medtronic Company) FSC France issued on 30-09-2016	Versatex™ Monofilament Mesh Class C Shelf Life 5 Years VTX1106, VTX1510, VTX1515, VTX1515M, VTX1106X3, VTX1510X3, VTX1515X3, VTX1515MX3, VTX2020M, VTX3030M, VTX4530M, VTX5050M.	Versatex™Monofilament Mesh Is intended for the repair of abdominal wall hernias or other fascial deficiencies that require the addition of a reinforcing material.	**Approved** subject to provision of notarized ISO 13485.

178.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Covidien AG, Victorvon Bruns-Strasse 19, 8212 Neuhausen am Rheinfall, Switzerland (Medtronic Company) **Manufacturing Site** Sofradim Production, 116 avenue du Formans, 01600 Trevoux, France (Medtronic Company) FSC France issued on 30-09-2016	ProGrip™ Self Gripping Polypropylene Mesh Abdominal Hernia surgical mesh, composite-Polymer. **ProGrip™ Self Gripping Polypropylene Mesh** **PP1208DR** Eliptic, slit with flap left side 12 x 8 cm **PP1208DL** Eliptic, slit with flap right side 12 x 8 cm **PP1509G** Rectangular 15 x 9 cm Class- D Shelf Life : 5 Years	Inguinal Hernia repair via anterior tension free approach.	**Approved s**ubject to provision of Notorized Design Exam. Certificate.
179.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** Covidien AG, Victorvon Bruns-Strasse 19, 8212 Neuhausen am Rheinfall, Switzerland (Medtronic Company) **Manufacturing Site** Sofradim Production, 116 avenue du Formans, 01600 Trevoux, France (Medtronic Company)	Parietene™ Macroporous Mesh Abdominal Hernia surgical mesh, Synthetic Polymer, non bioabsorbable Class –C Shelf Life: 5 Years (Sizes & Codes as Per FSC) PPM1106, PPM1106X3, PPM1106X6, PPMK1106, PPMK1106X3, PPMK1106X6,	Parietene™Macroporous Mesh Is intended for the repair of hernias or other fascial deficiencies that require the addition of a reinforcing material.	**Approved.**

		FSC France issued on 30-09-2016	PPM1508, PPM1508X3, PPM1508X6, PPMK1508, PPMK1508X3, PPMK1508X6, PPM1510 PPM1510X3, PPM1510X6, PPM1515, PPM1515X3, PPM1515X6, PPM2020, PPM2020X3, PPM3030, PPM3030X3, PPM4530, PPM4530X3 (PPM: Rectangular) (PPMK: Pre-cut)		
180.	M/s Hashir Surgical Services, 1. Office No.16, Street 1, F-2, Phase 6, Hayatabad, Peshawar. 2. Office No.05, 2nd Floor, Syed's Tower, University Road, Peshawar. 3. House No.2, Street No.1, Gulshan Colony, GT Road, Peshawar ELI-00075	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang, Malaysia. FSC Malaysia Issued on 09.05.2013	**ECOSORB** (Poly Glycolide-co-lactide) Rs. 50,000/- **Codes/ Sizes:** E07RH300, E07RH350 E07RH370, E07RH400 E07RH360, E09RH300 E09RH350, E09RH370 E09RH37h, E09RH400 E09RH40h, E09RH480 E07RP300,	Synthetic braided absorbable suture made up of Poly Glycolide-co-lactide coated with glycomer 91.	**Approved** for registration as medical device as the inspection was conducted in 2016. The Board also acceded to the request of the firm to cancel the product simultaneously as drug.

			E09CH400 E09CH40h, E07VH350 E07CD370, E09CD400 E09CD40W, E08-P010 E050-LT0, E07RJ350 E05-P100, E17RH400 E17RH300, E17RH370 E17CD300, E19RH37h E19RH400, E19RH40h E19RH480, E19BH400 E17CH40h, E19CH400 E19CH40h, E17VH35h E19VH350, E19VH35h E19VH40h, E19CD400 E19CD40W, E15-P100 E18-P010, EA9RH480 EA5-P100, EA7CD400 EA7RH400, EA7RH450 EA7RH480, E27RH220 E27RH260, E27RH300 E27RH370, E27RH37h E29RH260, E29RH300, E29RH370, E29RH37h, E27RP260, E27RP300, E27CH260, E29CH260 E27VH350, E27VH35h E29VH370, E27CD240,		

			E27CD24W, E29CD240 E29CD24W, E29TH370 E27PD24W, E25-P100, E25-P050, E28-P010 E250-LT0, E27RJ350 E27RH350, E27RH360 E27RH250, E27CD260 E37RH170, E37RH200 E37RH220, E37RH260 E37RH300, E37RH370 E39RH170, E39RH220 E39RH260, E39RH370 E39RH37h, E37RP170 E37RP200, E37RP260 E34CD160, E34CD16W E37CD16W, E37CD190 E37CD19W, E37CD240 E37CD24W, E37CD260 E37CD26W, E37CD350 E37CD35W, E37CD350 E37CD35W, E39CD190 E39CD19W, E39CD240 E39CD24W, E39CD260 E39CD26W, E39CD350 E39CD35W, E37MD26W E37MD35W, E37TH260		

			E37TH370, E39TH260 E39TH370, E37CS60W E37PD24W, E35-P100 E38-P010, E37RH250 E37CD400, E47RH170 E47RH200, E47RH220 E49RH170, E49RH200 E49RH220, E47RP170 E47RP200, E44CH20W E44CD160, E44CD16W E47CD160, E47CD16W E47CD190, E47CD19W E47RH190, E47CD240 E47CD24W, E49CD160 E49CD16W, E49CD190 E49CD19W, E49CD240 E49CD24W, E44MD13W E44MD19W, E47PD19W E44NH20W, E44ND19W E45-P100, E54RH130 E54RH13W, E54RH170 E57RH170, E54CD120 E54CD160, E54CD16W E54MD11W, E54MD13W E54MD16W, E54PD11W E54PD13W, E64RH130		

			E64RH13W, E67RH130 E64PD11W, E64PD08W E64PD082, E47RH190 Class D Shelf Life : 05 years		
181.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang , Malaysia. FSC Malaysia Issued on 03.12.2012	**VIGIMESH** (Polypropylene Monofilament Mesh) Rs. 50,000 **Codes/ Sisez:** RM6110SP, RM7150SP RM1015SP, RM1515SP RM3030SP, RM6110LP RM7150LP, RM1015LP RM1515LP, RM3030LP RM6110CP, RM7150CP RM1015CP, RM1515CP RM3030CP Class D Shelf Life : 05 years	Sterile, non-absorbable, knitted polypropylene monofilament mesh material for hernia repair.	**Approved** for registration as medical device as the inspection was conducted in 2016. The Board also acceded to the request of the firm to cancel the product simultaneously as drug.
182.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang , Malaysia. FSC Malaysia Issued on 09.05.2013	**ESTERON** (Polyester) **Codes/ Sisez:** T07RH260, T07RH300 T07RH370, T07CD240 T07TH260, T07TH370 T07CD300, T07CH260 T07VH260, T07CH300 T17CH300, T17RH370 T17CD240,	Synthetic, braided non absorbable suture made of Polyester.	**Approved** for registration as medical device as the inspection has been conducted. The Board also acceded to the request of the firm to cancel the product

			TA7VH450 TD7VH550, T24RH170 T27RH222, T27RH260 T27RH300, T27RH370 T29RH262, T27CH300 T27CD240, T27CD300 T27CD390, T27CS600 T27TH260, T27TH370 T27VH170, T27VH260 T29VH262, T37CH300 T34RH170, T37RH220 T37RH222, T37RH260 T37RH300, T37RH370 T39RH172, T39RH262 T37CD160, T37CD190 T37CD240, T37CD300 T37CS600, T37TH170 T39TH262, T44RH170 T47RH130, T47RH222 T49RH172, T44CD120 T47CD160, T47CD190 T47CD240, T47CD300 T44FQ082, T54RH170 T59RH172, T54CD120 T57CD160, T57CD190 T64CD120 Class D		simultaneously as drug.

			Shelf Life : 05 years Rs.50,000/-		
183.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang , Malaysia. FSC Malaysia Issued on 09.05.2013	CATGUT CHROM (Collagen of the gut wall of cattle (serosa) or sheep (submucosa)) **Codes/ Sisez:** C07RH220, C07RH260 C07RH27h. C07RH300 C0RH340, C07RH350 C07RH370, C07RH37h C07RH400, C07RH430 C07RH480, C07RH760 C07CH260, C07CH37h C07CH400, C07CH480 C07TH37h, C07CD240 C05-P030, C07CD300 C07CD370, C07BD640 C17RH260, C17RH27h C17RH430, C17TH37h C17CD300, C17CD400 C17RH300, C17RH370 C17RH37h, C17RH400 C17RH480, C17CH37h C17BD640, CA7RH430 CA7RH400, CA7RH480 CA7RH760, C27RH170 C27RH260, C27RH300 C27RH350,	Sterile, absorbable suture, produced from collagen of the gut wall of cattle (serosa) or sheep (submucosa).	**Approved** for registration as medical device as the inspection has been conducted. The Board also acceded to the request of the firm to cancel the product simultaneou sly as drug.

			C27RH37h C27RH430, C27RH480 C29RH370, C27CH37h C27TH260, C27TH37h C29TH370, C27CD240 C27BD640, C27CS510 C25-P030, C27-P020 C28-P010, C27RH220 C27RH370, C27CH260 C27CD190, C27CD300 C27CD370, C37CD300 C37RH170, C37RH200 C37RH260, C37RH300 C37RH350, C37RH220 C37RH370, C37CH260 C34CD120, C34CD160 C34CD190, C37CD190 C37CD240, C35-P030 C44RH100, C44RH130 C47RH170, C47RH200 C47RH220, C47RH260 C47RH300, C47RH370 C44CH150, C47CH210 C44CD120, C44CD160 C44CD190, C47CD160 C47CD190, C47CD240 C48-P010, C54RH100 C54RH130,		

			C57RH200 C54CD120, C54CD160 C57CD190, C57CD240 C64CD120, C67CD190 C25-P100, C05-P100 C15-P030, CA5-P030 C37-P020, C07-P020 C17-P020, CA7-P020 C38-P010, C08-P010 C18-P010, CA8-P010 CB8-P010 Class D Shelf Life : 05 years Rs.50,000/-		
184.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang ,Malaysia. FSC Malaysia Issued on 09.05.2013	**ECOSORB FAST** (Poly glyscolide-co-lactide) Class D Shelf Life : 05 years Rs. 50,000 **Codes/ Sizes:** **As per FSC**	Synthetic, absorbable, braided sterile suture made of Poly glycolide-co-lactide coated with Glacomer 91	**Approved** for registration as medical device as the inspection has been conducted. The Board also acceded to the request of the firm to cancel the product simultaneously as drug.
185.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang , Malaysia.	**ECOLENE** (Polypropylene) **Codes/ Sisez:** R07RH260, R07RH300 R07RH370, R00RH300 R00RH400, R07CD390 R07RH400,	ECOLENE is a sterile, synthetic, non-absorbable monofilament surgical suture made of polypropylene.	**Approved.** Inspection has been conducted. Firm has requested to cancel their product already registered as

		FSC Malaysia Issued on 09.05.2013	R09RH300 R17RH300, R17RH370 R17RH400, R10RH400 R10RH300, R17CD350 R17CD360, R19CH45H R19RH40H, R27RH260 R27RH300, R27RH370 R29RH252, R29RH262 R27CD190, R27CD240 R27CD300, R27CD390 R27MD240, R27CS600 R27TH260, R27CD400 R27CS550, R27RH250 R37CD260, R37RH250 R37RH262, R37RH240 R37RH300, R37RH170 R37RH220, R37RH260 R39RH162, R39RH222 R39RH252, R39RH262 R37CD190, R37CD240 R37CD300, R37CD390 R34MD240, R37MD190 R37MD240, R37CS600 R37TH170, R37TH260 R37TD180, R37TD260 R39XH262,		Drug and applied as Medical Device fresh

			R3BXH262 R3BXD262, R47RH170 R47RH220, R47RH260 R49RH172, R44CD120 R44CD160, R47CD190 R47CD240, R44MD130 R44MD160, R44MD190 R44MD240, R47MD190 R47TH170, R47TH200 R47TD180, R47TD260 R49RD172, R49XH192 R4BXD192, R44RH200 R47RH200, R47RH250 R49RH202, R57CD160 R57RD120, R57RH172 R59RH172, R57RH130 R57RH170, R54CD120 R54CD160, R57CD190 R54MD110, R54MD130 R54MD160, R54MD190 R57TH170, R57TD120 R57TD180, R57RD122 R57RD182, R57XD132 R67RH100, R67RH130 R64CD120, R64CD160 R64MD110,		

			R64MD130 R67TD120, R67RD102 R67RD122, R66XD112 R64CD130, R67CD130 R67RD082, R67RD132 R67RH102, R76RD082 R74XD082, R76XD082 R79XD082, R76XD092 R86RD062, R86XD062 R84RD062, R86RD092 R86XD092, RE3FD062 Rs. 50,000 Class D Shelf Life : 05 years		
186.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. VIGILENZ Medical Devices SdnBhd 2A, LPBM 2, Taman Perindustrian Bukit Minyak, 14100 Pulau Penang , Malaysia. FSC Malaysia Issued on 09.05.2013	**VIGILENZ SILK** (Non-absorbable, braided, wax or silicone coated, sterile suture) Rs. 50,000 S07RH260, S07RH300 S07RH370, S07CS600 S07CH300, S07CH500 S04CD390, S07CD240 S07CD300, S07CD350 S07CD370, S07CD390 S07CD400, S07CD450 S04-P100, S04-P170 S06-P130, S06-P150 S07-P100, S08-P010 S0A-P010, S17RH27h S17RH300, S17RH360	Silk is a non-absorbable, braided, wax or silicone coated, sterile suture material, made of Silk Fibroin. Silk is intended for use in general soft tissue approximation and/or ligation such as dermal suture and not intended for use in cardiovascular and neurosurgical.	**Approved** for registration as medical device as the inspection has been conducted. The Board also acceded to the request of the firm to cancel the product simultaneously as drug.

			S17RH370, S17RH37h S17RH480, S14CD390 S17CD300, S17CD350 S17CD390, S14-P100 S14-P170, S16-P130 S16-P150, S17-P100 S18-P010, S1A-P010 SA7CD390, SA7RH400 SA7RH37h, SAA- P010 S27RH170, S27RH220 S27RH260, S27RH300 S27RH370, S24RS510 S27CS600, S27CH300 S24CD390, S24CD800 S27CD160, S27CD240 S27CD300, S27CD260 S27CD220, S27CD350 S24-P100, S24-P170 S26-P130, S26-P150 S27-P100, S28-P010 S2A-P010, S37RH170 S37RH200, S37RH220 S37RH260, S37RH300 S37CS600, S34NH200 S34CH150, S34CH230 S37CH260, S37CH300 S34CD160, S34CD190 S37CD160, S37CD190 S37CD220, S37CD240 S37CD260, S37CD300 S37CD350, S34-P100 S34-P170, S36-P130 S36-P150, S38-P010 S3A-P010, S47RH170 S47RH200, S47RH220 S47RH260, S44RD150 S47RD120, S47RD150		

			S44RS190, S47RS190 S44CH150, S44CH210 S47CH260, S44CD120 S44CD160, S47CD160 S47CD190, S47CD240 S44CD190, S44-P100 S44-P170, S46-P150 S48-P010, S4A-P010 S57RH170, S54RD100 S54RD120, S54CH150 S54CH210, S57CH260 S54MD110, S54CD120 S54CD160, S54CD190 S57CD120, S57CD160 S57CD190, S54-P170 S64RD120, S64CH210 S64MD070, S64MD110 S64CD090, S64CD120 S64CD160, S74MD070 Class C Shelf Life : 05 years		
187.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. TOP CORPORATION 19-10 Senju Nakai-Cho, Adachi-ku, Tokyo 120-0035, Japan. **Manufacturing site:** MEDITOP CORPORATION (MALAYSIA) SDN. Plant-2 No.3, Persiaran Usahawan Taman IKS Sekyen 9, 43650 Bandar Baru Bangi, Selangor	**TOP Spinal Needle** **Sizes**: 18G, 19G,20G, 21G, 22G, 23G, 25G, 27G Class D Shelf Life : 05 years Rs.50,000/-	Used for sampling the cerebrospinal fluids & spinal anesthesia.	**Approved.**

		Darul Ehsan, Malaysia. FSC Japan Issue Date: 06-09-2018			
188.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. TOP CORPORATION 19-10 Senju Nakai-Cho, Adachi-ku, Tokyo 120-0035, Japan. **Manufacturing site:** No.3, Persiaran Usahawan Taman IKS Sekyen 9, 43650 Bandar Baru Bangi Selangor Darul Ehsan Malaysia. FSC Japan Issue Date: 06-09-2018	**TOP Suction Catheter** **Sizes**: 6FR, 8FR, 10FR, 12FR, 14FR, 16FR, 18FR Class B Shelf Life : 05 years Rs.25,000/-	The device is intended to be inserted into oral or nasal cavities and used for suction of oral, pharynx and tracheal cavities secretion.	**Approved.**
189.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. TOP CORPORATION 19-10 Senju Nakai-Cho, Adachi-ku, Tokyo 120-0035, Japan. **Manufacturing site:** MEDITOP CORPORATION (MALAYSIA) SDN. Plant-1 Lot 1, Jalan P/1B Kawasan Perindustrian Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan	**TOP Winged Infusion Set** **Sizes**: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 27G Class B Shelf Life : 05 years Rs.25,000/-	Scalp vein infusion set with wings	**Approved.**

		Malaysia. FSC Japan Issue Date: 06-09-2018			
190.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** **M/s. Keisei Medical Industrial Co., Ltd.,** 19-6,Hongo 3-chome, Bunkyo-ku, Tokyo, Japan. **Manufacturing Site:** **M/s. Keisei Medical Industrial Co., Ltd.,** 96 yoshida-Konosu, Tsubame-shi, Nigata-ken, Japan. FSC Japan Issued on 19.03.2019	**Skin Stapler** (Sterile Surgical Stapler) Class B Shelf Life : 05 years Code: AZHK-35W Rs.25,000/-	Used to close skin in various surgical procedures like plastic surgery, gynecology, and orthopedics surgery.	**Approved.**
191.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. USM Healthcare Factory JSC, Lot I - 4b -1.3, Street N3, Saigon Hi-tech Park, Long thanh My Ward, District 9, Ho Chi Minh City, Vietnam. FSC Vietnam Issued on 25.03.2019	**Favocath IV Catheter** (I.V catheter with injection valve) Codes/Sizes: 14G, 16G, 17G Class B Shelf Life : 05 years Rs.25,000/-	IV catheter with injection valve	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve

					the manufacturing plant.
192.	M/s. Healthline Pharmaceutical Pvt Ltd.Office No.402, Al-Hafeez Heights, Gulberg-3, Lahore. ELI-00060 **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer** M/s. Novatech SA, Z.I Athelia III, voie Antiope, 13705 La Ciotat, France. FSC France Issued on 09.10.2017	**Steritalc F4 4g vial** (Sterile Talcum Powder) Class D Shelf Life: Not mentioned Rs.50,000/-	Sterile Talcum Powder used in pleurodesis (a procedure to prevent recurrence of pneumothorax or recurrent pleural effusion)	**Approved** subject to provision of stability studies.
193.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi. ELI-00020 **Evaluator:** Hira Bhutto	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**Solus Laryngeal Mask Airways** **8001000**-Solus, neonate, laryngeal mask airway, size 1 (<5kg) **8002000**-Solus, small paediatric, laryngeal mask airway, size 2 (10-20kg) **8003000**-Solus, small adult, laryngeal mask airway, size 3 (30-50kg) **8004000**-Solus, medium adult, laryngeal mask airway, size 4 (50-70kg) **8005000**-Solus, large adult, laryngeal mask airway, size 5 (70+kg) **8015000**-Solus, infant, laryngeal mask airway, size 1.5 (5-10kg) **8025000**-Solus, large paediatric, laryngeal	Solus LMA use to secure and maintain a patient Airway and to provide a conduit for the delivery of respiratory gases to the patient.	**Approved.**

			mask airway, size 2.5 (20-30kg) Class B Shelf Life : 05 years Rs.25,000/-		
194.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingham, Berkshire, United Kingdom. **Manufacturing Site** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**EcoMask Anaesthetic Face Mask** **7090000**-EcoMask, neonate, anaesthetic face masks with light blue cushion, 15M, size 0 **7091000**- EcoMask, infant, anaesthetic face masks with grey cushion, 15M, size 1 **7092000**- EcoMask, paediatric, anaesthetic face masks with white cushion and hook ring, 22F, size 2 **7093000**- EcoMask, small adult, anaesthetic face masks with yellow cushion and hook ring, 22F, size 3 **7094000**- EcoMask, medium adult, anaesthetic face masks with green cushion and hook ring, 22F, size 4 **7095000**- EcoMask, large adult, anaesthetic face mask with orange cushion and hook ring, 22F, size 5	Anaesthetic Face Mask	**Approved.**

			Class B Shelf Life : 05 years Rs.25,000/-		
195.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**Scented Anaesthetic Face Masks** (Anaesthetic Face Mask) **Product Code:** 1120000 1121000 1122000 1123000 1124000 1125000 Class B Shelf Life : 03 years Rs.25,000/-	To deliver anaesthetic gas and oxygen to patient.	**Approved** subject to provision of ISO 13485.
196.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 01.03.2016	**Laryngoscope Blades** **7040000**- Laryngoscope blades, size 0 **7041000**- Laryngoscope blades, size 1 **7042000**- Laryngoscope blades, size 2 **7043000**- Laryngoscope blades, size 3 **7044000**- Laryngoscope blades, size 4 Class B Shelf Life : 05 years	Laryngoscope blades use to lift tongue of a patient and facilitate intubation.	**Approved** subject to provision of ISO 13485 and Stability Data.
197.	M/s. Fresenius Medical Care Pakistan Pvt. Ltd., TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore	**Legal manufacturer** Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg	**BCM** (Body Composition Monitor) Class B	The BCM – Body Composition Monitor assists the physician in assessing the	**Approved** subject to clarification regarding requirement of shelf life

	54660 ELI-00315 **Evaluator:** Ms. Hira Bhutto	Germany. **Manufacturing Site Name:** M/s. Fresenius Medical Care Deutschland GmbH., Hafenstraße 9, 97424 Schweinfurt, Germany. FSC Germany Issued on 05, April, 2016	Shelf Life : The Technical Safety Checks (TSC) must be carried out every 2 years (24 months). Rs.25,000/-	hydration status by a bioimpedance spectroscopy measurement of the body composition from which the level of over hydration can be derived.	studies.
198.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site Name:** M/s. Nipro (Thailand) Corporation Ltd., 10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110, Thailand. FSC Germany Issued on 11 November, 2016	**Fistula Needle (Fixed Wing)** 15G A (5082761) 15G V (5082891) 16G A (5082771) 16G V (5082901) 17G A (5082781) 17G V (5082911) Class B Shelf Life : 05 years Rs.25,000/-	Fistula needles are designed for central venous access in haemodialysis, haemofiltration , plasmapheresis and hemoperfusion.	**Approved**
199.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care Deutschland	**DIASAFE Plus** **(Dialysis Fluid Filter)** 008201 DIASAFE® Plus Class B Shelf Life : 03 years Rs.25,000/-	Fluid filters are applied in the preparation of dialysis fluid at the end of the water treatment chain.As the fibers have a good endotoxin retention capability these filters help to ensure high	**Approved**

		GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. FSC Germany Issued on 22 May, 2017		microbiological quality of the dialysis fluid.	
200.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. RUHL AG & Co. Chemische Fabrik KG Hugenottenstrabe 105, 61381 Friedriechsdorf, Germany. FSC Germany Issued on 31st May, 2016	**PURISTERIL 340** (Cold Disinfectant for Haemodilaysis Machines) 085621 — Puristeril 340 5kg Class B Shelf Life : 18 months Rs.25,000/-	Puristeril 340 is intended for the cold disinfection of haemodialysis machine. It is used for cleaning, decalcification and disinfection of haemodialysis system.	**Approved** subject to submission of Original Free Sale Certificate
201.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Vital d Healthcare Sdn. Bhd., Lot 3, Jalan Sultan mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia. FSC Malaysia Issued on 6th February, 2018	**Vital** (Tubing Set for Hemolialysis) Tubing Sets for Hemodialysis — BLU001E -do- — BLU002E -do- — BLU003E -do- — BLU004E -do- — BLU005E -do- — BLU006	It consists of a collection of tubing required to transport blood or other fluid from a patient's vascular access device to the appropriate dialyzer unit for processing.	**Approved** subject to inspection by the panel of inspectors. The board also authorized secretary MDB to issue registration certificate in case of recommendation by

			<table><tr><td></td><td>E</td></tr><tr><td>-do-</td><td>BLU007E</td></tr><tr><td>-do-</td><td>BLU008E</td></tr><tr><td>-do-</td><td>BLU009E</td></tr><tr><td>-do-</td><td>BLU0010E</td></tr><tr><td>-do-</td><td>BLU0011E</td></tr><tr><td>-do-</td><td>BLU0012E</td></tr><tr><td>-do-</td><td>BLU0013E</td></tr></table> Class B Shelf Life : 03 years Rs.25,000/-		panel of inspectors
202.	-do- **<u>Evaluator:</u>** Hira Bhutto	**Legal Manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Sites:** Dr. Schumacher GmbH, Am roggenfeld 3, 34323 Malsfeld, Germany. FSC Germany Issued on 31st May, 2016	**Clearsurf** (Surface Disinfectant for Dialysis Machines) 5085731 Class B Shelf Life : 03 years Rs.25,000/-	ClearSurf is a disinfectant for the use of disinfection and cleaning of medical devices especially dialysis machine.	**Approved**
203.	-do- **<u>Evaluator:</u>** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany.	**CITROSTERIL** (Heat Disinfectant for Haemodialysis Machines with Recirculation) F00005157 AP0005157 AP0005158	Citrosteril is intended for heat disinfection of haemodialysis machines.	**Approved**

		Manufacturing Site: M/s. RUHL AG & Co. Chemische Fabrik KG Hugenottenstrabe 105, 61381 Friedriechsdorf, Germany. FSC Germany Issued on 31st May, 2016	Class B Shelf Life : 02 years Rs.25,000/-		
204.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical care (Jiangsu) Co.Ltd., Guli Industrial Park, Guli Zhen, Changshu City, Jiangsu Province, China, 215533 FSC China Issued on June 22, 2017	**AV-Set-DT-E** **AV-Set-E** (Hemodialysis Bloodlines) Class B Shelf Life : 03 years Rs.25,000/-	Bloodlines are intended for single use only for extracorporeal blood purification.	**Approved** subject to inspection by the panel of inspectors. The board also authorized secretary MDB to issue registration certificate in case of recommend ation by panel of inspectors
205.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St.	**Ultraflux®** **Capillary Hemofilter** (Dialysers / Filters) Ultraflux AV 400 S — 5007341 Ultraflux AV 600 S — 5007361 Ultraflux AV 1000 S — 5008981 Class C Shelf Life : 3 years Rs.50,000/-	The Ultraflux-filters contain a Fresenius polysulfone membrane specially developed for continuous renal replacement therapy	**Approved** subject to provision of ISO 13485

		Wendel, Germany. FSC Germany Issued on 6th May, 2016			
206.	-do- **<u>Evaluator:</u>** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Sites:** 1. Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany 2. Fresenius Medical Care-SMAD Z.I. de la Pontchonniere Route De la Chanade/Savigny 69591 L ' Arbresle Cedex France 3. Fresenius Medical Care (Jiangsu) Co., Ltd. Guli Industrial Park, Guli Zhen Changshu City, Jiangsu Province china FSC Germany Issued on 6th May, 2016	**FX-Class Low-flux Dialysers)** (Dialysers / Filters) FX 5 — 5004831 FX 8 — 5004731 FX 10 — 5004741 Class C Shelf Life : 3 years Rs.50,000/-	Dialysers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis) . This may be a transient acute therapy until restoration of renal function or a permanent (chronic) use.	**Approved** subject to attested FSC and ISO 13485
207.	-do-	**Legal manufacturer**	**(FX Classix Dialyzers** (Dialysers / Filters)	Dialysers are applied for	**Approved** subject to

	Evaluator: Hira Bhutto	M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. FSC Germany Issued on 6th May, 2016	FX 60 Classix F00002386 FX 80 Classix F00002387 FX 100 Classix F00002388 Class C Shelf Life : 3 years Rs.50,000/-	single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis) . This may be a transient acute therapy until restoration of renal function or a permanent (chronic) use.	Original Embassy Attested Free Sale Certificate and ISO 13485
208.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. FSC Germany Issued on 5th July, 2016	Tenckhoff-catheter (Peritoneal Dialysis Catheters) Tenckhoff-catheter 215 519611 Tenckhoff-catheter 180 5019901 Class C Shelf Life : 5 years Rs.50,000/-	Fresenius Medical Care (FME) Catheters for Peritoneal Dialysis are applied for single use in peritoneal dialysis (CAPD or APD).	**Approved** subject to Original embassy attested FSC Required and ISO 13485
209.	-do- **Evaluator:** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care Technologies (M) SDN BHD, 8 & 10, Persiaran Klebrang 1, Taman Perusahaan IGB,	**MX Eco 2** **MX Eco 3** **MX Eco 4** **MX Eco 6** (Reverse Osmosis Water Purification System) MX Eco MY700023	The MX Eco reverse osmosis system is intended for the economical and environmentally compatible production of	**Approved** subject to provision of Stability Data and inspection of foreign manufacturer abroad

		31200 IPOH, Perak, Malaysia. FSC Malaysia Valid till 26.06.2023	2		permeate used for dialysis.	by the panel of inspectors. the board also authorized the secretary MDB to issue registration certificate if recommended by panel of inspectors
			MX Eco 3	MY700027		
			MX Eco 4	MY700024		
			MX Eco 6	MY700025		
			Class C Shelf Life : 05 years Rs.50,000/-			
210.	-do- **<u>Evaluator:</u>** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. Fresenius Medical Care Deutschland GmbH., Hafenstraße 9, 97424 Schweinfurt, Germany. FSC Germany Issued on 5th April, 2016	**4008 S** (Haemodialysis device)		The device is used for the extracorporeal blood treatment of patients suffering from renal insufficiency.	**Approved** subject to provision of Aging Data
			4008 S	M204001		
			Class C Shelf Life : 10 years Rs.50,000/-			
211.	-do- **<u>Evaluator:</u>** Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. Vivonic	**AquaUNO 220** (Water Treatment Equipment)		The AquaUNO is a single-station reverse osmosis system exclusively intended for the economical and environmentally compatible production of dialysis	**Approved** subject to provision of Stability Data
			AquaUNO 220	6297531		
			Class C Shelf Life : 05 years Rs.50,000/-			

		GmbH, Kurfurst-Eppstein-Ring 4, 63877 Sailauf, Germany. FSC Germany Issued on 10th March, 2016		permeate for one dialysis device. A booster pump, a membrane module and appropriate monitoring equipment (conductivity cell) are used to produce dialysis permeate from drinking water.	
212.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. RUHL AG & Co. Chemische Fabrik KG Hugenottenstrabe 105, 61381 Friedriechsdorf, Germany. FSC Germany Issued on 31st May, 2016	**PURISTERIL 340** (Cold Disinfectant for Haemodilaysis Machines) 5085621 Puristeril 340 5kg Class B Shelf Life : 18 months **Rs. 25000/-**	Puristeril 340 is intended for the cold disinfection of haemodialysis machine. It is used for cleaning, decalcification and disinfection of haemodialysis system.	**Duplication and already approved at serial no. 200.**
213.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing**	**FX-Class Low-flux Dialysers)** (Dialysers / Filters) FX 5 5004831 FX 8 5004731 FX 10 5004741 Class C	Dialysers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis) . This may be a	**Duplication and already approved at serial no. 206.**

		Sites: Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany Fresenius Medical Care- SMAD Z.I. de la Pontchonniere Route De la Chanade/Savigny 69591 L ' Arbresle Cedex France Fresenius Medical Care (Jiangsu) Co., Ltd. Guli Industrial Park, Guli Zhen Changshu City, Jiangsu Province china FSC Germany Issued on 6th May, 2016	Shelf Life : 3 years	transient acute therapy until restoration of renal function or a permanent (chronic) use.	
214.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. FSC Germany Issued on 6th May, 2016	**(FX Classix Dialyzers** (Dialysers / Filters) FX 60 Classix — F00002386 FX 80 Classix — F00002387 FX 100 Classix — F00002388 Class C Shelf Life : 3 years	Dialysers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis) . This may be a transient acute therapy until restoration of renal function or a permanent (chronic) use.	**Duplication and already approved at serial no. 207**
215.	-do-	**Legal**	Tenckhoff-catheter	Fresenius	**Duplication**

	Evaluator: Ms. Hira Bhutto	**manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. FSC Germany Issued on 5th July, 2016	(Peritoneal Dialysis Catheters) Tenckhoff-catheter 215 — 519611 Tenckhoff-catheter 180 — 501990 1 Class C Shelf Life : 5 years	Medical Care (FME) Catheters for Peritoneal Dialysis are applied for single use in peritoneal dialysis (CAPD or APD).	**and already approved at serial no. 208**
216.	M/s. Renacon Pharma Ltd. House No,3 Street No 1, 18 Km, Ferozepur Road, Mujahid Colony Lahore. (ELI-00177) **Evaluator:** Hira Bhutto	**Manufacturer** M/s. Jiangxi Sanxin Medtee Co., Ltd, No.999 Fushan Road, Xiaolan Economic Development Zone, Nanchang, Jiangxi, 330200, P.R. China. FSC China Valid till November 18th, 2019.	**Renaf** (Hollow Fibre Hemodialysis Dialyzer) (Codes As per FSC Class C Shelf Life : 02 years Rs.50,000/-	Hollow Fibre Hemodialysis Dialyzer (Disposable)	**Approved** subject to provision fresh FSC and foreign inspection abroad by the panel of inspector. the board also authorized the secretary MDB to issue registration certificate if recommend ed by panel of inspectors
217.	M/s Fresenius Kabi Pakistan Pvt Ltd.Tanwir Ahmad Medical Center (TAMC), First Floor MM Alam Road, 27-	**Legal Manufacturer** M/s. Fresenius Kabi AG 61346 Bad Homburg,	**AmiCORE Apheresis Kit Single Needle** (Disposable Apheresis Kit) P6R8880 – AmiCORE Apheresis Kit.	Disposable Apheresis Kit use with AmiCORE Apheresis system which is	**Approved** subject to provision of Aging data

	C/3, Gulberg 111, Lahore. ELI-00266 **Evaluator:** Hira Bhutto	Germany. **Manufacturing Site:** M/s. Fenwal International, Inc., Carretera Sanchez Km 18. Parque Industrial Itabo, Zona Franca Ind. de S.c., Haina, Dominican Republic. FSC Germany Issued on 2nd May, 2018	Class C Shelf Life : 02 years Rs.50,000/-	an automated blood cell separator indicated for collection of blood components.	
218.	-do- **Evaluator:** Hira Bhutto	**Legal Manufacturer** M/s. Fresenius Kabi AG 61346 Bad Homburg, Germany. **Manufacturing Site:** M/s. Fenwal International, Inc., Carretera Sanchez Km 18. Parque Industrial Itabo, Zona Franca Ind. de S.c., Haina, Dominican Republic. FSC Germany Issued on 2nd May, 2018	**AmiCORE Apheresis Kit Single Needle with two platelet Containers** (Disposable Apheresis Kit) P6R8882 – AmiCORE Apheresis Kit. Class C Shelf Life : 02 years Rs.50,000/-	Disposable Apheresis Kit use with AmiCORE Apheresis system which is an automated blood cell separator indicated for collection of blood components.	**Approved** subject to provision of Aging data
219.	-do- **Evaluator:** Hira Bhutto	**Legal Manufacturer** M/s. Fresenius Kabi AG 61346 Bad Homburg, Germany.	**AmiCORE Apheresis System** (Automated Blood Cell Separator) 6R8800 – AmiCORE Apheresis System.	AmiCORE Apheresis system is an automated blood cell separator indicated for collection of	**Approved** subject to supporting documents for service life of device

		Physical Manufacturer: M/s. Plexus Manufacturing Sdn. Bhd. Plot 87, Lebuhraya Kampung Jawal 1900, Bayan Lepas, Penang, Malaysia. FSC Germany Issued on 2nd May, 2018	Class C Shelf Life : 30 years Rs.50,000/-	blood components.	
220.	M/s. Iqbal & Company Alfalah Manzil Opp: National Police Foundation, Street No.26, Sector E-11/4, Islamabad. ELI-00117 **Evaluator:** Hira Bhutto	**Manufacturer** M/s. Medical Components Inc, DBA-Medcomp 1499 DELP DRIVE HARLEYSVILLE, PA USA 19438 **Manufacturing Site** M/S. MARTECH MEDICAL PRODDUCTS, Calle Mercurio N 46 Parque Industrial Mexicali 1 Mexicali, Baja California MEXICO 21210 Fsc USFDA Valid till January 22, 2021	**Titan HD Catheter Sets** (Hemodialysis Catheter) THD155024SE THD155028SE THD155032SE THD155036SE THD155040SE THD155055SE THD155224E THD155228E THD155232E THD155236E THD155224SE HD 155228SE THD155232SE THD155236SE. THD155424SE. THD155428SE. THD155432SE. THD155436SE. THD155440SE. THD155624E. THD155628E THD 155632E. THD155636E. THD155624SE. THD155628SE. THD155632SE. THD 155636SE. Class D Shelf Life : 05 years Rs.50,000/-	The Medcomp® Titan HDTM is a long term (greater than 30 days) hemodialysis catheter indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis	**Approved**

221.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Medical Components Inc, DBA-Medcomp 1499 Delp Drive Harleysville, PA USA 19438 **Manufacturing Sites:** 1. M/s. MARTECH MEDICAL PRODUCTS, Calle Mercurio N 46 Parque Industrial Mexicali, 1 Mexicali, Baja California MEXICO 21210 2. M/s. Medical Components Inc, DBA-Medcomp 1499 Delp Drive Harleysville, PA USA 19438 FSC US FDA Valid till January 22, 2021	**Hemo-Flow® Catheter Set (**Polyurethane) Sizes and codes as per Free Sale Certificate No. 4219-1-2019 Class D Shelf Life: 05 years Fee submitted: Rs 50,000/-	Indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.	**Approved**
222.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Medical Components Inc, DBA-Medcomp 1499 Delp Drive Harleysville, PA USA 19438 **Manufacturing Sites:** 1. M/s. MARTECH MEDICAL PRODUCTS, Calle Mercurio N 46 Parque Industrial Mexicali, 1 Mexicali, Baja	**Hemo-Cath® (Long Term) Catheter Set (silicone)** Sizes and codes as per Free Sale Certificate No. 4219-1-2019 Class D Shelf Life : 05 years Fee submitted: Rs 50,000/-	Indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.	**Approved**

		California MEXICO 21210 2. M/s. Medical Components Inc, DBA-Medcomp 1499 Delp Drive Harleysville, PA USA 19438 FSC US FDA Valid till January 22, 2021			
223.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Medical Components Inc, DBA-Medcomp, 1499 Delp Drive Harleysville, PA USA 19438 **Manufacturing Site/Contract Manufacturer:** M/S. MARTECH MEDICAL PRODUCTS, Calle Mercurio No. 46 Parque Industrial Mexicali 1 Mexicali, Baja California MEXICO 21210 FSC US FDA Valid till 14th November, 2019 FSC Germany issuance date: 28-June-2019	TRI-FLOW TRIPLE LUMEN CATHETER SET **XTP3114MTE** 11.5F x 12CM STRAIGHT TRI-FLOW™ CATHETER SET **XTP3116MTE** 11.5F x 15CM STRAIGHT TRI-FLOW™ CATHETER SET **XTP3118MTE** 11.5F x 20CM STRAIGHT TRI-FLOW™ CATHETER SET **XTP3119MTE** 11.5F x 24CM STRAIGHT TRI-FLOW™ CATHETER SET **XTP3116IJSE** 11.5F x 15CM cE TRI-FLOW™ CATHETER SET **XTP3118IJSE** 11.5F x 20CM CE TRI-FLOW™ CATHETER SET	Triple lumen polyurethane catheter indicated for use in attaining short-term vascular access for Hemodialysis and Apheresis.	**Approved**

			Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-		
224.	M/s. Schazoo Spl Consumer Healthcare, 71-B/C2, Gulberg III, Lahore. ELI-00095 **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Apharm S.r.l., Roma 26 – 28041, Arona (NO), Italy. FSC Italy Issued on 30.05.2016	**Hyamira Basic** (Reticulated Hyaluronic Acid: 20mg/ml) Class D Shelf Life : 02 years Fee submitted: Rs. 50,000/-	Colourless gel in a prefilled syringe. A temporary filler for treatment of wrinkles around the lips	**Approved**
225.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Apharm S.r.l., Roma 26 – 28041, Arona (NO), Italy. FSC Italy Issued on 30.05.2016	**Hyamira Forte** (Reticulated Hyaluronic Acid: 25mg/ml) Class D Shelf Life : 02 years Fee submitted: Rs. 50,000/-	Colourless gel in a prefilled syringe. A temporary filler for treatment of deep facial wrinkles	**Approved**
226.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Apharm S.r.l., Roma 26 – 28041, Arona (No), Italy. FSC Italy Issued on 30.05.2016	**Hyamira Soft** (Reticulated Hyaluronic Acid: 15mg/ml) Class D Shelf Life : 02 years Fee submitted: Rs. 50,000/-	Colourless gel in a prefilled syringe. A temporary filler for treatment of periocular wrinkles	**Approved**
227.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Apharm S.r.l., Roma 26 – 28041, Arona (NO), Italy.	**Hyamira** (Cross-linked Hyaluronic Acid Sodium Salt in prefilled syringe) 1.6% - 16mg/1ml and	Used as corrective and filler for papillary dermis defects, soft tissue contours such	**Approved**

		FSC Italy Issued on 30.05.2016	32mg/2ml 2.0% - 20mg/1ml and 40mg/2ml Class D Shelf Life : 03 years Fee submitted: Rs. 50,000/-	as acne and other scars; recovery of tissue tropism	
228.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Apharm S.r.l., Roma 26 – 28041, Arona (No), Italy. **Manufacturing site:** S.I.I.T. S.r.l. Via Canova, 2-4-20090 Trezzano sul Naviglio (MI), Italy. FSC Italy Issued on 20.02.2019	**Esoxx** Hyaluronic acid, Chondroitin Sulphate) 20 stick packs of 10 ml Class D Shelf Life : 03 years	Non-sterile mechanical medical device for the treatment of gastro-esophageal reflux. Sodium Hyaluronate, Sodium Chondroitin Sulphate	**Approved**
229.	M/s. A & E Medical 323-Ata Turk Block, New Garden Town, Lahore. ELI-00023 **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal manufacturer:** M/s. FIAB SpA. Via Paolo Costoli 4, 50039 VICCHIO – Florence – ITALY **Manufacturing sites**: 1. M/s. FIAB SpA.Via Paolo Costoli 4, 50039 VICCHIO – Florence – ITALY 2. Via Bruno Passerini 2, 4, 6 50039 VICCHIO – Florence – ITALY	**SPIKE LC S (Bipolar)** (Electrocatheters for temporary endocardial pacing and electrophysiological studies) Size: 4FR Codes: 52164S,52264S, 52364S SIZE: 5FR Codes: 52165S, 52265S, 52365S SIZE: 6FR Codes: 52166S,52266S,52366S	Temporary Leads with not braided shaft. Intended for temporary use inside of the cardiac cavities for short-term treatment of pathologies requiring stimulation of the heart by means of electrical energy delivered by external	**Approved**

		3. Via Della Resistenza 18, 50039 VICCHIO – Florence – ITALY FSC Italy Issued on 06.04.2018	Class D Shelf Life: 04 years Fee Submitted: Rs 50,000/-	stimulators	
230.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal manufacturer:** M/s SIS Medical AG, Hungerbuelstrasse 12A, 8500 Frauenfeld, Switzerland. FSC Switzerland Valid till 05.02.2022	**Inflation Device** Inflation Device 40 ATM REF# 96346 Inflation Device 55ATM REF# 96463 Class B Shelf Life : 03 years Fee submitted: Rs 25,000/-	Used to inflate PTCA Balloons During Angioplasty Procedures	**Approved** subject to provision of Manufacturing, QC data, Shelf life and EPSP
231.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal manufacturer:** M/s SIS Medical AG, Hungerbuelstrasse 12A, 8500 Frauenfeld, Switzerland. FSC Switzerland Valid till 05.02.2022	**NIC 1.1 hydro (PTCA Balloon Catheter)** 110-006-134 110-010-134 110-015-134 110-020-134 Class D Shelf Life : 02 years Fee submitted: Rs 50,000/-	PTCA balloon catheter	**Approved** subject to provision of Manufacturing, QC data, Shelf life and EPSP
232.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal manufacturer** M/s. SIS Medical Distribution AG, Hungerbuelstrasse 12a/ CH-8500 Frauenfeld, Switzerland. FSC Switzerland Valid till 05.02.2022	**NIC Nano Hydro (PTCA Balloon Catheter)** 085-006-134 085-010-134 085-015-134 Class D Shelf Life : 02 years	PTCA balloon catheter	**Approved** subject to provision of Manufacturing, QC data, Shelf life and EPSP

			Fee submitted: Rs 50,000/-		
233.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal manufacturer** M/s. SIS Medical Distribution AG, Hungerbuelstrasse 12a/ CH-8500 Frauenfeld, Switzerland. FSC Switzerland Valid till 05.02.2022	**BEO NC** (PTCA Non Compliant Balloon Catheter) Class D Shelf Life : 03 years Fee submitted: Rs 50,000/-	PTCA Non Compliant Balloon Catheter	**Approved** subject to provision of Stability studies
234.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. EP Flex Feinwerktechnik GmbH, 72581 Dettingen, Im Schwollbogen 24, Germany. FSC Germany Valid till 17.01.2021	**Angiographic Guide Wire** Class D Product name and sizes mentioned on FSC are in German language Shelf Life : 05 years Fee submitted: Rs 50,000/-	PTCA guidewire	**Approved** subject to provision of EPSP and labels
235.	M/s. SES Associates. 148-Ejaz Park, Model Town Link Road Lahore. ELI-00041 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. AndraTec GmbH, Simmerner Str. 70, D-56075 Koblenz, Germany. FSC Germany Issued on 28.11.2018	AltoSa-XL Gemini Balloon Catheter Sizes and codes as per Free Sale Certificate issued on 28.11.2018 Class D Shelf Life: 02 years Fee submitted: Rs. 50,000/-	Percutaneous Transluminal Angioplasty Balloon Catheter	**Approved** subject to provision of Design examinatio n certificate, EPSP and full QA certificate
236.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. AndraTec GmbH, Simmerner Str. 70, D-56075 Koblenz, Germany.	Lokum Amplatz Guide Wire Sizes and codes as per Free Sale Certificate	Guide Wire	**Approved** subject to provision of Design examinatio

		FSC Germany Issued on 28.11.2018	issued on 28.11.2018 Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-		n certificate, EPSP and full QA certificate
237.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. AndraTec GmbH, Simmerner Str. 70, D-56075 Koblenz, Germany. FSC Germany Issued on 28.11.2018	Exeter Retrieval Snare Preloaded Sizes and codes as per Free Sale Certificate issued on 28.11.2018 Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-	For interventional retrieval of displaced foreign bodies	**Approved** subject to provision of Design examinatio n certificate, EPSP and full QA certificate
238.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. AndraTec GmbH, Simmerner Str. 70, D-56075 Koblenz, Germany. FSC Germany Issued on 28.11.2018	AltoSa-XL PTA Balloon Catheter Sizes and codes as per Free Sale Certificate issued on 28.11.2018 Class D Shelf Life: 02 years Fee submitted: Rs. 50,000/-	Percutaneous Transluminal Angioplasty Balloon Catheter	**Approved** subject to provision of Design examinatio n certificate, EPSP and full QA certificate
239.	M/s. Cardiac Care 848-C Shadman-I, Lahore. ELI-00070 **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Insightra Medical Inc., 141 Hatcher Lane, Clarksville, Tennessee, 37043, USA. **Contract Manufacturer:** M/s. Life Science Outsourcing Inc., 830 Challenger Street, Brea, CA	**Ultra IABP Catheter Kit (7Fr)** IMU7F-20 IMU7F-25 IMU7F-30 IMU7F-35 IMU7F-40 Class D Shelf Life : 05 years Fee submitted: Rs. 50,000/-	A sterile, single-patient use disposable device. The Intra Aortic Baloon (IAB) Pump Catheter is used for emergency mechanical left heart assist in conjunction with an IAB Catheter pumping	**Approved** subject to provision of Design examinatio n certificate, EPSP and full QA certificate

		USA 92821 FSC US FDA Valid till February 20, 2020.		circuit.	
240.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Vygon GmbH & Co. KG, Prager Ring 100, 52070 Aachen, Germany. FSC Germany Issued on 26-07-2016 FSC Germany Issued on 29-03-2019.	**Multicath 3** (3- lumen, Central Venous Catheter) Sizes and codes per free sale certificates of Germany issued on 26-07-2016 and 29-03-2019 Class D Shelf Life: 05 years Fee submitted: Rs. 50,000/-	It is a radiopaque polyurethane three lumen central venous catheter intended for use in patients requiring short to mid term intravenous therapy (less than 29 days) for injecting different solutions or medications simultaneously	**Approved** subject to provision of Design examination certificate, EPSP and full QA certificate
241.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer** M/s. Vygon gmbH & Co. KG, Prager Ring 100, 52070 Aachen, Germany. FSC Germany Issued on 26-7-2016. FSC Germany Issued on 29-03-2019	**Multicath 4** (Central Venous Catheter) Sizes and codes per free sale certificates of Germany issued on 26-07-2016 and 29-03-2019 Class D Shelf Life : 05 years Fee submitted: Rs 50,000/-	It is a radiopaque polyurethane four lumen central venous catheter intended for use in patients requiring short to mid term intravenous therapy (less than 29 days) for injecting different solutions or medications simultaneously	**Approved** subject to provision of Design examination certificate, EPSP and full QA certificate
242.	-do- **Evaluator:** Mr. Shahid Muhammad Iqbal	**Legal Manufacturer** M/s. Pacific Hospital Supply Co, Ltd., 4F, No.160, Daye Road, Beitou District 11268	**Thoracic Catheter** (Thoracic Drainage Catheter) I12108 Straight thoracic catheter 8FR I12110 Straight thoracic catheter	Thoracic Drainage Catheter	**Approved**

		Taipei, Taiwan. **Manufacturing Site** M/s. Pacific Hospital Supply Co, Ltd., 4F, No.160, Daye Road, Beitou District 11268 Taipei, Taiwan. **Authorized Representative:** M/s. MDI Europa GmbH, Langenhagener Strabe 71, 30855, Langenhangen, Germany. FSC Germany Issued on 05.06.2018.	10FR I12112 Straight thoracic catheter 12FR I12114 Straight thoracic catheter 14FR I12116 Straight thoracic catheter 16FR I12120 Straight thoracic catheter 20FR I12122 Straight thoracic catheter 22FR I12124 Straight thoracic catheter 24FR I12128 Straight thoracic catheter 28FR I12132 Straight thoracic catheter 32FR I12134 Straight thoracic catheter 34FR I12136 Straight thoracic catheter 36FR Class B Shelf Life : 05 years		
243.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer** M/s CryoLife Europa Ltd. Bramley house, the Guildway, Old Portsmouth Road, Guildford Surrey GU3 1LR U.K. **Manufacturing Site** M/s. On-X Life Technologies, Inc. 1300 East,	**On-X Prosthetic Heart Valves (Mitral)** Name of Product(s) ONXM-25, ONXM-27/29, ONX-M-31/33 ONXMC-25/33, Class D Shelf Life : 06 years Rs.50,000/-	The On-X Prosthetic heart valve is a bileaflet mechanical heart valve, which consists of orifice housing and two leaflets. The valves are supplied sterile, and mounted on the associated valve holder,	**Approved** subject to provision of Full Quality Assurance and design examinatio n certificate

		Anderson, Lane Building B, Austin, Texas 78752, USA. FSC USFDA Valid till March 7, 2020.		which corresponds to the size of the valves.	
244.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer** M/s. Atrium Medical Corporation, 40 Continental Blvd, Merrimack, NH 03054, USA. **Authorized Distributor** Getinge Group Middle East FZ-LLC, office G 05, Laboatory complex, P.O. Box 214742, Dubai science park, UAE FSC USFDA Valid till December 06, 2019.	Flixene Grafts, **Standard Wall (SW)** 25052, Flixene, 6X50, 1GDS, STR 25053, Flixene, 6X10, NGDS, STR 25054, Flixene, 7X10, NGDS, STR 25056, Flixene, 7X50, 1GDS, STR 25057, Flixene, 8X50, NGDS, STR 25142, Flixene, 6X30, 1GDS, STR Class C Shelf Life : 05 years	The Flixene Vascular graft is a 2 layer graft employing a single layer ePTFE graft, which is then wrapped with an additional layer of ePTFE for increased support.	**Approved**
245.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer** M/s. Atrium Medical Corporation, 40 Continental Blvd, Merrimack, NH 03054, USA. **Authorized Distributor** Getinge Group Middle East FZ-LLC, office G 05, Laboatory complex, P.O. Box 214742, Dubai science park, UAE	**Advanta Vascular Grafts** (mmXcm) **Advanta VXT Standard wall** 21000, 6X10, SW, ADVANTA VXT 21001, 7X10, SW, ADVANTA VXT 21002, 8X10, SW, ADVANTA VXT 21007, 6X30, SW, ADVANTA VXT 21015, 4X50, SW, ADVANTA VXT 21017, 6X50, SW, ADVANTA VXT 21020, 10X50, SW,	The Advanta VXT graft is a 2 layer graft employing a single layer ePTFE graft, which is then wrapped with an additional layer of ePTFE for increased support.	Approved

		FSC USFDA Valid till December 06, 2019.	ADVANTA VXT 21024, 4X70, SW, ADVANTA VXT 21029, 10X70, SW, ADVANTA VXT 21276, 4X10, SW, ADVANTA VXT 21277, 5X10, SW, ADVANTA VXT 22011, 5X40, SW, ADVANTA VXT, GDS 22012, 6X40, SW, ADVANTA VXT, GDS 22014, 8X40, SW, ADVANTA VXT, GDS 22016, 5X50, SW, ADVANTA VXT, GDS 22017, 6X50, SW, ADVANTA VXT, GDS 22018, 7X50, SW, ADVANTA VXT, GDS 22019, 8X50, SW, ADVANTA VXT, GDS 22025, 5X70, SW, ADVANTA VXT, GDS 22026, 6X70, SW, ADVANTA VXT, GDS 22027, 7X70, SW, ADVANTA VXT, GDS 22028, 8X70, SW, ADVANTA VXT, GDS Class C Shelf Life : 05 years		
246.	M/s UDL Distribution (Pvt) Limited, 1-D-13, Sector 30, Korangi Industrial	**Manufacturer:** M/s Vascular Solutions LLC., 6464 Sycamore Court, North	SuperCross Micro Catheter Class D	Single lumen catheter intended to be used in conjunction	**Approved** subject to provision of Design examinatio

	Area, Karachi (ELI-00073) **Evaluator:** Ms. Unum Zia Shamsi	Maple Grove, MN 55369, USA (FSC US FDA Valid Till 14-06-2020)	Codes: 5300, 5301, 5302, 5303, 5304, 5305, 5306, 5307, 5308, 5309 Shelf Life: 26 Months Fee submitted: Rs. 50,000/-	with steerable guidewires to access discrete regions of the coronary and or peripheral vasculature	n certificatean d ISO 13485
247.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Vascular Solutions LLC., 6464 Sycamore Court, North Maple Grove, MN 55369, USA (FSC US FDA Valid Till 14-06-2020)	TrapLiner Catheter Class D Codes: 5566, 5567, 5568 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Intended for use in conjunction with guide catheters to access discrete regions of the coronary and or peripheral vasculature etc	**Approved** subject to provision of Design examinatio n certificate and ISO 13485
248.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Vascular Solutions LLC., 6464 Sycamore Court, North Maple Grove, MN 55369, USA (FSC US FDA Valid Till 14-06-2020)	Turnpike Catheter Class D Codes: 5642, 5643 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Intended to be used to access discrete regions of the coronary and or peripheral vasculature etc	**Approved** subject to provision of ISO13485
249.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Vascular Solutions LLC., 6464 Sycamore Court, North Maple Grove, MN 55369, USA (FSC US FDA Valid Till 14-06-2020)	Twin-Pass Torque Dual Access Catheter Class D Code: 5201 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Intended to be used to access discrete regions of the coronary and or peripheral vasculature etc	**Approved** subject to provision of ISO13485
250.	-do- **Evaluator:** Ms. Unum Zia	**Manufacturer:** M/s Vascular Solutions LLC., 6464 Sycamore	GuideLiner V3 Catheter Class D	Intended to be used to access discrete regions of the coronary	**Approved** subject to provision of ISO13485

	Shamsi	Court, North Maple Grove, MN 55369, USA (FSC US FDA Valid Till 14-06-2020)	Codes: 5569, 5570, 5571, 5572, 5573 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	and or peripheral vasculature etc	
251.	M/s Allmed Solutions, A-21/3 KDA Scheme 1 (Ext) Opposite National Stadium Road, Karachi (ELI-00029) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Bactiguard AB, Alfred Nobels Alle 150, 146 48 Tullinge, Sweden (FSC Sweden Valid Till 01-10-2023)	BIP Endotracheal Tube Evac (BIP ETT Evac) Class B Shelf Life: 5 Years 31VC06010 BIP Endotracheal Tube EVAC ID 6,0 31VC06510 BIP Endotracheal Tube EVAC ID 6,5 31VC07010 BIP Endotracheal Tube EVAC ID 7,0 31VC07510 BIP Endotracheal Tube EVAC ID 7,5 31VC08010 BIP Endotracheal Tube EVAC ID 8,0 31VC08510 BIP Endotracheal Tube EVAC ID 8,5 31VC09010 BIP Endotracheal Tube EVAC ID 9,0 Fee submitted: Rs. 50,000/-	A tube designed for insertion through the mouth into the trachea for airway management.	**Approved**
252.	M/s Oriental Sales Corporation, 327, DMCHS, Clock-3, Haider Ali Road, Karachi. (ELI-00025) **Evaluator:**	**Manufacturer:** Cochlear Ltd, 1 University Avenue, MACQUARIE UNIVERSITY, NSW, 2109 AUSTRALIA	Cochlear™ Nucleus® CI24RE (CA) cochlear implant with Contour Advance® electrode Code : Z401299 Class C	Intended for long term implantation in the mastoid region of either side or both sides of the head to restore a level of	**Approved** in Class D

	Ms. Unum Zia Shamsi	(FSC Issuance 11-10-2018)	Shelf Life: 2 years Fee submitted: Rs. 50,000/-	auditory sensation via electrical stimulation of the cochlea. Active implantable medical device	
253.	M/s. Ever-X, I-E Samanberg, Johar Town Lahore. ELI-00139 **Evaluator:** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, IkitelliKucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	**A2F6002B Flow Art ® Double Lumen Filter Set 0.2** (Micron Baby) Class B Shelf Life : 05 years Rs. 25,000/-	A2F6002B Flow Art ® Double Lumen Filter Set 0.2 Micron Baby Filter is an extension line with filter which houses a needle-free system. that has fully transparent clear housing with an integrated flat silicone seal to allow clear view into fluid pathway that protects the patient and nursing staff from exposures to sharps during liquid transfer. The product is used to filter air, particles, bactaria, fungus and fungus spores during IV infusions administered to neonates.	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485
254.	-do- **Evaluator:** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San.	**ATU3010 Flow Art Needle-Free Connector With Three-Way Stopcock**	ATU3010 Flow Art Needle-Free Valve with	**Approved** subject to provision of Original

		Sit. M Blok No. 7/A, IkitelliKucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	(Split-septum needleless valve-connector) Class B Shelf LIfe : 05 years	extension line is a needle free valve system that has fully transparent clear housing with in integrated flat split septum silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures to infectants and sharp injuries.	notarized free sale certificate and ISO 13485
255.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, IkitelliKucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	**AF6012B Flow Art® Needle-free Valve Setwith 1.2 micron Baby Filter** (Intravenous line filter) Class B Shelf LIfe : 05 years	AF6012B Flow Art® Needle-free Valve Setwith 1.2 micron Baby Filter is an extension line with filter which houses a needle-free system. that has fully transparent clear housing with an integrated flat silicone seal to allow clear view into fluid pathway that protects the patient and nursing staff from exposures to sharps during liquid transfer. The product is used to filter air, particles, bactaria,	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485

				fungus and fungus spores during IV infusions administered to neonates.	
256.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, IkitelliKucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	**AF6302B Flow Art® Triport Set with 0.2 Micron Baby Filter** (Intravenous line filter) Class B Shelf LIfe : 05 years	AF6302B Flow Art® Triport Set with 0.2 Micron Baby Filter is an extension line with filter which houses a needle-free system. It protects the patient and nursing staff from exposures to sharp injuries while filtering the infusion fluid.	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485
257.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, Ikitelli Kucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	**AUL1010 Flow Art® Needle-free Valve with extension line** (split-septum needleless valve-connector) Class B Shelf LIfe : 05 years	AUL1010 Flow Art® Needle-free Valve with extension line is a needle free valve system that has fully transparent clear housing with an integrated flat split septum silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures to infectants and sharps injuries.	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485

258.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, Ikitelli Kucukcekmece 34303 ISTANBU, Turkey . FSC Australia Issued on 29 May 2019	**A2010 Flow Art ® Double Lumen Needle-free Valve Port** (split-septum needleless valve-connector) Class B Shelf LIfe : 05 years	A2010 Flow Art ® Double Lumen Needle-free Valve Port Is a needle-free system that has fully transparent clear housing with an integrated flat silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures to infectants and sharps injuries.	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485
259.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, Ikitelli Kucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	**AS5010 Flow Art ® Valve for Bag Access** (Vial transfer spike) Class B Shelf LIfe : 05 years	AS5010 Flow Art ® Valve for Bag Access is an IV bag spike with a needle-free valve that has fully transparent clear housing with an integrated flat silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures.	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485
260.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, Ikitelli Kucukcekmece 34303 ISTANBUL.	**A3010 Flow Art ® Triple Lumen Needle-free Valve Port** (split-septum needleless valve-connector) Class B Shelf LIfe : 05 years	A3010 Flow Art ® Triple Lumen Needle-free Valve Port Is a needle-free system that has fully transparent clear housing	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485

		FSC Australia Issued on 29 May 2019		with an integrated flat silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures to infectants and sharps injuries.	
261.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s. Asset Medikal Tasarim A.S. Marmara San. Sit. M Blok No. 7/A, Ikitelli Kucukcekmece 34303 ISTANBUL. FSC Australia Issued on 29 May 2019	**A1010 Flowart Needle Free Valve Port** (split-septum needleless valve-connector) Class B Shelf LIfe : 05 years	A1010 Flowart Needle Free Valve Port is a needle-free system that has fully transparent clear housing with an integrated flat silicone seal and internal fluid pathway that protects the patient and nursing staff from exposures to infectants and sharps injuries.	**Approved** subject to provision of Original notarized free sale certificate and ISO 13485
262.	M/s. Asto Life Sciences. 44/1.K Block Model Town Lahore. ELI-00103 **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Becton, Dickinson and Company, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP United Kingdom FSC UK issuance date: 31-05-2018	BD Arterial Blood Collection Syringe A-Line™ (1ml, 3ml) Class B Shelf Life: 14 months Fee submitted: Rs. 25,000/-	Sterile, Arterial Blood Collection Syringe without needle. IVD device	**Approved**
263.	M/s. Health Tec, House No. 10-B, Street 24, Valley Road, Westridge 1, Rawalpindi.	**Manufacturer:** M/s. SCW Medicath Ltd., No.4, Baolong 6th Road, Baolong	**SCW Hemostasis Valve Sets** Model SCW-HV-1	Hemostatis valve set is intended to connect/introd uce catheter /	**Approved** subject to provision of Codes

	ELI-000046 **Evaluator:** Ms. Unum Zia Shamsi	Industrial Town, Longgang, District Shenzhen, China FSC Belgium Issued on 01.10.2018 FSC China Valid till 23.01.2020	SCW-HV-2 (Models mentioned in China FSC. Belgium FSC doesnot have codes) Class B Shelf Life : 03 years Fee submitted: Rs. 50,000/-	guide wire to facilitate the fulfillment of surgery.	
264.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. SCW Medicath Ltd., No.4, Baolong 6th Road, Baolong Industrial Town, Longgang, District Shenzhen, China FSC Belgium Issued on 01.10.2018 FSC China Valid till 11.10.2019	**SCW Transradial Introducer Sets** Model RD-0409 RD-0416 RD-0511 RD-0516 RD-0611 RD-0616 (Models mentioned in China FSC. Belgium FSC doesnot have codes) Class B Shelf Life : 03 years Fee submitted: Rs. 50,000/-	The transradial introducer set is designed for the introduction of balloon, diagnostic and guiding catheters or other devices for diagnosis and intervention in radial artery access procedures.	**Approved** subject to provision of Codes
265.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. SCW Medicath Ltd., No.4, Baolong 6th Road, Baolong Industrial Town, Longgang, District Shenzhen, China FSC Belgium Issued on 01.10.2018 FSC China Valid till	**SCW Introducer Sets** Model SCW-IS-0409 SCW-IS-0511 SCW-IS-0523 SCW-IS-0611 SCW-IS-0623 SCW-IS-0711 SCW-IS-0723 SCW-IS-0811 SCW-IS-0823 SCW-IS-0911 SCW-IS-0923 (Models mentioned in China FSC. Belgium	The introducer set is intended for percutaneous introduction of guide wire or catheter into the vascular system through introducer needle. Not for use in coronary or cerebral vasculature	**Approved** subject to provision of Codes

		09.10.2019	FSC does not have codes) Class B Shelf Life: 03 years Fee submitted: Rs. 50,000/-		
266.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. SCW Medicath Ltd., No.4, Baolong 6th Road, Baolong Industrial Town, Longgang, District Shenzhen, China FSC Belgium Issued on 01.10.2018 FSC China Valid till 22.08.2019	**SCW Guide Wire** Model: SCW-GW-0. 014in SCW-GW-0. 018in SCW-GW-0. 021in SCW-GW-0. 030in SCW-GW-0. 032in SCW-GW-0. 035in SCW-GW-0. 038in Class B Shelf Life : 03 years Fee submitted: Rs. 50,000/-	The guide wire is intended for percutaneous entry of peripheral vessels. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. Not for use in coronary or cerebral vasculature	**Approved**
267.	M/s. Optisurg 17- C1, Valencia Town, Lahore. ELI-00305 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer** M/s. Medicontur Medical Engineering Ltd., Herceghalmi Road H-2072 Zsambek, Hungary. FSC Hungary Issued on 31st January, 2018	Medjet B1B2.2 (Single use injector) Micron M7 Class B Shelf Life: 30 months	Single use, sterile, disposable device for the implantaton of a foldable hydrophilic intracocular lens (IOL) into the eye.	**Approved** subject to foreign inspection abroad. The board also authorized the secretary MDB to issue the registration certificate if recommended by panel of inspectors.

268.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Excelsius Medical GmbH, Magirus-Deutz-Str.14, 89077, Ulm, Germany. FSC Germany Issued on 13.11.2018	**Micron M7** (Excimer Refractive Laser System) Micron M7 Class C Service life: 09 years Fee submitted: Rs. 50,000/-	Designed for the correction of opthalmic refractive defects as myopia, hyperopia and astigmatism	**Approved**
269.	M/s. Bio Medics Medical System. F -597, F- Block, Satelite Town Rawalpindi. ELI-00022 **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer** M/s. Ideal Healthcare Sdn. Bhd., No. 70 & 71, Jalan Sungai Tukang 2/1, Kawasan Perusahaan Sungai Tukang, 08000 Sungai Petani, Kedah, Malaysia. FSC Malaysia (copy) Valid till 26-08-2020 FSC Belgium Issued on 08.05.2018.	**Idealcare** (Intravenous Catheter) Class B Shelf Life: 05 years IC2003-14, IC2003-16, IC2003-18, IC2003-20, IC2003-22, IC2003-24, IC2003-26 Fee submitted: Rs. 25,000/-	I.V catheter without port and without wings, sterile	**Approved** subject to provision of original FSC and ISO13485
270.	M/s Royal Enterprises, Shop No. 5, Karimji Building, Opp HBL North Napier Road, Karachi (ELI-00062) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 31-08-2019)	Folee Air Compressing Nebulizer (W003, W003-A, W003-B) Class B Shelf Life: Not Applicable Fee Submitted: Rs. 25,000/-	Intended for use in the treatment of asthma, COPD and other respiratory ailments in which aerosolized medication is required during therapy	**Approved** subject to provision of valid FSC and foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to

					issue registration of the product, if the panel of experts approve the manufacturing plant.
271.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till 31-08-2019)	Folee Arm Blood Pressure Monitor Class B Shelf Life: Not Applicable DX-B1, DX-B1Y, DX-B2, DX-B2Y, DX-B3, DX-B3Y, DX-B4, DX-B10, DX-B10Y, DX-B15, DX-B15Y, DX-B16, DX-B17, DX-B17Y Fee Submitted: Rs. 25,000/-	Electronic blood pressure monitor-upper arm. It monitors and displays diastolic, systolic blood pressure and pulse rate.	**Approved** subject to provision of valid FSC and foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
272.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Jiangsu Folee Medical Equipment Co., Ltd., No. 16, Xingmao Road, Zhenjiang City, China (FSC China Valid Till	Folee Electric Suction Unit Class B Shelf Life: Not Applicable H001, H002	For suction of blood, phlegm and other thick liquid during induced abortions and surgical operation	**Approved** subject to provision of valid FSC and foreign inspection of manufactur

		31-08-2019)	Fee Submitted: Rs. 25,000/-		er abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
273.	M/s. Zaidi Chemist, 15 Soekarno Square, Khyber Bazar, Peshawar. ELI-00338 **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s. Farmac Zabban S.p.A. Via Persicetana 26 - 40012 Calderara di Reno (Bologna - Italy) FSC Italy FSC Issued on 20.06.2016	**FARMACTIVE SILVER SPRAY** (Powder Spray) Class B Shelf Life: 03 years Rs.25,000/-	Farmactive Silver spray is a powdered Spray device containing parts of colloidal silver and hyaluronic acid sodic salt. The colloidal silver has antibacterial properties helping to prevent the microbe contamination of the dressing and keep wound environment clear from external bacteria. Hyaluronic acid is a polysaccharide naturally contained into connecting tissues of the	**Approved**

				human body where it has moisturizing and lubricating function.	
274.	M/s. Future Scientific, FS House, Opposite Street No. 4, Main Road Shaheen Town, Gangal West, Post Office, Fazaia Colony, Rawalpindi. ELI-00209 **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s. D-TeK s.a. Belgium Parc Initialis Rue Rene Descartes, 19 BE-7000 Mons BELGIUM. **Manufacturing Site** M/s. D-TeK s.a. Belgium Parc Initialis Rue Rene Descartes, 19 BE-7000 Mons BELGIUM. FSC Belgium Issued on 06.02.2019	**ENE02-96** BlueWell Endomysium IgA ELISA Kit **ANA12SDIV-24** BlueDiver Dot ANA^{12} Screen IgG **ANA25Q-24** Blue Diver Quantrix ANA^{25} Screen IgG **CHRDIV-24** BlueDiver Dot Chromatin IgG **ANCAGDIV-24** BlueDiver Dot ANCA^{+GBM} IgG **ENDGDIV-24** BlueDiver Dot Celiac IgG **ENDADIV-24** BlueDiver Dot Celiac IgA **LI10DIV-24** BlueDiver Dot Liver^{10} IgG Class B Shelf Life : 13 months for all kits	BlueWell Endomysium IgA ELISA Kit Celiac disease Blue Diver Dot ANA^{12} Screen IgG (12 antigens) For connective tissue diseases Blue Diver Quantrix ANA^{25} Screen IgG (22 antigens) Connective Tissue diseases Blue Diver Dot Chromatin IgG (Nucleosome, dsDNA, Histones) For connective tissue diseases Blue Diver Dot ANCA+GBM IgG (3 antigens) For Vasculitis and Good Pasture Syndrome Blue Diver Dot Celiac IgG (2 antigens) Blue Diver Dot Celiac IgA (2 antigens) For Celiac disease	**Deferred. The board form the committee comprising of Prof. Dr. Saqib Shafi and Dr. Abdul Haleem Khan, members MDB to comeup with recommend ation of registration / enlistment of Clusters of Medical Devices the board also proposed Mr. Siraj uddin, head of regulatory affairs Medical Devices/Di agnostics, Roche to assist the committee if required**

				Blue Diver Dot Liver 10 IgG (10 antigens) For Autoimmune Liver disease	
275.	M/s. Claris Medical.Unit 27, 3rd Floor, Twin City Plaza I-8 Markaz Islamabad. ELI-00269 **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer** M/s. Osypka Medical, Albert-Einstein-Strasse 3, 12489, Berlin, Germany. **Manufacturing Site** M/s. Osypka Medical, Albert-Einstein-Strasse 3, 12489, Berlin, Germany. FSC Germany Issued on 31.10.2018.	**Pace 101 (External Single Chamber Pacemaker)** Pace 101 Class C Shelf Life : 05 years Rs.50,000/-	External Single Chamber Pacemaker	**Approved** subject to provision of of MFG, QMS certificate, ISO 13485 and Stability studies
276.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer** M/s. Osypka Medical, Albert-Einstein-Strasse 3, 12489, Berlin, Germany. **Manufacturing Site** M/s. Osypka Medical, Albert-Einstein-Strasse 3, 12489, Berlin, Germany. FSC Germany Issued on 31.10.2018.	**External Dual Chamber Pacemaker Pace 203** Pace 203 Class C Shelf Life : 05 years Rs.50,000/-	External Dual Chamber Pacemaker	**Approved** subject to provision of Stability studies

277.	M/s B.Braun Pakistan (Pvt) Ltd., The Forum, Suite 216, Khayaban-e-Jami, Block 9, Clifton, Karachi (ELI-00006) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany (FSC Germany Issuance Date 12-02-2019)	Certofix® Perfect Mono Class D Shelf Life: 5 Years 4160266P, 4160290P, 4160320P, 4160789P	Central Venous Catheter	**Approved**
278.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany (FSC Germany Issuance Date 12-02-2019)	Certofix® Protect Trio Class D Shelf Life: 5 Years 4162153P, 4163214P, 4163311P, 4160622P	Central Venous Catheter	**Approved**
279.	-do- **Evaluator:** Shahid Muhammad	**Legal Manufacturer:** M/s B. Braun Melsungen AG	Certofix® Protect Duo Class D Shelf Life: 5 Years	Central Venous Catheter	**Approved**

	Iqbal	Carl-Braun-Strabe 1, 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany (FSC Germany Issuance Date 12-02-2019)	4161211P, 4161319P, 4166159P, 4168534P		
280.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany (FSC Germany Issuance Date 12-02-2019)	Certofix® Protect Quinto Class D Shelf Life: 5 Years 4166868P	Central Venous Catheter	**Approved**
281.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany **Manufacturing**	Certofix® Protect Quattro Class D Shelf Life: 5 Years 4167767P, 4167775P, 4167783P	Central Venous Catheter	**Approved**

		Site: M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany (FSC Germany Issuance Date 12-02-2019)			
282.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany **Manufacturing Site:** M/s B. Braun Melsungen AG Carl-Braun-Strabe 1, 34212 Melsungen, Germany (FSC Germany Issuance Date 18-02-2019)	In-Stopper Class B Shelf Life: 5 Years 4238010	Male luer lock closing cone with injection port for intermittent injections through injection membrane	**Approved**
283.	-do- **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1, 34212 Melsungen Germany **Manufacturing Site:** B.Braun Aseculap Japan Co. Ltd. Tochigi Factory Hospital Care 285	Stimuplex®Ultra 360® Needles and Catheter kits for Plexus Anaesthesia Class B Shelf Life: 5 Years 4892503-20, 4892508-20, 4892515-20, 4892505-20 4892510-20	The Stimuplex® Ultra® needle is insulated for using electrical impulses to stimulate the target nerve structure via Nerve Stimulation that can be connected via the attached stimulation cable.	**Approved**

		Ogaki, Tsuga-machi, Tochigi-shi Tochigi 328-0101 Japan. (FSC Germany issuance 15-05-2019 and 11-03-2019)			
284.	-do- **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacturer:** B. Braun Melsungen AG Carl-Braun-StraBe 1 34212 Melsungen Germany **Production Facility:** B.Braun Medical AG Hauptstrasse 39, 6182 Escholzmatt Switzerland. (FSC Germany issuance 22-05-2019)	Discofix® Multidirectional Stopcocks for infusion therapy and monitoring. Class B Shelf Life: 3 Years 4095111 4098102	Multidirectiona l Stopcocks for infusion therapy and monitoring.	**Approved subject to provision of ISO 13485**
285.	M/s. Cor-Med, 2nd Floor 38/62 Rehman Plaza Bank Road Saddar, Rawalpindi. (ELI-00226) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	**AcuMark Sizing Balloon** **Sizing Balloon** Sizes: LT-SZB-24 LT-SZB-34 LT-SZB-44 Class D Shelf Life : 03 years Rs.50,000/-	It is used for those patients with cardiovascula r defect where in accurate measurement of the defect is important to select an appropriately sized occlusion device.	**Approved**

286.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	**Steer EASE Introducer** (Steer ease sheath) SFP5F, SFP6F, SFP7F, SFP8F, SFP9F, SFP10F, SFP11F, SFP12F, SFP14F, SFA5F, SFA6F, SFA7F, SFA8F, SFA9F, SFA10F, SFA11F, SFA12F, SFP13F, SFP14F, SFP5F-f, SFP6F-f, SFP7Ff-f, SFP8F-f, SFP9F-f, SFP10F-f, SFP11F-f, SFP12F-f, SFP13F-f, SFP14F-f, SFA5F-f, SFA6F-f,SFA7F-f, SFA8F-f, SFA9F-f, SFA10F-f, SFA11F-f, SFA12F-f, SFA13F-f, SFP14F-f. Class B Shelf Life : 03 years Rs.50,000/-	Introducer is intended to reach the cardiovascular system or the peripheral vasculature and would provide a pathway to perform the delivery of the devices.	**Approved**
287.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	**CeraFlex ™ ASD Occluders** LT-ASDf-06,LT-ASDf-08,LT-ASDf-10,LT-ASDf-12,LT-ASDf-14,LT-ASDf-16,LT-ASDf-18,LT-ASDf-20,LT-ASDf-22,LT-ASDf-24,LT-ASDf-26,LT-ASDf-28,LT-ASDf-30,LT-ASDf-32 Class D Shelf Life : 05 years Rs.50,000/-	The ASD occluders are precutaneous, transcatheter closure devices intended for the occlusion of atrail septal defect (ASD) or multi-fennestrated atrial septal defects.	**Approved**

288.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	**Konar MF VSD occluder** LT-MFO-5-3,LT-MFO-6-4,LT-MFO-7-5,LT-MFO-8-6,LT-MFO-9-7,LT-MFO-10-8,LT-MFO-12-10,LT-MFO-14-12. Class D Shelf Life : 05 years Rs.50,000/-	MF VSD Occluder is a percutaneous, transcatheter, intended for the occlusion of ventricular septal Defect (VSD).	**Approved**
289.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	**Cera ™ VSD Occluders** LT-VSD-MU-04,LT-VSD-MU-05,LT-VSD-MU-06,LT-VSD-MU-07,LT-VSD-MU-08,LT-VSD-MU-10,LT-VSD-MU-12,LT-VSD-MU-14,LT-VSD-MU-16,LT-VSD-MU-18,LT-VSD-MU-20,LT-VSD-MU-22,LT-VSD-MU-24,LT-VSD-Sym-04,LT-VSD-Sym-05,LT-VSD-Sym-06,LT-VSD-Sym-07,LT-VSD-Sym-08,LT-VSD-Sym-10,LT-VSD-Sym-12,LT-VSD-Sym-14,LT-VSD-Sym-16,LT-VSD-Sym-18,LT-VSD-Sym-20,LT-VSD-Sym-22,LT-VSD-Sym-24,LT-VSD-Asym-04,LT-VSD-Asym-05,LT-VSD-Asym-	The VSD occluders are closure system, transcatheter closure devices intended for the non surgical closure of ventricular septal defect.	**Approved**

			06,LT-VSD-Asym-07,LT-VSD-Asym-08,LT-VSD-Asym-10,LT-VSD-Asym-12,LT-VSD-Asym-14,LT-VSD-Asym-16,LT-VSD-Asym-18,LT-VSD-Asym-20,LT-VSD-Asym-22,LT-VSD-Asym-2,LT-VSD-Ecc-04,LT-VSD-Ecc-05,LT-VSD-Ecc-06,LT-VSD-Ecc-07,LT-VSD-Ecc-8,LT-VSD-Ecc-10,LT-VSD-Ecc-12,LT-VSD-Ecc-14,LT-VSD-Ecc-16,LT-VSD-Ecc-18,LT-VSD-Ecc-20,LT-VSD-Ecc-22,LT-VSD-Ecc-24 Class D Shelf Life : 05 years Rs.50,000/-		
290.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	**Cera ™ ASD Occluders** LT-ASD-06,LT-ASD-08,LT-ASD-10,LT-ASD-12,LT-ASD-14,LT-ASD-16,LT-ASD-18,LT-ASD-20,LT-ASD-22,LT-ASD-24,LT-ASD-26,LT-ASD-28,LT-ASD-30,LT-ASD-32,LT-ASD-34,LT-ASD-36,LT-ASD-38,LT-ASD-40,LT-ASD-42 Class D Shelf Life : 05 years Rs.50,000/-	The ASD occluders are precutaneous, transcatheter closure devices intended for the occlusion of atrail septal defect (ASD) or multi-fennestrated atrial septal defects .	**Approved**
291.	-do- **Evaluator:**	**Legal Manufacturer:**	**Cera ™ PDA Occluders**	PDA Occulder is a precutaneous,	**Approved**

	Hafiz Muhammad Asif Iqbal	M/s. Lifetech Scientific (Shenzhen) Co., Ltd., Floor 1-5, Cybio Electornic Building, Langshan 2nd Street, North Area of High-tech Park Nanshan Dist, Shenzhen 518057 P.R China. FSC Netherland Valid till January 28, 2021	LT-PDA-0406, LT-PDA-0608, LT-PDA-0810, LT-PDA-1012, LT-PDA-1214, LT-PDA-1416,LT-PDA-1618, LT-PDA-1820, LT-PDA-2022, LT-PDA-2224 Class D Shelf Life : 05 years Rs.50,000/-	transcatheter Occuluder for the closure of PDA. Patients have PDA or PDA accompanies with other mild cardiac disease. Patients weight less than 6kgs, and 6 month old and above. The narrowest portion of the PDA is 2mm or larger.	
292.	M/s Hakimsos (Pvt) Ltd., Hakimsons House, A-56/B SITE, Manghopir Road, Karachi (ELI-00396) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s Omisan Farmaceutici Via Galileo Galilei snc, 00012 Guidonia Montecelio (RM), Italy (FSC Italy Issuance Date 16-10-2018)	Lumixa (Ophthalmic solution) Class C Shelf Life: 24 Months Rs.50,000/-	Ophthalmic Solution Hyaluronic Acid 0.15%, Liposomes, Crocin	**Approved** subject to provision of EPSP &DoC
293.	M/s Sultansons, 133 Kutchi Gali #1, Marriott Road, Karachi (ELI-00051) **Evaluator:** Ms. Hira Bhutto	**Manufacturer:** M/s Shandong Wuzhou Medical Equipment Co., Ltd., Dingtao (YanTai) Industrial Zone, China (FSC China Valid Till 05-02-2020)	ST Classic Disposable Sterile Insulin Syringe Class B Shelf Life: 5 Years U-100 (1ml, 0.5ml) Rs.25,000/-	Disposable Insulin Syringe U-100 Sterile	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the

					manufacturing plant.
294.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s Shandong Wuzhou Medical Equipment Co., Ltd., Dingtao (YanTai) Industrial Zone, China (FSC China Valid Till 05-02-2020)	ST Classic Disposable Sterile Infusion Set with Needle (100ml, 150ml) Class B Shelf Life: 5 Years Rs.25,000/-	Disposable Infusion Set with Needle Sterile	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
295.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s Shandong Wuzhou Medical Equipment Co., Ltd., Dingtao (YanTai) Industrial Zone, China (FSC China Valid Till 05-02-2020)	ST Classic Intravenous Infusion Sets with Burette Class B Shelf Life: 5 Years 100ml, 150ml Rs.25,000/-	IV Infusion Set	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve

					the manufacturing plant.
296.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/s Shandong Wuzhou Medical Equipment Co., Ltd., Dingtao (YanTai) Industrial Zone, China (FSC China Valid Till 05-02-2020)	ST Classic Disposable Sterile Syringes Class B Shelf Life: 5 Years 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml Rs.25,000/-	Disposable Syringes	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve the manufacturing plant.
297.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Changzhou Zhongyou Medical Device Co., Ltd Wugang Zhenglu Town, Changzhou City, Jiangsu Prov., China. (FSC Valid till 09-12-2019) FSC of Spain issued on 25th March, 2019	Classic Disposable Nelaton Catheter Setrile Class B Shelf Life 5 Years Sizes: (FR6, FR8, FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24,) Rs.25,000/-	Nelaton cathter is used for intermittent catheterization of urethera for those individuals who are unable to promote natural urine flow or having a significant volume of residual urine following a voiding episode	**Approved**
298.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Changzhou Zhongyou Medical	Classic Disposable Rectal Catheter Sterile	Disposable Rectal Catheter Sterile	**Approved**

		Device Co., Ltd Wugang Zhenglu Town, Changzhou City, Jiangsu Prov., China. (FSC Valid till 09-12-2019) FSC of Spain issued on 25th March, 2019	Class B Shelf Life : 05 Years Sizes: FR24, FR26, FR28, FR30, FR32, FR34, FR36, Rs.25,000/-		
299.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Changzhou Zhongyou Medical Device Co., Ltd Wugang Zhenglu Town, Changzhou City, Jiangsu Prov., China. (FSC Valid till 09-12-2019) FSC of Spain issued on 25th March, 2019	Classic Disposable Feeding Tube Sterile Class B Shelf Life: 5 Years Sizes: (FR4, FR5, FR6, FR8, FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24,)	Disposable Urine Bag Sterile	**Approved**
300.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Changzhou Zhongyou Medical Device Co., Ltd Wugang Zhenglu Town, Changzhou City, Jiangsu Prov., China. (FSC Valid till 09-12-2019) FSC of Spain issued on 25th March, 2019	Classic Disposable Stomach tube Sterile Class B Shelf Life 5 Years (Sizes: FR6, FR8, FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24, FR26, FR28)	Disposable Stomach tube Sterile	**Approved**
301.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Suzhou Health Medical Plastic	Classic Disposable I.V.Flow Regulators, Sterile.	The Infusion flow regulator is mainly used in conjunction with other	**Approved**

		Prodcuts Co., Ltd. Donggu Road (Middle), Quishe Industrial Park, Tongli Town Wujinag Suzhou 215216 Jiangsu, China. (FSC valid 14-03-2021) (FSC of MHRA issued on 07-03-2019)	Class B Shelf Life: 5 Years I.V Flow Regulators HRSI-3 Code: 20197008	disposable medical devices. It is used to regulate the infusion flow rate during intravenous injection or infusion of human body and blood transfusion. It can accurately control the flow rate during infusion, and prevent the special patient from using special drugs. The Body can't bear it.	
302.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Suzhou Health Medical Plastic Prodcuts Co., Ltd. Donggu Road (Middle), Quishe Industrial Park, Tongli Town Wujinag Suzhou 215216 Jiangsu, China. (FSC of MHRA issued on 07-03-2019) (FSC valid 14-03-2021)	Classic Disposable Three way Stop Cock, Sterile Class B Shelf Life: 5 Years Three way stopcock HRSS-2 Code:20197007	Three way stopcock is used in human body vein injection, transfusion and blood transfusion, together with other medical device for single use.	**Approved**
303.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Suzhou Health Medical Plastic Prodcuts Co., Ltd. Donggu Road (Middle), Quishe	Classic Disposable Heparin Cap Sterile. Class B Shelf Life: 5 Years	Heparin cap used with indewelling needle or other infusion apparatus, used for intravenous injection ofr	**Approved**

		Industrial Park, Tongli Town Wujinag Suzhou 215216 Jiangsu, China. (FSC valid 14-03-2021) (FSC of MHRA Issued on 07/03/2019)	Heparin Caps Model: HRSH-1 Code: 20197006	infusion to human body, blood transfusion. To reduce the pain of the patients, no cross contamination.	
304.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Changzhou Zhongyou Medical Device Co., Ltd Wugang Zhenglu Town, Changzhou City, Jiangsu Prov., China. (FSC Valid till 09-12-2019) FSC of Spain issued on 25th March, 2019	Classic Disposable Suction Catheter Sterile Class B Shelf Life: 5 Years Sizes: (FR5, FR6, FR8,FR10, FR12, FR14, FR16, FR18, FR20, FR22, FR24,	Disposable Suction Catheter Sterile	**Approved**
305.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal manufacturer:** Zehjiang Star Enterprise Co.,Ltd No. 1, West JINHUA ROAD, Mazhang District, 524094 Zhanjiang, People's Republic of China. (FSC Valid till 13-02-2021)	CLASSIC Endotracheal Tubes Sterile, With Cuff (Size: 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm) Endotracheal Tubes Sterile, Without Cuff (Size: 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm,	Single intended use endotracheal tube mainly for patients require long term or repeated anesthesia, artificial ventilation and assisted breathing.	**Approved** subject to foreign inspection of manufacturer abroad. The Board also authorized the Secretary MDB to issue registration of the product, if the panel of experts approve

			8.5mm, 9.0mm, 10.0mm) Class B Shelf Life: 5-Years		the manufacturing plant.
306.	M/s Gene-Tech Laboratories, 246/B, PECHS, Block 6, Karachi (ELI-00089) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s Helsinn Healthcare SA, Via Pian Scairolo 9, 6912 Pazzallo, Switzerland **Manufacturing Site:** M/s Biokosmes s.r.l., Via dei Livelli No. 1, 23842 Bosisio Parini, Lecco, Italy (FSC Switzerland Valid Till 14-01-2021)	Xonrid® Topical Gel for Radiotherapy induced Dermatitis, 75ml Bottle Class B Shelf Life: 36 Months Rs.25,000/-	Xonrid® is a topical gel that prevents and treats skin symptoms such as erythema, itching, burning sensation and pruritus, induced by radiotherapy or other causes.	**Approved**
307.	M/s Johnson & Johnson (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** M/s Biosense Webster, Inc., 33 Technology Drive Irvine, CA 92618, USA **Manufacturer:** i) M/s Biosense Webster, Inc. 15715 Arrow Hwy., Irwindale, CA 91706, USA ii) M/s Biosense Webster, Inc., Circuito Interior Norte, No. 1820 Parque Industrial	Pentaray® NAV catheters Class D Shelf Life: 1 Years Codes: D128201 D128202 D128203 D128204 D128205 D128206	High Density Mapping Catheters	**Approved** subject to provision of Credientials of Manufacturer and valid FSC

		Salvarcar Juarez, Chihuahua 32574, Mexico (FSC USFDA Valid Till 26-07-2019)			
308.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** M/s Biosense Webster, Inc., 33 Technology Drive Irvine, CA 92618, USA **Manufacturer:** i) M/s Biosense Webster, Inc. 15715 Arrow Hwy., Irwindale, CA 91706, USA ii) M/s Biosense Webster, Inc., Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua 32574, Mexico (FSC USFDA Valid Till 26-07-2019)	Navistar® Catheters Class D Shelf Life: 3 Years Codes: 34A15M 34A25M 34A35M 34A55M 34A45M 34AJ5M SW1183022 SW1183-030 SW1183-031 SW1183-032 SW1184030 SW1184-031 SW1184-032 34J17M 34J27M 34J37M 34J57M 34JJ7M	Navigation Ablation Catheters	**Approved** subject to provision of Credientials of Manufacturer and valid FSC
309.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** M/s Biosense Webster, Inc., 33 Technology Drive Irvine, CA 92618, USA **Manufacturer:** i) M/s Biosense Webster, Inc. 15715 Arrow Hwy., Irwindale, CA 91706, USA ii) M/s Biosense	Lasso® Mapping catheter Catheters Class D Shelf Life: 1 Years Codes: 35026R 35036R 35016R 35046R 35056R 35066R 35T46R	Diagnostic Catheters	**Approved** subject to provision of credentials of manufacturer, Stability data and valid FSC

		Webster, Inc., Circuito Interior Norte, No. 1820 Parque Industrial Salvarcar Juarez, Chihuahua 32574, Mexico (FSC USFDA Valid Till 26-07-2019)	35T26R 35T36R 35T56R SW1220-073		
310.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK (FSC UK Issuance Date 22-03-2018)	Kaltostat (Calcium Sodium Alginate Wound Dressing) Class C Shelf Life: 36 Months Code: 168117 2g, 5 dressings Rs.50,000/-	Calcium Sodium Alginate Wound Dressing	**Approved** subject to provision of ISO 13485
311.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Manufacturer:** M/s ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, UK (FSC UK Issuance Date 12-03-2018)	Granugel H/Gel W/Nozzle 15G (1x10) Ster GB (Hydrocolloidal Gel) Class C Shelf Life: 2 Years Code: 401802 Rs.50,000/-	Hydrocolloid Gel for ulcerative and pressure wounds.	**Approved** subject to provision of ISO 13485
312.	M/s Roche Pakistan Limited, 37-C, Block-6, P.E.C.H.S, Karachi (ELI-00009) **Evaluator:** Shahid Muhammad Iqbal	**Legal Manufacture:** Roche Diabetes care GmbH Sandhofer Str. 116, 68305 Mannheim Germany. **Manufacturing Site:** Bionostics Inc. 7 Jackson Road,	Accu-Chek Performa Control Cat No.04861736001 Class C Shelf Life 24 months Rs.50,000/-	Control Solution for performance checks on the Accu-Chek Performa.	**Approved** subject to provision of ISO 13485 and Full Quality Assurance

		Devens MA 01434 USA. FSC Germany issued on 27-03-2019			
313.	**-do-** **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacture:** Roche Diabetes care GmbH Sandhofer Str. 116, 68305 Mannheim Germany. **Manufacturing Site:** Bionostics Inc. 7 Jackson Road, Devens MA 01434 USA. FSC Germany issued on 27-03-2019	Accu-Chek Active Control Accu-Chek Active Control Cat No. 03146324195 Class C Shelf life 24 Months Rs.50,000/-	The control Solution is intended for performing control test.	**Approved** subject to provision of ISO 13485 and Full Quality Assurance
314.	**-do-** **<u>Evaluator:</u>** Shahid Muhammad Iqbal	**Legal Manufacture:** Roche Diabetes care GmbH Sandhofer Str. 116, 68305 Mannheim Germany. **Manufacturing Site:** Bionostics Inc. 7 Jackson Road, Devens MA 01434 USA. FSC Germany issued on 27-03-2019	Accu-Chek Guide Control Accu-Chek Guide Controls Cat No. 07748906020 Class C Shelf Life: 24 Months Rs.50,000/-	The control Solution is intended for performing control test on Accu-Chek Guide blood Glucose meters and Accu-Chek Guide test strips.	**Approved** subject to provision of ISO 13485 and Full Quality Assurance
315.	**-do-** **<u>Evaluator:</u>**	**Legal Manufacture:**	Accu-Chek Instant Control	The control Solution is intended for	**Approved** subject to provision of

	Shahid Muhammad Iqbal	Roche Diabetes care GmbH Sandhofer Str. 116, 68305 Mannheim Germany. **Manufacturing Site:** Bionostics Inc. 7 Jackson Road, Devens MA 01434 USA. FSC Germany issued on 27-03-2019	Accu-Chek Instant Control Cat No.07869525020 Class C Shelf life: 24 Months Rs.50,000/-	performing control test on Accu-Chek Instant &Accu-Chek Instant S blood Glucose meters and Accu-Chek Instant test strips.	ISO 13485 and Full Quality Assurance
316.	M/s Greenstar Social Marketing (Guarantee) Pakistan Limited, 8th Floor, Ocean Tower, Clifton, Karachi (ELI-00253) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Pregna International Limited, Plot Number 219, Survey No.168, Dabhel Co., Op. Industrial Soc. Ltd, Dabhel Daman 396 210 (U.T) (FSC India issue date 11-02-2017)	Copper T 380 A with Safeload (Pregna Model T Cu 380A with Safe Load) Class D Shelf Life: 7 Years Fee submitted: Rs 50,000/-	Long term implantable intrauterine contraceptive device	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors. If the firm/company provides valid WHO prequalified evidence the inspection is exempted
317.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Pregna International Limited, Plot Number 219,	Protect 5- CU 375 (Pregna Model Cu 375) Class D	Long term implantable intrauterine contraceptive device	**Approved** subject to inspection abroad by the panel of

		Survey No.168, Dabhel Co., Op. Industrial Soc. Ltd, Dabhel Daman 396 210 (U.T) (FSC India issue date 11-02-2017)	Shelf Life: 5 Years Fee submitted: Rs 50,000/-		inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the panel of inspectors. If the firm/compa ny provides valid WHO prequalified evidence the inspection is exempted
318.	M/s 3M Pakistan (Pvt) Ltd., Islamic Chamber of Commerce Building, St No.2/A, Block 9, KDA Scheme 5, Clifton, Karachi (ELI:00259) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s 3M Company, 3M Health Care 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN 55144, USA **Manufacturing Facility:** M/s Benchmark Electronics, Inc. 4065 Theurer Blvd., Winoma, MN 55987, USA (FSC US FDA Valid Till 05-12-2019)	3M ™ Bair Hugger™ Warming Unit Model 675 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	To prevent and treat patient hypothermia	**Approved** subject to provision of ISO 13485
319.	M/s Lab Link Enterprises, M-203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi	**Manufacturer:** M/s PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta Jl. Surya Utama Kav.	Nipro Disposable Syringe (with needle) Class B Shelf Life: 3 Years	Sterile, single use syringe	**Approved**

	(ELI-00007) **Evaluator:** Ms. Unum Zia Shamsi	I-22B, 23 & 24 Desa Kutamekar, Kec. Ciampel, Karawang Jawa Barat, Indonesia (FSC Indonesia Valid Till 23-04-2020) (FSC Australia Issue Date 7-01-2019)	Sizes: 1ml, 3ml, 5ml, 10ml, 20ml (Sizes mentioned on FSC Indonesia. Sizes not mention on FSC Australia) Fee submitted: Rs. 25,000/-		
320.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan **Manufacturing Site:** M/s Nipro Corporation Odate Factory 8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794, Japan (FSC Japan Issuance Date 13-08-2018)	Nipro Surefuser + Class C Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Elastomeric Disposable infusion pump. To be used for continuous drug infusion therapy; post operative pain control, carcinomatous pain control, chemotherapy for cancer etc	**Approved**
321.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta Jl. Surya Utama Kav. I-22B, 23 & 24 Desa Kutamekar, Kec. Ciampel, Karawang Jawa Barat, Indonesia (FSC Indonesia Valid Till 23-04-2020) (FSC Australia Issue Date 7-01-2019)	Nipro Infusion Set Class B Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	Sterile, single use Infusion Set	**Approved**

322.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta Jl. Surya Utama Kav. I-22B, 23 & 24 Desa Kutamekar, Kec. Ciampel, Karawang Jawa Barat, Indonesia (FSC Indonesia Valid Till 23-04-2020) (FSC Australia Issue Date 7-01-2019)	Nipro Wing Cath IV Cannula with Injection Port and Wing ETFE Radiopaque Catheter Class B Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	Sterile, single use IV Cannula	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors
323.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s PT. Nipro Indonesia Jaya Kawasan Industri Suryacipta Jl. Surya Utama Kav. I-22B, 23 & 24 Desa Kutamekar, Kec. Ciampel, Karawang Jawa Barat, Indonesia (FSC Indonesia Valid Till 23-04-2020) (FSC Australia Issue Date 7-01-2019)	Nipro Syringe U-100 Insulin with Needle 1ml 29G, 30G, 31G (Sizes mentioned on FSC Indonesia. Sizes not mention on FSC Australia) Class B Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	Sterile, single use Insulin Syringe	**Approved**
324.	M/s. Kiswa Cares. Office No.07, Gulf Plaza Chandni Chowk, Rawalpindi. ELI-00211 **Evaluator:** Ms. Unum Zia	**Legal Manufacturer:** M/s. Avizor, S.A., C/LA Canada, 17-28850, Torrejon De Ardoz (Madrid), Spain. **Manufacturing Site:** Avenida De	**All Clean® Soft** 60ml 100ml 350ml Class C Shelf Life: 3 years	All-in-one protein remover solution for all types of soft contact lenses. Composition: Buffered isotonic	**Approved**

	Shamsi	La Innovacion, 2-28919, Leganes (Madrid), Spain FSC Spain Issued on 17th September, 2018	Fee submitted: Rs 50,000/-	aqueous solution with poloxamer, EDTA, PVP, polyhaxanide 0.0002% and protein removing agent.	
325.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Avizor, S.A., C/LA Canada, 17-28850, Torrejon De Ardoz (Madrid), Spain. **Manufacturing Site:** Avenida De La Innovacion, 2-28919, Leganes (Madrid), Spain FSC Spain Issued on 17th September, 2018	**Alvera®** 60ml 100ml 350ml Class C Shelf Life: : 3 years Fee submitted: Rs 50,000/-	Multipurpose solution with Aloe Vera for silicone hydrogel lens users. Composition: Poloxamer, EDTA, Aloe Vera, Polyhexanide 0.0002% in a buffered isotonic and sterile solution.	**Approved**
326.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Avizor S.A. La Canada 17, Torrejon de Ardoz 28850 Madrid (Spain). FSC Spain Issued on 17th September, 2018	**Avizor GP Multi** 120ml 240ml Class C Shelf Life: : 3 years Fee submitted: Rs 50,000/-	Solution for rigid and gas-permeable contact lenses. Composition: Poloxamer 0.25%, EDTA 0.10%, Polyhexanide 0.0002% in a buffered isotonic and sterile solution.	**Approved**
327.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Avizor S.A. La Canada 17, Torrejon de Ardoz 28850 Madrid (Spain). FSC Spain	**Avizor Lacrifresh Moisture** 15ml Class C Shelf Life: 3 years Fee submitted: Rs	Wetting and Lubrifing Solution for all types of contact lenses	**Approved**

		Issued on 17th September, 2018	50,000/-		
328.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Avizor S.A. La Canada 17, Torrejon de Ardoz 28850 Madrid (Spain). FSC Spain Issued on 17th September, 2018	**Avizor Unica® Sensitive** 60ml 100ml 350ml Class C Shelf Life: : 3 years Fee submitted: Rs 50,000/-	All-in-one solution for users with sensitive eyes. For all types of soft contact lenses. Composition: Sodium hyaluronate, poloxamer, EDTA, polyhexanide 0.0001% in a buffered isotonic and sterile solution	**Approved**
329.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** M/s. Avizor S.A. La Canada 17, Torrejon de Ardoz 28850 Madrid (Spain). FSC Spain Issued on 17th September, 2018	**Avizor Lacrifresh Comfort** 15ml Class C Shelf Life: : 3 years Fee submitted: Rs 50,000/-	Comfort and wetting solution for all contact lenses. Composition: Isotonic, buffered and aqueous solution, Povidone 1% , EDTA 0.1% and polyhexanide 0.0002%	**Approved**
330.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan **Evaluator:** Hafiz Muhammad	**Legal Manufacturer:** M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA	**ChoICE™ PT Guidewire with ICE™ Hydrophilic Coating** Class D Shelf Life: 24Month H74912154011	The Boston Scientific ChoICE Magnet, Mailman Magnet, Luge Magnet, ChoICE PT Magnet, and PT Graphix	**Approved**

	Asif Iqbal	**Manufacturing Site:** M/s Boston Scientific Corporation 302 Parkway, Global park, La Aurora, Heredia, Costa Rica (FSC USFDA valid till 05-08-2020)	08714729252467 0.014", 300cm, Straight H74912154012 08714729150633 0.014", 300cm, Straight, 5 pk H7491215401J1 08714729252474 0.014", 300cm, J Tip H7491215401J2 08714729193708 0.014", 300cm, J Tip, 5 pk H74912155011 08714729303039 0.014", 300cm, Straight H74912155012 08714729177012 0.014", 300cm. Straight, 5 pk H7491215501J1 08714729252498 0.014", 300cm, J Tip H7491215501J2 08714729176947 0.014", 300cm, J Tip, 5 pk	Magnet Guidewires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature. They are available with a nominal diameter of 0.014 in (0.37 mm) and in nominal lengths of 182 or 300 cm. These CV Guidewires contain a 304 stainless steel core wire. The proximal section of the core wire of all models is coated with polytetrafluoro ethylene (PTFE) for lubricity. The distal end of the core wire is formed (flattened) to allow for shaping. All models are	

			H74912160011 08714729252504 0.014", 182cm, Straight H74912160012 08714729150626 0.014", 182cm, Straight, 5 pk H7491216001J1 08714729252511 0.014", 182cm, J Tip H7491216001J2 08714729193715 0.014", 182cm, J Tip, 5 pk H74912161011 08714729252528 0.014", 182cm, Straight H74912161012 08714729176992 0,014", 182cm, Straight, 5 pk H7491216101JI 08714729252535 0.014", 182cm, J Tip H749121610 1J2	available with a shapeable Straight Tip or a preformed "J" Tip to address user preference. Varying tapers along the distal core wire and differing tip materials (spring coil or polymer) provide combinations of rail support and tip flexibility to address user requirements	

			08714729177005 0.014", 182cm, J Tip, 5 pk		
331.	M/s Global Health Care, Midway Commercial Plaza No. 20, BackSide of prism Arcade 2, Phase 7 Bahria Town, Rawalpindi. (ELI-00086) **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC South Korea Issuance 19-10-2018)	**ichroma™ Cortisol** Test for Cortisol Class B Shelf Life: 20 Months for Kit, 12 Months for Control (Codes /sizes) As per FSC	**ichroma™ Cortisol** flourescence Immunoassay (FIA) for quantitative determination of Cortisol in human whole blood/serum/plasma.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.
332.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC South Korea Issuance 19-10-2018)	**ichroma™ Cortisol** Test for Cortisol Class B Shelf Life: 20 Months for Kit, 12 Months for Control (Codes /sizes) As per FSC	**The** flourescence Immunoassay (FIA) used for quantitative determination of Cortisol in human whole blood/serum/plasma.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.
333.	-do- **Evaluator:** Hafiz Muhammad	**Legal Manufactuer:** Boditech Med Inc.	**ichroma™ Vitamin D** Test total 25(OH)D2/D3	Is a fluorescence Immunoassay (FIA) used for	**Approved** subject to inspection abroad by

	Asif Iqbal	43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC South Korea Issuance 19-10-2018)	Class B Shelf Life: 20 Months For Kit, 12 Months for control (Codes /sizes) As per FSC	quantitative determination of total 25(OH)D2/D3 level in regulating the concentration of calcium and phosphate in the bloodstream .	the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the panel of inspectors.
334.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC South Korea Issuance 19-10-2018)	**ichroma™ Progestrone, ichroma™ FSH, ichroma™ LH, ichroma™ PRL, ichroma™ B-HCG. ichroma™ Testosterone** Test for Progesterone, Test for follicle stimulating hormone (FSH) Test for Luteinizing hormone (LH), Test for prolactin, Test for B-hCG, Test for cardiac Test for cardiac Testosterone. Class B Shelf Life: 20 Months test Kit 12 Months control. (Codes /sizes) As per FSC ichroma™ Progestrone, ichroma™ FSH, ichroma™ LH, ichroma™ PRL,	**ichroma™ Progestrone,** Is a flourescence Immunoassay (FIA) for quantitative determination of total progestrone human serum/ plasma. It is useful as an aid in management and monotoring of the cause of intertility, track ovulation ,diagnose and ectopic or failing preganancy, monitor the heatlh of pregnancy. **ichroma™ FSH,** Is a flourescence Immunoassay (FIA) for quantitative determination of follicle	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the panel of inspectors.

			ichroma™ B-HCG. ichroma™ Testosterone	stimulating hormone FSH in human serum/plasma. **ichroma™ LH,** flourescence Immunoassay (FIA) for quantitative determination of luteinizing hormone (LH) in human serum/plasma. **ichroma™ B-HCG.** flourescence Immunoassay (FIA) for quantitative determination of total B-Hcg in human whole blood/serum/plasma. gonadotropin (total B-hcg) level in human. **ichroma™ PRL,** flourescence Immunoassay (FIA) for quantitative determination of Prolactin (PRL) in human serum/plasma. **ichroma™ Testosterone** flourescence Immunoassay (FIA) for quantitative determination of Testosterone in human blood/serum/p	

				lasma.	
335.	-do- **<u>Evaluator:</u>** Hafiz Muhammad Asif Iqbal	**Legal Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC South Korea Issuance 19-10-2018)	**ichroma™ Cortisol** Test for Cortisol Class B Shelf Life: 20 Months for Kit, 12 Months for Control (Codes /sizes) As per FSC	**ichroma™ Cortisol** flourescence Immunoassay (FIA) for quantitative determination of Cortisol in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of concentration of cortisol. For in vitro diagnostic use only.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.
336.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Issuance 19-10-2018)	**ichroma™ HbA1c** Test for Hemoglobin A1c Class C Shelf Life: 20 Months for Kit 12 Months for Control Codes As per FSC **ichroma™ HbA1c** Prodcut License No. 14-2684 IVD Reagents for clinical Immnochemistry.	**ichroma™ HbA1c** is a fluorescence immunoassay (FIA) for the quantitative determination of Hemoglobin A1c in human whole Blood It is ueful as an aid in management and monitoring of the long – term glycemic status in patients with diabetes mellitus. For in vitro diagnostic use only.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.

337.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Issuance 19-10-2018)	**ichroma™ RF IgM** Test for RF IgM Class C Shelf Life: 20 Months for Kit 12 Months for Control Codes As per FSC ichroma™ RF IgM Product License No. 17-80 IVD reagents for autoimmune disease.	**ichroma™ RF IgM** is a fluorescence immunoassay (FIA) for the quantitative determination of RF IgM in Human whole blood/serum/plasma. It is ueful as an aid in management and monitoring of rheumatoid arthritis. For in vitro diagnostic use only.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.
338.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Issuance 19-10-2018)	**ichroma™, T3** **inchroma™, T4** **ichroma™ TSH** Test for triiodothyronine (total T3) Test for throxine (T4) Test fpr thyroid stimulating hormone. Class B Shelf Life: 20 Months Hormone control 12 Months Codes As Per Fsc ichroma™, T3 License No. 14-3261 inchroma™, T4 License No.14-2666 ichroma™ TSH	ichroma™ T3 is a flourescence immunoassay (FIA) for quantitative determination of triiodothyronine (total t3) in human serum/plasma. It is usefu las an aid in management and monitoring of determination of thyroid disorders. for invitro idagnostic use only.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.

339.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Issuance 22-10-2018)	**ichroma™ PSA** Test for Prostate Specific antigen Class C Shelf Life 20 Months Codes As per FSC ichroma™ PSA	**ichroma™ PSA** is a Flourescence Immunoassay (FIA) for the quantitative determination of Prostate Specific Antigen (PSA) in human whole blood/serum/plasma. It is useful as an aid management and monioring of prostate cancer or other prostate disorders. For in vitro diagnostic use only.	**Approved** subject to inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors.
340.	M/s. Alliance Medical, 12-B, 1st Floor, Agro Flats, Shadman, Lahore. ELI-00147 **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** **Entity:** Neuromedex GmbH **Address:** Vierenkamp 15, D-22453 Hamburg, Germany. FSC Germany Issued on 09.07.2019.	DISPOMEDICA (Temporary Bipolar Pacing Catheter) SIZES / CODES AS PER FSC: 24.40110000, 24.50110000, 24.60110000, 24.40100000, 24.50100000, 24.60100000, 24.70100000, 24.40151100, 24.50151100, 24.60151100, 24.70151100, 24.40151110, 24.50151110, 24.60151110, 24.70151110, 024.BP51, 20.24001, 20.24002. Class D Shelf Life: 05 years	After being placed into the heart, Temporary Bipolar Pacing Catheters can be used for the stimulation of the heart with the aid of an external pacemaker .	**Approved**

341.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Osypka Medical, Albert-Einstein-Strasse 3, 12489, Berlin, Germany. FSC Germany Issued on 15.02.2019.	**Pace 101H** (External Single Chamber Pacemaker) Model: 101H Class C Shelf Life: Not provided	An external single chamber temporary pacemaker is intended to be used in conjuction with a cardiac pacing lead system for temporary single chamber pacing in a clinical environment by trained personnel.	**Approved**
342.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Osypka Medical, Albert-Einstein-Strasse 3, 12489, Berlin, Germany. FSC Germany Issued on 15.02.2019.	**Pace 203H** (External Dual Chamber Pacemaker) Model: 203H Class C Shelf Life: Not provided	An external dual chamber temporary pacemaker used for temporary dual chamber pacing.	**Approved**
343.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinglong 1st Road, Baolong Industrial Zone , LongGang District, 518116 Shenzhen, Guangdong, China. **Manufacturing Location:** M/s. Huizhou Branch of Shunmei	**Shunmei (Disposable Pressure Transducer)** 612101, 612102, 612103, 612104, 612105, 612106, 612107, 612108, 612109, 612201, 612202, 612203, 612204, 612205, 612206, 612207, 612208, 612209, 612261, 612262, 612263, 612264, 612265, 612266, 612267, 612268,	Active medical device intended for diagnosis of invasive blood pressure monitoring.	**Approved**

		Medical Co., Ltd., Vifa 3rd Road, Vifa Industrial Zone, Pingtan town, Huiyang District, Huizhou, guangdon, China. FSC U.K Issued on 20-04-2017	612269, Class B Shelf Life: 3 years		
344.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinlong 1st Road, Baolong Industrial Zone , Long Gang District, Shenzhen , China. FSC U.K Iissued on 20-04-2017	**SHUNMEI Introducer Sets** (Femoral, Radial) Class B Shelf Life 3 Years (Codes /sizes) As per FSC	The Introducer set is single use device allowing for introduction, manipulation, and remoal of stimulation leads after percutaneous entry is gained with a needle.	**Approved**
345.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** Shunmei medical co. Ltd, R401 of building b, No.8 Jinlong 1st road, baolong industrial zone , Long gang district, Shenzhen , China. FSC U.K Issued on 20-04-2017	**SHUNMEI Connecting Tubing** (Pressure Extension Line) Class B Shelf Life: 3 Years (Codes /sizes) As per FSC	Connecting Tubing is applicable as a non-invasive medical device. It is indicated for providing channel for infusion and pressure monitoring.	**Approved**
346.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd,	**SHUNMEI Teflon Coated Guidwire** Class B	PTFE Coated Guidewire is used for guiding and assisting	**Approved**

		R401 of building B, No.8 Jinlong 1st Road, Baolong Industrial Zone , Long Gang District, Shenzhen , China. FSC U.K Issued on 20-04-2017	Shelf Life: 3 Years (Codes /sizes) As per FSC	insertion of precutaneous catheters.	
347.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinlong 1st Road, Baolong Industrial Zone , Long Gang District, Shenzhen , China. (FSC U.K issued on 20-04-2017)	**SHUNMEI Introducer Needle** Class B Shelf Life: 3 Years (Codes /sizes) As per FSC	Introducer needle does not have any accessory but when used, has has to be used in comnination with; Syringe, Guide wire	**Approved**
348.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer:** M/s. Shunmei Medical Co., Ltd, R401 of building B, No.8 Jinlong 1st Road, Baolong Industrial Zone , Long Gang District, Shenzhen , China. FSC U.K Issued on 20-04-2017	**SHUNMEI Balloon Inflation Devices** Class B Shelf Life: 3 Years (Codes /sizes) 617101, 617102, 617103, 617104, 617105, 617106, 617107, 617108, 617109, 617110, 617111, 617112, 617113, 617114, 617115, 617116, 617117, 617118, 617119, 617120	A dedicated hand-held device, e.g. a syringe or small pump, with a pressure gauge that is used for inflating the balloon of an angioplasty balloon of an angioplasty ballooon catheter when this is in situ.	**Approved**
349.	M/s. TEK Enterprises, Office No. MZ-9, al-Hafeez Heights Sir Syed	**Legal Manufacturer :** M/s. ASAHI Intecc co., ltd.,3-	**ASAHI Neurovascular Guide Wire** (Neurovascular Guide	**Intended use:** This guide wire is intended to be used in the	**Approved.**

	Road, Gulberg, Lahore. (ELI-00189) **Evaluator:** Hafiz Muhammad Asif Iqbal	100 Akatsuki-cho, Seto, Aichi 489-0071 Japan. **Manufacturing Sites:** M/s. ASAHI Intecc co., LTD. SETO Factory 3-100 akatuski-cho , Seto,aichi 489-0071,Japan ASAHI INTECC (Thailand) CO., LTD., 158/1 Moo 5 Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang, Pathumthani 12000, Thailand. FSC Japan Issued on 04.03.2019	Wire) (Codes /sizes) As per FSC Class D Shelf Life : 03 years	neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during neuroradiology .	
350.	-do- **Evaluator:** Hafiz Muhammad Asif Iqbal	**Legal Manufacturer :** M/s. ASAHI Intecc co., ltd.,3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan. **Manufacturing Sites:** M/s. ASAHI Intecc co., LTD. SETO Factory 3-100 akatuski-cho , Seto,aichi 489-0071,Japan ASAHI INTECC (Thailand) CO., LTD., 158/1 Moo 5 Bangkadi Industrial Park,	**ASAHI Masters Parkway Microcatheter** (Codes /sizes) As per FSC Class B Shelf Life : 03 years	Peripheral Microcatheter for peripheral vasculature not for cardiovascular and cereberal vasculature.	**Approved.**

		Tiwanon Road, Tambol Bangkadi, Amphur Muang, Pathumthani 12000, Thailand. FSC Japan Issued on 07.08.2018			
351.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer :** M/s. ASAHI Intecc co., ltd.,3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan. **Manufacturing Sites:** i. ASAHI INTECC (Thailand) Co., Ltd., 158/1 Moo 5 Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang, Pathumthani 12000, Thailand. ii. M/s. ASAHI Intecc co., ltd.,3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan. FSC Japan Issued on 25.07.2018 FSC Thailand Valid on 2.07.2020	**ASAHI Corsair Armet Microcatheter** Codes /sizes as per FSC Japan dated 25.07.2018 Class B Shelf Life : 03 years Fee submitted: Rs. 50,000/-	Intended to provide support to facilitate the placement of guidewires or assist in th delivery of contrast media into the peripheral vasculature. Not for use in coronary or neuro vasculature	**Approved.**
352.	M/s Atlantic Pharmaceuticals, 445, Sodawaterwala Building, DrZiauddin Ahmed Road, Near Light House, Karachi (ELI-00260) **Evaluator:**	**Manufacturer:** M/sInnvol Medical India Limited S.No: 396/1A3G, 3F, 3I, 388/1A, 1B and 2: 389/1, 1C and 2A Walajabad Road, Kunnam,	Innvol Triple Blood Bag 500ml CPDA-1 Class D Shelf Life:24 Months (Sizes & Codes as Per FSC)	Anticoagulant Citrate Phosphate Dextrose Adenine Solution	**Approved** subject to provision fo ISO 13485, full quality assurance certificate, FSC, Credentials

	Ms. Hira Bhutto	SriperumbudurTaluk, Kanchipuram Dist., Tamilnadu 631 604, India . (FSC India Valid 28.02.2019)	500ml CPDA-1		of manufacturer abroad, EPSP and Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors
353.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/sInnvol Medical India Limited S.No: 396/1A3G, 3F, 3I, 388/1A, 1B and 2: 389/1, 1C and 2A Walajabad Road, Kunnam, SriperumbudurTaluk, Kanchipuram Dist., Tamilnadu 631 604, India . (FSC India Valid 28.02.2019)	Innvol Single Blood Bag 500ml CPDA-1 Class D Shelf Life:24 Months (Sizes & Codes as Per FSC) 500ml CPDA-1	Anticoagulant Citrate Phosphate Dextrose Adenine Solution	**Approved** subject to provision fo ISO 13485, full quality assurance certificate, FSC, Credentials of manufacturer abroad, EPSP and Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the

					panel of inspectors
354.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Manufacturer:** M/sInnvol Medical India Limited S.No: 396/1A3G, 3F, 3I, 388/1A, 1B and 2: 389/1, 1C and 2A Walajabad Road, Kunnam, SriperumbudurTaluk, Kanchipuram Dist., Tamilnadu 631 604, India . (FSC India Valid 28.02.2019)	Innvol Double Blood Bag 500ml CPDA-1 Class D Shelf Life:24 Months (Sizes & Codes as Per FSC) 500ml CPDA-1	Anticoagulant Citrate Phosphate Dextrose Adenine Solution	**Approved** subject to provision fo ISO 13485, full quality assurance certificate, FSC, Credentials of manufacturer abroad, EPSP and Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommended by the panel of inspectors
355.	M/s Meximp Technologies, B-62, Block 5, Gulshan-e-Iqbal Karachi. (ELI-00052) **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal manufacturer:** DAKO NORTH AMERICA, INC. 6392 via real Carpinteria, CA USA. (FSC valid till 20-05-2020)	Dako North America, Inc. (A Subsidiary of Agilent Technologies) ER/PR PharmDx Kit for Automated Link Platforms Class C Shelf life : 20 months assigned to SK310 based on real time stability studies.	Dako ER/PR PharmDx™ Kit is a semi-quantative immunochistochemical (IHC) assay to identify estrogen receptor (ER) and progesterone receptor (PR) expression in normal and	**Approved** subject to provision of Stability data

			1. ER/PR PharmDX Epitome Retrieval solution (10X) 2. ER/\pr PharmDx peroxidase blocking reagent 3. ER/PR PharmDx Mouse anti Human ER Antibody Cocktail 4. ER/PR pharmDx Mouse Anti human PR antibody 5. ER/PR PharmDx Negative Control Reagent 6. ER/PR PharmDx Visualization Reagent 7. ER/PR PharmDx DAB+Substrtr ate Buffer 8. ER/PR PharmDx DAB+Chromo gen 9. User-Fillable Reagent bottle 12ml capacity 10. Wash Buffer (10x) 11. ER/PR PharmDx Control slides	neoplastic tissues that are formalin-fixed and paraffin-embeeded for histoloical evaluation.	
356.	-do-	**Legal manufacturer:**	HER2 IQFISH pharmDx™	FISH assay for quantitative	**Approved**

	Evaluator: Shahid Muhammad Iqbal	Dako Denmark A/S Building A, 1st floor, Produktionsvej 42, DK -2600 Glostrup, Denmark. (Subsidiary of Agilent technologies) **Manufacturing Site:** Dako Denmark A/S Building A, 1st floor, Produktionsvej 42, DK -2600 Glostrup, Denmark (FSC Denmark valid till 22 -02-2020)	K5731 HER2 IQFISH pharmDx™ Class C Shelf Life: 24 months. Rs.50,000/-	determination of *HER2* gene amplification in formalin-fixed, paraffin-embedded breast cancer and adenocarcinoma of stomach.	
357.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Dako Denmark A/S Produktionsvej 42, DK-2600 Glostrup Denmark. (FSC valid till 22-02-2020)	HercepTest™ for Automated Link Platforms Product code: SK001 Class C Shelf Life: 9 Fees submitted 50,000/-	Semi-quantitative immunocytochemical assay to determine HER2 protein over expression in breast cancer tissues and cancer tissue from patients with adenocarcinoma of the stomach	**Approved**
358.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Nantong EGENS BIOTECHNOLOGY CO., LTD Block A Fifteenth Factory-Building No. 1692 Xighu Avenue Nantong Economic & Technological	PERFECT HCG Pregnancy Test (Urine) Class B Shelf Life: 3 Years Strip I Type: 50 Test Kit/Box, 100 Test Kit /Box	Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic Gonadotropin	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary

		Development Zone, China (FSC Valid 19-12-2019)	Cassette I Type: 25 Test Kit/Box, 40 Test Kits/Box Midstream I Type: 1 Test Kits/Box, 25 Test Kit/Box	(HCG) in urine sample to aid in the early detection of pregnancy by both professional and home users.	MDB to issue registration certificate if recommend ed by the panel of inspectors
359.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Suzhou Lingyan Medical Technology Co., Ltd 99 Maopeng RD, Xujiang Industrial Park, Wuzhong District Suzhou, China. FSC Valid till 08-04-2022)	Perfect Disposable I.V. Catheter, Sterile (Sizes: 18G, 20G, 22G, 24G) Class B Shelf Life: 05 Years	Disoposable I.V. Catheter, Sterile	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the panel of inspectors
360.	M/s Aftab LifeCare Impex, 1st Floor Al-Falah Chambers Tilak Road Hyderabad. (ELI-00357) **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** EPS Bio Technology Corp No. 8 R&D III, Hsinchu Scien Park, Sinchu, T*aiwa*n. (FSC of Taiwan valid till 02-05-2023) **(FSC of Taiwan but not embassy attested)**	EASYMAX® EasyMax MU Self-Monitoring Blood Glucose System Class C **Shelf Life: 1 Year** Codes: • EasyMax MU Self-Monitoring Blood Glucose System, • EasyMax MU Blood Glucose meter x1, • EasyMax MU Blood Glucose Test Strips 10pcs x1,	EasyMax MU Self-Monitoring Blood Glucose System is intended for the measurement of glucose in fresh capillary whole blood and venous blood from fingertip, palm and forearm. It is indicated for self-testing by persons with diabetes, or in clinical settings by health care	**Approved** subject to provision of Stability data and Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the

			• Lancing Device x1, Lancets 10 pcs x1, • Normal Control solution x1, • EasyMax MU Blood Glucose Test Strips: 25 pcs, 50pcs (25pcs x2)	professionals, as an aid to monitor the effectiveness of diabetes control.	panel of inspectors
361.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** EPS Bio Technology Corp No. 8 R&D III, Hsinchu Scien Park, Sinchu, T*aiwa*n. (FSC Valid till23-09-2021) **(FSC of Taiwan but not embassy attested)**	EASYMAX® EasyMax Individual Foil Pack Blood Glucose Test Strips Class C Shelf Life: 24 Months EasyMax Blood Glucose Test Strips 25 pcs, 50 pcs (25 pcs x 2)	The EASYMAX® Series SMBG System is intended for the quantitative measurement of glucose in fresh venous blood and capillary whole blood sample drawn from the fingertip, palm and forearm. Testing is done outside the body (in vitro diagnostic use). It is indicated for self testing by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the panel of inspectors
362.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) **Evaluator:** Ms. Hira Bhutto	Legal Manufacturer: Jiangsu WeikangJiejing Medical Apparatus Co., Ltd. 18# Wenzhou Rd. Economical development	PERFECT FINE Disposable Nelaton Catheter (Urinary Catheter), Sterile Class B Shelf Life : 5 Years	Nelaton Catheter is used for drainage the urine from the bladder through Urethra.	**Approved.**

		district, Shuyang, 223600 Jiangsu, China. (FSC 10-07-2020) (FSC of Germany issued on 03-12-2018)	Codes: 6fr, 8fr, 10fr, 12fr, 14fr, 16fr, 18fr, 20fr		
363.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Jiangsu WeikangJiejing Medical Apparatus Co., Ltd. 18# Wenzhou Rd. Economical development district, Shuyang, 223600 Jiangsu, China. (FSC china 10-07-2020) (FSC Germany issued on 03-12-2018)	PERFECT FINE Disposable Feeding Tube (Ryle Tube), Sterile Class B Shelf Life : 5 Years Code: 4fr, 5fr, 6fr, 7fr, 8fr, 10fr	Feeding Tube is use to provide nutrition to patient who cannot obtain nutrition by mouth, or unable to swallow safely	**Approved.**
364.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Jiangsu WeikangJiejing Medical Apparatus Co., Ltd. 18# Wenzhou Rd. Economical development district, Shuyang, 223600 Jiangsu, China. (FSC China 10-07-2020) (FSC Germany issued on 03-12-2018)	PERFECT FINE Disposable Stomach Tube (Ryle Tube) Sterile. Class B Shelf Life : 5 Years Code: F6, F8, F10, F12, F14, F16, F18	Stomach Tube is inserted through a small incision in the abdomen into the stomach and is used to administer medications, absorbing gastric juice.	**Approved. The FSC from Germany was inadvertenely missed while typing.**

365.	M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi. (ELI-00001) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Peters Surgical-42 rue Benoit Frachon-93013 BoBigny Cedex-France. Manufacturing Site: Peter Surgical ZA Vague de la Noe 35682 Domalain France. (FSC of France issue 29-11-2018)	SLS-CLIP® Vitalitec Titanium Hemostatic Clip Class D Shelf Life: 5 years. Codes: As per FSC	The Titanium Haemostatic clip is intended to be used by clinically trained surgical staff. It can be used in every surgical specialty and for any patient when complete occlusion of a vessel or tissue is required, except for Fallopian Tube Ligation. Vitalitec® Appliers are intended for the loading, holding and optimal close of vitalitec® Hemostatic Clips.	**Approved**
366.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Peters Surgical-42 rue Benoit Frachon-93013 BoBigny Cedex-France. Manufacturing Site: Peter Surgical ZA Vague de la Noe 35682 Domalain France. (FSC of France issue 29-11-2018)	Clip 9 Vitalitec® Titanium Hemostatic Clip. Class D Shelf Life: 5 years (Sizes & Codes as Per FSC)	The Titanium Hemostatic clip is intended to be used by clinically trained surgical staff. It can be used in every surgical specialty and for any patient when complete occlusion of a vessel or tissue is required, eccep for fallopian tube ligation. Vitalitec® Appliers are intended for the loading,	**Approved**

				holding and optimal close of vialitec® Hemostatic clips.	
367.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** LSI Solutions INC. 7796 Victor-Mendon Rd. Victor, NY USA 14564. (FSC of USFDA Valid 01-10-2020)	COR-KNOT® QUICK LOAD® 6-Pouch (PN 030902) Class D Shelf Life: 3 Years	Use of Cor-Knot product family is to fasten and trim suture in general and cardiovascular surgical applications The COR-KNOT® QUICK LOAD® provides one sterile COR-KNOT® FASTNER held in a customized loading unit consisting of a purple target, a wire snare, and a blunt curved handle. Made from medical grade titanium, a COR-KNOT® DEVICE (or COR-KNOT MINI® DEVICE) to fasten together segments of suture.	**Approved**
368.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** LSI Solutions INC. 7796 Victor-Mendon Rd. Victor, NY USA	COR-KNOT® DEVICE Kit (PNs 030925 and 031105) Class D Shelf Life: 3 Years	Use of Cor-Knot product family is to fasten and trim suture in general and cardiovascular	**Approved**

		14564. (FSC of USFDA Valid 01-10-2020)	COR-KNOT® DEVICE Kit	surgical applications .Each Sterile package (kit) contains two 31 cm long single patient use COR-KNOT® DEVICES and twelve COR-KNOT® QUICK LOADS® (COMBO KIT) or two COR-KNOT® DEVICES only (DEVICE KIT). A COR-KNOT® FASTENER is loaded into the distal tip of the 5mm diameter shaft. A white handle and purple lever are located at the proximal end of the device. By squeezing the purple lever , the COR-KNOT® DEVICE Crimps the COR-KNOT® FASTNER at the closure site and can trim away excess suture tails.	
369.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** LSI Solutions INC. 7796 Victor-Mendon Rd. Victor, NY USA	COR-KNOT® QUICK LOAD® Single (PN 030950) Class D Shelf Life: 3 Years	Use of Cor-Knot product family is to fasten and trim suture in general and cardiovascular	**Approved**

		14564. (FSC of USFDA Valid 01-10-2020)	COR-KNOT® QUICK LOAD® SINGLES	surgical applications The COR-KNOT® QUICK LOAD® provides one sterile COR-KNOT® FASTNER held in a customized loading unit consisting of a purple target, a wire snare, and a blunt curved handle. Made from medical grade titanium, a COR-KNOT® DEVICE (or COR-KNOT MINI® DEVICE) to fasten together segments of suture.	
370.	M/s Life Cares Karachi, M-20 Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shah-rah-Faisal Karachi. (ELI-00077) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Rontis Corporation S.A., Bahnhofstrasse 7, CH-6301 Zug, Switzerland. (FSC Switzerland valid 30-5-2020)	Kyform™ Bone Expanding System Kyform™ Bone Expanding System Class B Shelf Life: 4 Years	The KYForm inflatable bone Expander system is designed to perform kyphoplasty to relieve pain due to vertebral compression fracture (VCF) through the use of a balloon Catheter. The device is intended to insert the bone cement into the cavity created by the balloon	**Approved** subject to provision of Stability data and Letter of authoriza-tion.

				in the fracture of the spinal bone	
371.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Rontis Corporation S.A., Bahnhofstrasse 7, CH-6301 Zug, Switzerland. (FSC of Switzerland valid 30-5-2020)	Triton™Family Peripheral Balloon Catheters Triton™Family Peripheral Balloon Catheters Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC)	Triton™Family Peripheral Balloon Catheters is a rapid exchange type balloon catheter. The distal part of the catheter is equipped with a semi-complaint balloon, inflatable at nominal pressure to a pre-determined diameter and length.	**Approved** subject to provision of Agency agreement.
372.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Rontis Corporation S.A., Bahnhofstrasse 7, CH-6301 Zug, Switzerland. (FSC Switzerland valid 30-5-2020)	Zeus CC™–Cobalt Chromium Balloon Expanding Peripheral Stent System-OTW Class C Shelf Life: 4 Years (Sizes & Codes as Per FSC)	Criteria for the use of Zeus® CC –Cobalt Chromium Balloon Expanding Peripheral Stent System are: An Atherosclerotic de-novo or restenosic lesion of the A. iliaca communis or extern, highA, femoralis and A.renalis.	**Approved** subject to provision of Agency agreement
373.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Rontis Corporation S.A., Bahnhofstrasse 7, CH-6301 Zug, Switzerland.	Zeus SX™Nitinol Self Expanding Peripheral Artery System OTW Class C Shelf Life: 2 Years	Zeus SX™Nitinol Self Expanding Peripheral Artery System OTW	**Approved** subject to provision of Agency agreement

		(FSC of Switzerland valid 30-5-2020)	(Sizes & Codes as Per FSC)		
374.	M/s Coral Pharmaceuticals , A-85, S.M.C.H.S Karachi (ELI-00065) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Dynek Pty Ltd of 9 Circuit Drive, Hendon, South Australia, 5014 Australia. (FSC issuance 27-08-2018)	Polypropylene (monofilament surgical suture) Class C Shelf Life: 5 Years	Monofilament Polypropylene Suture Surgical Procedures for tying off, ligation and/or tissue approximation, blue monofilament available in a range of thread lengths and diameters, according to surgical requirements	**Approved**
375.	M/s Ferozsons Laboratories Limited, P.O Ferozsons, Amangarh, Nowshera (KPK). (ELI-00120) **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland. (FSC Valid till 13-02-2020)	**VALITUDE™** Cardiac Re-Synchronization Therapy Pacemaker (CRT-P) Model: U125 Class D Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Active implantable medical device	**Approved**

376.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland. (FSC Valid till 13-02-2020)	**VIGILANT CRT-D** Cardiac Re-Synchronization Therapy Device (CRT-D) Model: G224, G225 Class D Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Active implantable medical device	**Approved**
377.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland.	**VIGILANT X4 CRT-D** Model: G228 G237:MR conditional G247:MR conditional G248 Class D Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Cardiac Re-Synchronization Therapy Device (CRT-D). Active implantable medical device	**The board approved** the model G228 and G248 and directed the firm to make separated application of MR Conditional

		(FSC Valid till 13-02-2020)			
378.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Legal Manufacturer:** Cardiac Pacemarkers Incorporated, a wholly owned subsidiary of Guidant Corporation, a wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112, USA. **Manufacturing Site:** Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland. (FSC Valid till 13-02-2020)	**VIGILANT EL ICD** Implantable Cardioverter Defibrillator (ICD) Model: D220: VR (single-chamber) D221: DR (dual-chamber) D232: VR (single-chamber: MR conditional) D233: DR (dual-chamber: MR conditional) Class D Shelf Life: 2 Years Fee submitted: Rs. 50,000/-	Active implantable Medical Device	**The board approved** the model D220:VR (Single Chamber) and directed the firm to make separated application for the rest of the model
379.	M/s IBL HealthCare Limited, First Floor, NICL Building, Abbasi Shaheed Road, Karachi (ELI-00119) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Dr. Gerhard Mann Chem-Pharm. Fabrik GmbH Brunsbutteler Damm 165-173 13581 Berlin, Germany (FSC Germany issuance 20-03-2019)	Bausch + Lomb Artelac Nighttime Gel Class C Shelf Life: 36 Months Fee submitted: Rs 50,000/-	Carbomer containing eye gel used as an eye lubricant to provide moistening and protection of the ocular surface in the presence of dry eye sensation	**Approved** subject to provision of EPSP
380.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Dr. Gerhard Mann Chem-Pharm. Fabrik GmbH Brunsbutteler Damm 165-173	Bausch + Lomb Artelac Advanced (Eye Drops) 30 single-dose vials of 0.5 ml solution	Hyaluronic acid 0.2%. For moistening eyes and contact lenses	**Approved** subject to provision of EPSP

		13581 Berlin. (FSC Germany issuance 20-03-2019)	Class C Shelf Life: 24 Months Fee submitted: Rs 50,000/-		
381.	M/s S. Ejazuddin & Co., Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del Valles, Barcelona, Spain. (FSC Spain Issue Date 31-01-2019)	Erytra Eflexis Class B Ref : 210600 Shelf Life:N/A Fee submitted: Rs, 50,000/-	Fully-automated analyzer designed to automate in-vitro immunohematological testing of human blood utilizing gel card technology	**Approved** in Class B subject to provision of Details of Manufacturing, QC and Operation manual
382.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del Valles, Barcelona, Spain. (FSC Spain Issue Date 31-01-2019)	DG Spin Class B Ref: 210363 Shelf Life: N/A Fee submitted: Rs, 50,000/-	Centrifugation of the DG Gel Cards	**Approved** as Class A subject to provision of Details of Manufacturing, QC and Operation manual
383.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del Valles, Barcelona, Spain. (FSC Spain Issue Date 31-01-2019)	DG Gel Coombs 50 cards Class C Shelf Life: 12.5 Months Fee submitted: Rs, 50,000/-	Performance of Coombs Direct and Coombs Indirect methods using gel technique	**Approved** subject to Stability studies and IFU
384.	-do- **Evaluator:** Ms. Unum Zia	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del	DG Therm Class B Ref: 213734	Incubator for Grifols gel cards and test tubes	**Approved** as Class A subject to Details of Mfg, QC

	Shamsi	Valles, Barcelona, Spain. (FSC Spain Issuance Date 31-01-2019)	Shelf Life: N/A Fee submitted: Rs, 50,000/-		and Operation manual
385.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del Valles, Barcelona, Spain. (FSC Spain Issue Date31-01-2019)	WADiana Compact Class B Ref: 213787 Shelf Life: N/A Fee submitted: Rs, 50,000/-	Fully automated analyzer designed to perform immunohematology tests with Grifol gel cards	**Approved** as Class B subject to provision of Details of Mfg, QC and Operation manual
386.	-do- **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** M/s Diagnostic Grifols S.A., Passeig Fluvial, 24, 08150, Parets del Valles, Barcelona, Spain. (FSC Spain Issue Date26-03-2018)	Serascan Diana 3 Class C Ref: 210206 3x10ml Shelf Life: 60 Days Fee submitted: Rs, 50,000/-	Reagent for detection of unexpected antibodies using the gel technique	**Approved** subject to provision of Stability studies and IFU
387.	M/s. Siemens Healthcare Pvt Ltd., 4th Floor, State Life Building 15-A, Sir Agha Khan Road, Lahore. ELI-00146 **Evaluator:** Ms. Unum Zia Shamsi	**Legal manufacturer** M/s. Siemens Medical Solutions USA, Inc. 2501 N. Barrington Road, Hoffman Estate, Illinois 60192, USA. FSC US FDA Valid till May 29, 2020	**Symbia Intevo** • Symbia Intevo Excel • Symbia Intevo Bold • Symbia Intevo 2 • Symbia Intevo 6 • Symbia Intevo 16 Class C Service life: 10 years Fee submitted: Rs. 50,000/- Copy of deposit slip no. 0530203 dated	SPECT/CT diagnostic imaging system	**Deferred.** The board deferred the case to Prof. Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi, Member MDB for his expert

			10.11.2016		opioion whether the applied models can be grouped as family in the light of MDR, 2017 or not ?
388.	-do- **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** M/s. Siemens Medical Solutions USA, Inc., 2501 N. Barrington Road, Hoffman Estates, Illinois, 60192 USA. FSC US FDA Valid till May 07, 2021	**Biograph, Vision** • Biograph Vision 600 • Biograph Vision 600 Edge • Biograph Vision 450 • Biograph Vision 450 Edge Class C Service life : 10 years Fee submitted: Rs. 50,000/-	PET / CT Diagnostic Imaging System	**Deferred.** The board deferred the case to Prof. Dr. Muhammad Nadeem Ahmad, Department of Radiology, Aga Khan University Hospital, Karachi, Member MDB for his expert opioion whether the applied models can be grouped as family in the light of MDR, 2017 or not ?
389.	M/s Pharma Supply Corporation. 49-J, Block-6, PECHS, Nursery Karachi. (ELI-00092) **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** Shantou Wealy Medical Instument Co., Ltd. North Jinhuan Road (Near Qishan Mid-School) Shantou. China (FSC Issuance 11-06-2019)	Wealy Saftey Syringe Automatically Retractable 3ml, 5ml, 10ml Class B Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Disposable automatically retractable safety syringe with needle	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to

					issue registration certificate if recommend ed by the panel of inspectorsa nd provision ofStability data and EPSP
390.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Yixing HBM Latex Production Co., Ltd No. 136 Yipu road Dinghsu Town Yixing city China. (FSC Issuance25-02-2019)	Medispo Surgical Gloves Class B Shelf Life: 05 Years Codes: 6.5, 7.0, 7.5, 8.0, 8.5 Rs.25,000/-	Surgical Gloves personal protection latex gloves used for surgical process.	**Approved** subject to Inspection abroad by the panel of inspectors. The board also authorized the secretary MDB to issue registration certificate if recommend ed by the panel of inspectorsa ndEPSP
391.	M/s Intra Health, 56A, Unit No.1, Justice Inamullah Road, Block 7/8, KCHS, Karachi (ELI-00049) **<u>Evaluator:</u>** Ms. Unum Zia Shamsi	**Manufacturer:** Mani, Inc., 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231, Japan **Manufacturing Sites:** i. Mani, Inc., 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231, Japan ii. Mani Hanoi Co., Ltd Tan huong	Manipler S-2 (Skin Stapler) Class B Shelf Life: 5 Years Fees submitted 50,000/	Disposable surgical skin stapler	**Approved**

		Commune, Pho Yen Town, Thai Nguyen Province, Vietnam. (FSC Japan Issue 11.11.2016)			
392.	M/s Trans Angio System, 507, Progressive Square, Block 6, P.E.C.H.S, Shahrah-e-Faisal, Karachi. (ELI: 00172) **Evaluator:** Ms. Unum Zia Shamsi	**Manufacturer:** Innotherapy Inc. #1206-1210, ACE hightechcity 2 25, Seonyu-ro 13-gil, Yeongdeungpo-gu, Seoul, Seoul Teugbyeolsi Korea, 07282 (FSC US FDA valid till 04-02-2021) (FSC Korea issue date 05-06-2018)	InnoSEAL Hemostatic Pad (Topical hemostatic pad) Box of 10 Class B Shelf life: 3 Years Fee submitted: Rs. 50,000/-	A sterile, hydrophillic lyophilized sponge pad for local management of bleeding wound. Applied topically as adjunct to manual compression	**Approved**
393.	M/s Medisurg Innovatives Health care, 1/6-N, Block -6, PECHS, Main Nursery, Shahrah-e-Faisal, Karachi. (ELI-00242) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-01-2022)	Dynamic Renal Dynamic Renal – Renal Stent System Class C Shelf life: 3 years Sizes and Codes As per FSC.	Dynamic Renal –Renal Stent System is intended for dilatation of stenosis segments in renal arteries in order to improve the arterial luminal diameter in patients with clinical symptoms attributable to artherosclerotic stenosis of the renal arteries	**Approved**
394.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180	Passeo-14 Passeo-14 Peripheral Dilatation Catheter	Passeo-14 Peripheral Dilatation Catheter is intended for the	**Approved**

		BulachCH.Switzerland (FSC valid till 28-03-2022)	Class B Shelf Life: 36 Months Sizes and Codes As per FSC	dilatation of stenosis segments in lower limb arteries (Not for use in coronary or cerebral vasculature)	
395.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-01-2022)	ORSIRO Sirolimus Eluting Coronary Stent System. Class D Shelf Life: 24 Months Sizes and Codes As per FSC.	The Orsiro product is intended to improve coronary blood flow through the reopening of coronary vessels.	**Approved**
396.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 18-01-2022)	Pantera Leo Pantera Leo Fast-Exchange PTCA Catheter. Class D Shelf Life: 3 years Sizes and Codes As per FSC.	The Pantera Leo is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion and for post dilatation of coronary stents.	**Approved**
397.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-	Pro-Kinetic Energy (Coronary Stent System) Class D Shelf Life : 36 Months	Pro-Kinetic Energy Consists of a cobalt chromium alloy (L605), Balloon expandable stent mounted	**Approved**

		01-2022)	Sizes and Codes As per FSC.	on a fast exchange delivery system. It is intended as a permanent implant to improve the luminal diameter of obstructed coronary arteries	
398.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 08-01-2022)	Pulsar-35 Pulsar-35 Peripheral Self Expanding Nitinol Stent System. Class D Shelf Life: 3 years Sizes and Codes As per FSC	Pulsar-35 Peripheral Self Expanding Nitinol Stent System is to improve the luminal diameter of obstructed femoral and proximal popliteal artieries (SFA and Proximal PA).	**Approved**
399.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 25-01-2022)	Passeo-18 Lux Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter Class D Shelf Life: 24 Months Sizes and Codes As per FSC	Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter is intended for dilatation of stenosis segments in infrainguinal ateries with simultaneous release of Paclitaxel to the vessel wall in order to reduce occurrence of a restoenosis of the treated vessel segment	**Approved**

400.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 18-01-2022)	Pantera Lux (Pantera Lux paclitaxel releasing PTCA Balloon Catheter Class D Shelf Life: 24 Months Sizes and Codes As per FSC.	The Pantera Lux Catheter is intended for the treatment of coronary arteries with simultaneous release of Paclitaxel to the vessel wall.	**Approved**
401.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-01-2022)	Pulsar -18 Pulsar-18 Peripheral Self Expanding Nitinol Stent System Class D Shelf Life: 36 Months Sizes and Codes As per FSC	Pulsar-18 Peripheral Self Expanding Nitinol Stent System is indicated for use in patients with artherscleros is disease of the femoral and infrapopliteal arteries and for the treatment of insufficient results after percutenous transluminal angioplasty (PTA). Eg residual stenosis and dissection	**Approved**
402.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-01-2022)	PK Papyrus PK Papyrus Covered Coronary Stent System Class D Shelf Life: 24 Months Sizes and Codes As per FSC.	The PK Papyrus Covered Coronary Stent System consists of a balloon-expandables covered stent, premounted on a fast-exchange delivery system. It is intended to seal	**Approved**

				acute coronary perforations and acute coronary artery ruptures in native coronary vessel	
403.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-01-2022)	Passeo-18 Passeo-18 Peripheral Dilatation Catheter Class B Shelf Life: 36 Months Sizes and Codes As per FSC	Passeo-18 Peripheral Dilatation Catheter are intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae (Not for use in coronary or cerebral vasculature)	**Approved**
404.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 09-01-2022)	Passeo-35 Passeo-35 Peripheral Dilatation Catheter Class B Shelf Life: 36 Months Sizes and Codes As per FSC.	Passeo-35 Peripheral Dilatation Catheter are intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae (Not for use in coronary or cerebral vasculature)	**Approved**
405.	-do- **<u>Evaluator:</u>** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland	Pantera Pro Pantera Pro Coronary Dilatation Catheter Class D Shelf Life : 3 years (Sizes and Codes	Pantera Pro is intended to be used for dilatation of stenotic segments in coronary arteries or	**Approved**

		(FSC of Switzerland valid till 18-04-2022)	As per FSC)	bypass graft. The dilatation balloon is designed to inflate to a known diameter and length at recommended inflation pressure.	
406.	-do- **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Biotronik AG, Ackerstrasse 6, 8180 BulachCH.Switzerland (FSC valid till 11-01-2022)	Dynamic Dynamic Peripheral Stent and Delivery System. Class D Shelf Life: 2 years Sizes and Codes As per FSC	Dynamic Peripheral Stent and Delivery System. The dynamic is intended to improve the luminal diameter of obstructed iliac arteries	**Approved**
407.	M/s Musaji Adam & Sons, C-285, Block 10, Federal B Area, Karachi. (ELI-00239) **Evaluator:** Ms. Hira Bhutto	**Legal Manufacturer:** Medical Wire &Euipement, Leafield Industrial Estate, Corsham, SN13 9RT, United Kingdom (FSC issuance 27-03-2019)	Transwabs Prepared Culture Media Class B Shelf Life: 2 Year Size & Codes as per FSC	Transwab specimen collection and transport system is intended to preserve the viability and infectivity of microbiological speeciman after their collection and during transport from the collection site to the testing laboratory. Transwabs are processed using standard clinical laboratory procedures	**Approved**

==========