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

MINUTES OF THE 14TH MEETING OF THE MEDICAL DEVICE BOARD (MDB) HELD ON 11-10-2019

14th 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 11thOctober, 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.Muhammad Naeem, Additional Director, Directorate General Health Services, Lahoreto preside over the meeting as Chairman. Subsequently meeting was chaired by Dr. Muhammad Naeem, Additional Director, Directorate General Health Services, Lahoreand was attended by the following:-

S.No.	Name and Designation / Department	Position in the MDB
1.	Dr. Muhammad Naeem, Additional Director, Director General Health Services, Lahore. (Nominee of Director General Health, Punjab).	Chairman
2.	Mr. Imranullah, Chief Drug Inspector, Abbottabad, KPK, (Nominee of Director General Health, Khyber Pukhtunkhwa).	Member
3.	Brig (R) Dr. Waqar Asim Niaz, Consultant Urologist & Transplant Surgeon, Quaid-e-Azam International Hopspital, Golra More, Islamabad.	Member
4.	Mr. Muhammad Tahir Aziz, Chief Operating Officer, Shaukat Khanum Memorial Cancer Hospital & Research Centre, Peshawar.	Member
5.	Dr. Muhammad Farid Khan,Director Emegency Services, District Kasur.	Member
6.	Professor Dr. Ejaz Hassan Khan, Principal North West School of Medicine, Peshawar.	Member

7.	Mr. Muhammad Asghar, CEO, Cyber Soft Technologies, Lahore.	Member
8.	Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad.	Secretary / Member

The meeting commenced 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 13TH MEDICAL DEVICE BOARD MEETING.**

Decision: The Board confirmed the minutes of the 13th meeting of MDB.

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

The following firms have applied for grant of Establishment License to import medical devices under MDR, 2017 for which inspection panels were constituted for inspection of their establishments. The inspections were conducted according to the Checklist. Recommendations were placed before the MDB for consideration.

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

S.No	Name of Establishment	Director/Proprietor/ Partners	Name of panel Inspector (s)	Cold Chain (Yes/No)	Decision
1.	M/s NHK Healthcare, Plot No.63-C, Office No.4, 2nd Floor, 12th Commercial Street, DHA Phase-II Ext., Karachi.	Dr. Narish Kumar Mr. Muhammad Danish Butt,	Dr. Ghazanfar Ali Khan, Additional Director (MDMC), DRAP, Islamabad. Mr. Awais Ahmed, FID, DRAP, Karachi.	No.	**Approved**for room temperature medical devices without cold chain facility subject to verification of warehouse facility having appropriate size. It was informed to the Board that the size of the warehouse is 10x10 feet which is less for the import of syringes. The Board also authorized the Secretary to issue ELI after

					confirmation of additional warehouse of appropirate size.
2.	M/s Onyx International, M1, 107C, Ayesha Arcade, Khalid Bin Waleed Road, PECHS Block-2, Karachi.	Mr. Jawad Saleem Mr. Fawad Shaikh	Mr.Shahid Muhammad Iqbal, Assistant Director-III (MD&MC), DRAP, Islamabad. Mr. Awais Ahmed, FID, DRAP, Karachi.	No.	**Approved** for room temperature medical devices without cold chain facility.
3.	M/s Vision Pharma Network,E-2, 1st Floor, Block-A, Gulshan-e-Jamal, Dalmia, Karachi.	Mr. Sohail Ahmed Keshwani	-do-	No.	**Approved** for room temperature medical devices without cold chain facility subject to Provision of DSL.
4.	M/s Molecular Products Co, Office No. 208, 2nd Floor, Nafees Arcade, Plot No. SC-14, Opp. Askari Park, University Road, Karachi.	Mr. Riaz Ahmed	-do-	No.	**Approved** for room temperature medical devices without cold chain facility subject to verification of warehouse facility having appropriate size.
5.	M/s Karachi Medical Company, B-47, Al-Hilal Society, University Road, Karachi.	Mr. Tariq Mirza	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
6.	M/s Medicraft International, M-1, 107/D, West View Apartment, Khalid Bin Waleed Road, Block-2,PECHS, Karachi.	Mr. Shiekh Haris Hameed	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
7.	M/s S.M Impex, Office# B-309, 3rd Floor, New Challi Trade Centre, Shahrah-e-Liaquat,	Mr. NisarAkhtar	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.

	Karachi				
8.	M/s Zaman Enterprises & Diagnostic, Shop No.G-31, Ground Floor, Orison Tower, Block-10, KDA Scheme No.24, Gulshan-e-Iqbal, Karachi.	Mr. Akhtar Zeb	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
9.	M/s AMS Medraf, Office No. 3, 3rd Floor, 37-C, Lane No. 8, Bukhari Commercial Area, Phase VI, DHA. Karachi.	Mr. M. Rafiq Mst. Mishal Waleed Shah	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
10.	M/s Summit Inter Trade, R-142 Sir Syed Road, Block No. 2, PECHS, Karachi.	Mr. Shams Abbas Hasan Bilgrami	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
11.	M/s Medline Technologies (Pvt) Ltd, 95G, Block 2, PECHS., Off, Shahrah-e-Quaideen, Karachi.	Mr. Muhammad Fahim Mr. Muhammad Qaiser Ameen Mr. Muhammad Faizan Qaiser	-do-	No.	**Approved**for room temperature medical devices without cold chain facility**subject to** verification of warehouse facility having appropriate size.
12.	M/s Reckitt Benckiser Pakistan Limited, 3rd Floor, Tenancy – 04and 05, Corporate Office Block Dolmen City, HC3, Block 4, Scheme-5, Clifton, Karachi	Mr. Fahad Ashraf	-do-	No.	**Rejected** due to inappropriate control of temperature and humidity. The qualified person mentioned on DSL has also resigned.

13.	M/s Premier Agencies, 60 Muslimabad, Jamshed Quarters, , M.A. Jinnah Road Extension, Karachi. **Addition of new Godown in ELI-00050:** Plot No.D-3, D-4, D-5,sector 6-F Mehran Town, Karachi.	Mr. Ebrahim Qasim Mr. Salman Qasim Mr. M. Idrees	-do-	No.	**Approved**the addition of new warehouse at Plot No.D-3, D-4, D-5,sector 6-F Mehran Town, Karachi for room temperature medical devices without cold chain facility.
14.	M/s A.J & Company, Mandviwala Chambers, Talpur Road, Karachi.	Mr. Inayat Ullah Khan Mr. Zia Ullah Khan	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
15.	M/s Getz Pharma, 29-30/27, Korani Industrial Area, Karachi.	Mr. Khalid Mahmood	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.
16.	M/s Bright Vision, Suit No 103, 1st Floor, Fine Center Commercial, Block-V, Gulshan-e-Iqbal, Karachi.	Mr. Muhammad Mazhar Ismail Mr. Umair Bin Asrar	-do-	No.	**Approved** for room temperature medical devices without cold chain facility.

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

The below mentioned firm has applied for grant of Establishment License to manufacture medical devices under MDR, 2017 for which inspection panel was constituted for inspection of their establishment. The information about the firm and recommendations of the panel are submitted for consideration of MDB please:-

S.No	Name of	Address	Name of Qualified	Name of QC	Inspection panel & date of	Recommenda-

	Establish-ment		Person	Incharge	inspection	tions
1.	M/s Atco Laboratories Limited	**Factory Address:** 18, S.I.T.E, Karachi.	Mr. Ali Mustafa (Production Incharge)	Ms. Saeema Shahid (QC Incharge)	**Dr. Ghazanfar Ali Khan,** Additional Director MDMC, DRAP. **Mr. Sajjad Ahmed Abbasi,** FID, DRAP, Karachi. **Mr. Awais Ahmed,** Assistant Director/FID, DRAP, Karachi.	Based on the areas inspected, the people met and their positive intentions towards improvement, the documents reviewed, and considering the findings of the inspection M/s Atco Laboratories Pvt. Ltd is recommended for grant of Establishment Licence to manufacture medical devices in **Liquid Soap** and **Liquid Surfactant Sections.**
Decision: Approved the Establishment License to Manufacture Medical Devices alongwith following Sections:- **(i) Liquid Soap.** **(ii) Liquid Surfactant.**						

Item No. IV. **APPLICATION 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 establishment. The information about the firm/company and recommendations of the panel are submitted for consideration of MDB please:-

S.No	Name of Establish-ment	Address	Name of Qualified	Name of QC	Inspection panel & date of	Recommendations

			Person	Incharge	inspection	
1.	M/s Usman Enterprise	Plot No. A/116, S.I.T.E., Highway, Phase-I, Karachi.	Mr. Shahzad Hussain Qureshi (Production Manager)	Ms. Lubna Erum Siddiqui	Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi. Dr. Mehwish Taznveer, Assistant Director, DRAP, Karachi. Mrs. Unum Zia Shamsi, Assistant Director (MDMC), DRAP, Islamabad.	Based on the stated observations, submission of work-plan by the firm and strong commitment for continuous improvement, the panel recommends the grant of renewal of their DML No.000656 (Formulation) (Establishment License to manufacture medical devices) as per the Medical Devices Rules, 2017 to MDB for grant of Establishment Licence to Manufacture Medical Devices in First Aid Bandages and Surgical Tapes Section
Decision: Approved the Renewal of Establishment License to Manufacture Medical Devices alongwith following Sections. The firm has surrendered the Drug Manufacturing Licence and a fresh Establishment Licence to Manufcture Medical Devices shall be issued. **(i) First Aid Bandage.** **(ii) Surgical Tape.**						

Item No. V. **APPLICATION 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 establishment. The information about the firm/company and recommendations of the panel are submitted for consideration of MDB please:-

S.#	Name of Establish-	Address	Name of Qualified	Name of QC	Inspection panel & date	Recommendations

	ment		Person	Incharge	of inspection	
1.	M/s Uniferoz (Pvt) Ltd.	32/8 & 33/2, Sector-15, Korangi Industrial Area, Karachi.	Nazneen Merchant (Production Incharge)	Ms.Tajwer Siraj	Mr. Sajjad Ahmed Abbasi, FID, DRAP, Karachi. Dr. Mehwish Taznveer, Assistant Director, DRAP, Karachi. Mrs. Unum Zia Shamsi, Assistant Director (MDMC), DRAP, Islamabad.	Based on the stated observations, the panel recommends the grant of renewal of their DML No.000515 (Formulation) (Establishment License to manufacture medical devices) as per the Medical Devices Rules, 2017 to MDB for grant of Establishment Licence to Manufacture Medical Devices in Bandages and Surgical Tapes/Dressings Section.
Decision: Approved the Renewal of Establishment License to Manufacture Medical Devices alongwith following Sections. The firm has surrendered their Drug Manufacturing Licence and a fresh Establishment Licence to Manufcture Medical Devices shall be issued. **(i) Bandages.** **(ii) Surgical Tape/Dressing.**						

Item No. VI . **<u>APPROVAL OF TECHNICAL PERSON OF MARTIN DOW MARKER SPECIALITIES (PVT) LTD, KARACHI FOR THEIR WAREHOUSE BASED AT LAHORE.</u>**

M/s Martin Dow Marker Specialities (Pvt) Ltd, Karachi have stated that they have received Establishment Licence (ELI-00160) on 19th October, 2018 to import medical devices for their Karachi Warehouse and approval of Lahore Warehouse without mentioning the name of qualified person. **The firm has requested that the name of qualified person (Mr. Ali Raza Butt S/o Khalid Mehmood But, holding CNIC No.35202-1664131-3) may be approved for their Lahore Warehouse.**

It is submitted that the firm had applied for inclusion of Warehouse of Lahore pertaining the address 75/1-M, Industrial Estate, Township Kot Lakhpat , Lahore. After inspection of Warehouse, the case was placed before the MDB in its **12th meeting** and the Board approved the request of the firm. Decision of the MDB was conveyed to the firm. But the name of **qualified person was inadvertently missed on approval letter.**

Letter to firm conveying the approval of their qualified person for Lahore Warehouse namely Mr. Ali Raza Butt S/o Khalid Mehmood But, holding CNIC No.35202-1664131-3 resident of House No.20, Street No.9, Sultan Mehmood Road, Green Park, Tehsil Shalimar Town, Lahore has been issued.

Case is submitted for ratification of MDB please.

Decision: The MDB ratified and approved the letter issued to M/s Martin Dow Marker Specialities (Pvt) Ltd, Karachi for their qualified person of Lahore Warehouse namely Mr. Ali Raza Butt S/o Khalid Mehmood But, holding CNIC No.35202-1664131-3 resident of House No.20, Street No.9, Sultan Mehmood Road, Green Park, Tehsil Shalimar Town, Lahore.

Item No. VII. <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	Remarks
1.	Sapphire NC Coronary Dilatation Catheter	074674	01-01-2014	
2.	"Sapphire II (Rx)" Coronary Dilatation Catheter	074675	01-01-2014	The firm submitted 04 months late renewal application without additional fee of 100,000 PKR/- and now intends to deregister the product.

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

Item No. VIII. EXEMPTION FROM LABELING REQUIREMENTS UNDER MDR, 2017.

M/s Premier Agencies, Karachi informed that their medical device namely BD Micro-fine TM+Pen Needle (4, 5 and 8mm) has been registered (Registration No.MDIR-0000488, -0000489 and -0000487) 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 labeling requirement as per MDR, 2017. They have further stated that the relabeling of commercial product is a complex and time consuming job and need ample time to consume the existing labels and initiate the new labeling. 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 labeled as per Labeling Rules, 1986 hence need revision only at some points which include but 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 license owner will perform the additional labeling activity at their premises until 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 labeling 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 labeling 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 39

Location of labeling 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 packedtogether as one package, it may be appropriate to provide only a single copy of the label but more copies shall be supplied upon request.*

The Firm requests for the grant of exemption from labelling requirement till December, 2020 as per Rule 38(3) or grant permission for relabelling as per Rule 38 (2) of MDR, 2017.

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 inner and outer pack of their medical devices anemly BD Micro-fine TM+Pen Needle (4, 5 and 8mm) has been registered (Registration No.MDIR-0000488, 0000489 and 0000487) for a period of 12 months subject to the quality of printing on sample of inner and outer pack to be verified by Medical Device Division.

Item No. IX **CORRECTION OF BRAND NAME OF FLASHCAST FIBERGLASS BANDAGE CAST TAPE (ENLISTMENT NO.MDIE-0000010).**

M/s BSN Medical, Karachi has requested for correction of brand name and shelf life of their following enlisted medical devices for import:-

Enlistment No.	**Existing Brand Name of Medical Device**	**Approved Shelf Life**
Enlistment No. MDIE-0000010)	Flashcast Fiberglass Cast Bandage Tape	5 years

It is submitted that the brand name of above mentioned medical device was mentioned "Flashcast Fiberglass Cast Bandage Tape" inadvertently while the correct name is "Flashcast Fiberglass Cast Tape". Further the shelf life of the above mentioned medical was also mentioned 5 years instead of 3 years.

Decision: The MDB considered the request of the firm and approved the correction in brand name as "Flashcast Fiberglass Cast Tape" and 3 years shelf life instead of 5 years.

Item No.X. CHANGE OF QUALIFIED PERSON (QUALITY CONTROL MANAGER) OF M/S UNISA (PVT) LTD DISTRICT NOWSHERA.

M/s Unisa (Pvt) Ltd., Nowshera have requested for change of their quality control manager as per details given below:-

Pervious Quality Control Manager	**Current Quality Control Manager**
Mr. Ehsan Ullah (Pharmacist)	Mr. Fiaz Arshad (Pharm. D)

They have informed that their technical staff has resigned on 10th August 2019. The firm has submitted following documents:-

(i) Resignation Letter of Pervious Quality Control Manager.

(ii) Letter of Appointment of newly appointed Quality Control Manager .

(iii) Academic Documents

(iv) Experience Letter of newly appointed Quality Control Manager.

(v) Requisite Fee of Rs.50,000/-

Submitted for consideration of MDB please.

Decision: **The Board acceeded to the request of the firm /company and approved the change of qualified person(Quality Control Manager) from Mr. Ehsan Ullah (Pharmacist)to Mr. Fiaz Arshad (Pharm. D).**

Item No. XI.CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP) FOR ESTABLISHMENT MANUFACTURING MEDICAL DEVICES.

Under rule 6(2) (J) of Medical Devices Rules, 2017, the licensee shall comply with the requirements and the conditions in rspect of good manufacturing practices in the manufactur and quality control of medical devices.

Under rule 63 (3) of Medical Devices Rules, 2017, the Authority may, on the recommendation of MDB, amend Schedules A, B and D and the Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein

Therefore, a Form namely, **"Form-3A Certificate of Good Manufacturing Practice** is placed below for consideration of MDB:-

Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
2nd Floor, Telecom Foundation Complex,
Mauve Area, G-9/4, Islamabad
****

FORM-3A

[See rule 6(2) (j), 63(3)]

Certificate No.

Islamabad, the 20

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

It is certified that _____holding Establishment License to Manufacture Medical Devices Number _____is authorized to produce medical devices. I certify that the site indicated on this certificate complies with Good Manufacturing Practices (GMP) in terms of process control, maintenance of equipments, documentation and areas etc, as per provision of Medical Devices Rules, 2017 for following category of medical devices / section(s).

S No:	Name of Approved Areas

2. This certificate is based on the inspection and evaluation conducted on _____.

- This certificate is valid for one year from the date of issuance.
- The responsibility to maintain quality as per Good Manufacturing Standard throughout the period of validity of this certificate of the individual batches of the medical device manufacturing processes lies with the manufacturer.
- This certificate permits the firm to apply for registration of their products, manufactured as per Good Manufacturing Practices (GMP) under Drugs Regulatory Authority of Pakistan, in the importing country.
- The validity will automatically seize in case of reporting of non-compliance of Good Manufacturing Practices (GMP) under the Medical Devices Rules, 2017.

Name of certifying authority: **Secretary Medical Device Board**

Signature _____

Stamp: **----------**

Decision: **The Board recommended the FORM-3A, namely, Certificate Of Good Manufacturing Practices of Medical Device for the approval of the Authority.Board also recommended that training of technical staff of the Division regarding inspections (GDP/GMP) of establishments of medical devices shall be arrangedon priority basis.**

Item No. XII. **CERTIFICATE OF FREE SALE OF MEDICAL DEVICES (FSC)**

Under rule 63 (3) of Medical Devices Rules, 2017, the Authority may, on the recommendation of MDB, amend Schedules A, B and D and the Forms so as to omit any entry therefrom, add add entry thereto or amend any entry therein

Therefore, a Form namely, **"Form-8D Certificate of Free Sale of Medical Devices (FSC)** is placed below for consideration of MDB:-

Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan
2nd Floor, Telecom Foundation Complex,
Mauve Area, G-9/4, Islamabad
****

FORM-8D
[See rule 63(3)]
Certificate No.

Islamabad, the 20

CERTIFICATE OF FREE SALE OF MEDICAL DEVICES (FSC)

In order to allow the exportation of Islamic Republic of Pakistan's medical devices into foreign countries, the Drug Regulatory Authority of Pakistan certified the following information concerning the medical device(s) to be exported listed below:-

S.No.	Reg.No./ Enlitment No.	Name of Medical Device(s)	Brief Description	Name of Legal Manufacturer/ Contract Manufacturer/Manufacturing facility(ies)

The medical devices described above (and the manufacturing site (s) which produces it) is subject to the jurisdiction of the Drug Regulatory Authority of Pakistan under Medical Devices Rules, 2017.

It is certified that the above medical device(s) may be marketed in, and legally exported from, the Islamic Republic of Pakistan. The manufacturing facility(ies) in which the medical device(s) are produced is subject to periodic inspections. The last such inspection conducted on ---------- showed that the facility(ies) was/were in substantial compliance with current good manufacturing practice requirements for the medical device(s) listed above.

The present certificate is issued at the request of the firm in order to be submitted to the health authorities of ----------(country name).

This certificate is valid till two years from the date of issue.

Name of certifying authority: **Secretary Medical Device Board**

Signature **----------**

Stamp: **----------**

Decision: The Board recommended the FORM-8D, namely, Certificate of Free Sale of Medical Devices (FSC) for the approval of the Authority.

ITEM NO. XIII: REGISTRATION AS AN INDENTER UNDER RULE 72(1) OF MEDICAL DEVICES RULES, 2017.

M/s Muller & Phipps (Pvt) Ltd has submitted an application addressed to Additional Director (MD&MC) / Secreatary MDB requesting for Registration as an Indenter under Rule 72(1) of Medical Devices Rules, 2017. The extract of the letter is as under:

"We carry out all kind of operations for Johnson & Johnson Pakistan (Pvt) Ltd. As an authorised representative related to Marketing, Import, Sales, Storage & Distribution for their complete range of products

from last many years. Johnson & Johnson authorized M&P as distributor / indenter for importation of medical devices (see enclosed).

That Rule 72(1) of the Medical Devices Rules, 2017 states that medical devices may be imported through an indenter registered by the MDB. Muller & Phipps intends to import medical devices on behalf of M/s Johnson & Johnson as an authorize agent / distributor in Pakistan in order to ensure the continuous availability and accessibilioty of quality products for the patients & health care professionals. We request you to register us an an indenter for import of J&J medical devices on the basis of our long experience and fulfilling compliance requirements entrusted us by the Medical Device Board DRAP vide issuing Form-4.

We, Muller & Phipps Pakistan being medical devices importer and indenter shall be responsible to follow the essential principle of safety & performance of medical devices and complies with post market surveillance and any regulatory matter if ask by the MDB. We also take full responsibility for post marketing surveillance and pharmacovigilance system under guidance of Johnson & Johnson technical team and as per Medical Devices Rules requirements."

In 13th Meeting of MDB held on 05-08-2019, Muller & Phipps Pakistan (Pvt) Ltd made a similar request which was placed before the MDB for decision but was deferred due to comments / opinion of Dr. Abdul Haleem Khan, member MDB. The case along with decision is herein below:

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.

After the finalization of the minutes the following comments / opinion of Prof. Dr. Sajid Bashir was also received to include in 13th MDB meeting:

> *Refer to delibration made in 13th MDB meeting and above said facts and discussion, In my Opinion:-*
>
> *a) It is the Power of Federal Government to make rules for Indent under Section 43(1) of the Drugs Act, 1976.*
> *b) Under section 23 of the DRAP Act, 2012, Authority, with the approval of Federal Government, may make rules for carrying out the purposes of the Act.*
> *c) Furthermore, under rule 72 of MDR, 2017, such provision of indenting is specific to charitable or non-profit purposes and cannot of sold commercially. M/s Muller & Phipps has applied as commercial indentor. Therefore, does not comes under the scope of said rules.*
> *d) In addition to Facts Stated by worthy Dr. Haleem Khan, Member MDB, I would further like to add that Federal Government is also taking measures for Taxation and matters related to flow of cash in line with Financial Action Task Force recomendation. Therefore, this matter should also be referred to Finance Division and Ministry of Law & Justice to seek their opinion and legal obligations.*

Therefore, on such ground I am off the opinion that we may refer the matter to Authority to prescribe condition for indenting for all therapeutic goods including framing of rules approved by Federal Government after consultation with Finance Division & Ministry of Law & Justice. Till such time we may deferred the application of M/s Muller & Phipps.

Decision: Two MDB members, namely, Dr. Abdul Haleem Khan and Prof. Dr. Sajid Bashir who had reservations regarding indenting were not present in the meeting due to their pre-occupation, therefore the matter was deferred for discussion in coming MDB meeting .

Item No. XIV. RENEWAL OF LOCAL REGISTRATION OF MEDICAL DEVICES

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

Sr No.	Name and Address of Firm	Name of Medical Device	Brief Description/ Shelf Life/ Class of MD	Remarks
1.	M/s The National Absorbent Cotton Mills Co. A-37, S.I.T.E Manghophir Road, Karachi. **Evaluator: Ms. Hira Bhutto**	Guzae Swab/Spong U.S.P Type IV Sterile Guaze Swab/Sponge/Pad Size: 10 x 10 cm (4" x 4") 8 ply	Guaze Swab/Sponge/Pad Size: 10 x 10 cm (4" x 4") 8 ply Class B 3 Years **Rs.25,000/-**	• Proof of fee endorsement on covering letter required • Stability data required
2.	-do- **Evaluator: Ms. Hira Bhutto**	Eye Pad Sterile 100% Cotton Gauze Bandage Cloth	Eye Pad Sterile Class B 3 Years **Rs.25,000/-**	• Proof of fee endorsement on covering letter required • Stability data required
3.	-do- **Evaluator: Ms. Hira Bhutto**	X Ray Detectable Gauze Sponge Sterilzed X-Ray Detectable Gauze Sponge USP Type IV Sterilized	First Aid Bandage Class B 3 Years **Rs.25,000/-**	• Proof of fee endorsement on covering letter require • Stability data require •
Decision:	**The Board approved the renewal of above mentioned medical devices of M/s The National Absorbent Cotton Mills Co., Karachi subject to GMP inspection and provision of proof of fee endorsement on covering letter and submission of stability studies data.**			

Item No. XV. 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 each:-

S. No	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Decision
1.	M/s Life Cares Karachi, M-20 Mezzanine Floor Falaknaz Plaza Natha Khan Bridge, Shahrah-e-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)	Cronus™ Family Peripheral Balloon Catheters Cronus™ Family Peripheral Balloon Catheters Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC) **Rs.50,000/-**	The Balloon Catheter is intended for PTA Procedure on Atherosclerotically obstructed vessels. The catheter has been designed with a double lumen shaft. At the distal tip of which the balloon is welded.	**Approved** subjeect to provision of valid agency agreement.
2.	M/s Medinostic Healthcare (Pvt) Limited, B-18, SITE, Karachi (ELI-00012) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Pal International Limited, Bilton way Lutterworth Leicestershire LE17 4JA. (FSC issuance 29-05-2019)	Medipal® Hand Disinfectant Hand Disinfectant Class C Shelf Life: 2 Years **Rs.50,000/-**	Medipal® Hand Disinfectant	**Approved.**
3.	M/s Pharma Supply Corporation. 49-J, Block-6, PECHS, Nursery Karachi. (ELI-00092)	**Legal Manufacturer:** Shanghai Kinmed Import & Export Co., Ltd. Suit L, 12th Floor, No. 588 Yingkou	KinmedDisposable Syringe 3ml, 5ml, 10ml, 20ml Class B Shelf Life: 5 Years	Disposable Syringe	**Approved** subjet to inspection of manufacturer abroad under Rule 71 of MDR, 2017

	Evaluator: **Ms. Hira Bhutto**	Road, Shanghai. China. (FSC Issuance20-09-2018)	**Rs.25,000/-**		and provision of Stability data.
4.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** Shanghai Kinmed Import & Export Co., Ltd. Suit L, 12th Floor, No. 588 Yingkou Road, Shanghai, China. (FSC Issuance20-09-2018)	Kinmed Infusion Set (ST /SP, IV Burette) 100ml. Class B Shelf Life : 5 Years (Sizes & Codes as Per FSC) Infusion Set. ST /SP, IV Burette 100ml (Certificate No. 20150212) **Rs.25,000/-**	Infusion Set. ST /SP, IV Burette 100ml.	**Approved** subjet to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data.
5.	M/s Nisa Impex (Private) Limited., Maxim Arcade, Plot No. 13-14, Usman Block, Jeddah Town, Phase I, Opp. DHA-II, G.T. Road, Islamabad (ELI-00064) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Chengdu Xinjin & Instrument Co. Ltd., Room No.30, 3rd Floor, A2 Building, Tianfu Life Science Park, No.88, South Keyuan Road, Chengdu, P.R. China. (FSC Issuance20-09-2018)	Nisa Auto Disable Syringe (Self Destructive Disposable Syringe with Needle) Sizes: 1ml, 2ml, 5ml, 10ml Needle Size: 0.4, 0.45, 0.5, 0.55, 0.6, 0.7, 0.8, 0.9 Class B Shelf Life : 5 Years **Rs, 25000/-**	Syringe	**Approved** subjet to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision original Notraized FSC.
6.	M/s ACP Systems, 13 & 23 Naval Fleet Club, Iqbal (SJ) Shaheed Road, Karachi (ELI-00001) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA (FSC Valid till 22-08-2022)	Mobile Power Unit – 107754/ (107758)/(107758UK) (Accessories used for Heartmate II (LVAS) Class D Shelf Life: N/A **Rs.50,000/-**	External Component (Power Source) The Mobile power unit is for home or clinical use when the patient does not require monitoring using the system monitor. The mobile power	**Approved** as class A medical device instead of class D.

				unit is used when the patient is indoors, stationary or sleeping as a sleeping patient may not hear low battery power alarms.	
7.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA (FSC Valid till 22-08-2022)	HeartMate II Sealed Outflow Bend Relief Collar -107315 Implantable Component Class D Shelf Life : 3 Years **Rs.50,000/-**	Implantable Component The collar is intended for use with HeartMate II sealed outflow Graft during the HM-II LVAS implant procedure and intended to secure the connection between the sealed outflow Graft and bend relief.	**Approved.**
8.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA (FSC Valid till 22-08-2022)	Shower Bag (Pocket Controller) -104232 (Acessories (Paitent Wearable) Class D Shelf Life: N/ A **Rs.50,000/-**	(Acessories (Paitent Wearable) The shower bag is used to protect external system components from water or moisture.	**Approved** as class A medical device instead of class D.
9.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** LSI Solutions INC. 7796 Victor-Mendon Rd.	COR-KNOT® QUICK LOAD® MINI DEVICE (PNs 0314-00 and 031450)	The COR-KNOT® QUICK LOAD® provides one sterile COR-	**Approved.**

		Victor, NY USA 14564. (FSC USFDA Valid 01-10-2020)	Class D Shelf Life: 2 Years COR-KNOT MINI® DEVICE KIT **Rs.50,000/-**	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.	
10.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA (FSC Valid till 22-08-2020)	Consolidated Bag – Pocket Controller 14V Battery, Right -104233 (Accessories used for Heartmate II (LVAS) Class D Shelf Life: Not Applicable **Rs.50,000/-**	The consolidated bag is a convenient way to carry two heartmate 14 Volt Lithium-Ion batteries and attached battery clips during battery-powered operation.	**Approved** as class A medical device instead of class D.
11.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA (FSC Valid till 22-08-2020)	Universal Battery Charger -1440 (103869) External Component used for Heartmate II (LVAS) Class D Shelf Life: 3 Years	External Component The battery charger calibrates, charges, and tests the HeartMate 14 Volt Lithium-Ion batteries	**Approved** as class A medical device instead of class D.

			Rs.50,000/-	that are used to power the system during battery-powered operations	
12.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Thoratec Corp. 6035 Stoneridge Dr Pleasanton. CA USA 94588 (FSC Valid 24-04-2021)	HeartMate 3 Apical Cuff-[106522INT] left ventricular assist system Implantable component Class D Shelf Life: 3 Years **Rs.50,000/-**	The Apical Cuff is the interface between the heart and the HeartMate 3 LVAD. It is sewen to the exterior of the heart and anchors it to the LVAD via he cuff lock. The heartMate 3 LVAD is secured to the Apical Cuff with the Cuff Lock, which is a titanium clip secured to the welded motor assembly of the pump. The cuff Lock can translate in a direction perpendicular to the long axis of the Inflow Cannula. The Cuff Lock mates with features on the HM3 Apical cuff that is sewen to the epicardium by the surgeon thereby	**Approved.**

				securing the Pump to the heart. Once secured, an o-ring at the base of the Inflow Cannula establishes hemostatis between the pump and the ventricle.	
13.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA 94588 (FSC US FDA Valid till 22-08-2022)	Thoratec® HeartMate II ® LVAS Implant Kit (with Pocket System Controller and Sealed Grafts) – 106015 (106016) Class D Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Single use, implanted, electrically powered axial-flow rotary ventricular assist system. Intended to provide long term hemodynamic support in patients with end-stage refractory left ventricular heart failure; either for temporary support, such as bridge to cardiac transplantatio n, (BTT), or as permanent destination therapy.	**Approved.**
14.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA 94588 (FSC US FDA	Thoratec ® Heart Mate II ® System Controller (Pocket Controller with EBB) – 106762 (106017) Class D Shelf Life: 3 Years	Ventricular circulatory assist system control unit (External component)	**Approved** as class A medical device instead of class D.

		valid till 22-08-2022)	Fee submitted: Rs. 50,000/-		
15.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** THORATEC CORP, 6035 Stoneridge Dr PLEASANTON, CA USA 94588 (FSC US FDA valid till 22-08-2022)	Heart Mate® 14 Volt Li-Ion Battery Clip Set- 2865 Class D Shelf Life: N/A Fee submitted: Rs. 50,000/-	External Component of left ventricular assist system (LVAS). The battery clips transfer power from the batteries to the System Controller	**Approved** as class A medical device instead of class D.
16.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Thoratec Corp, 6035 Stoneridge Dr Pleasanton, CA USA 94588 (FSC US FDA valid till 20-09-2019) (FSC US FDA valid till 24-04-2021)	Thoratec ® HeartMate 3™ LVAS Implant Kit-106524US/ (106524INT) Class D Shelf Life: 3 years Fee submitted: Rs 50,000/-	Single use, implanted, electrically powered, centrifugal ventricular assist system. Intended to provide long term hemodynamic support in patients with advanced, refractory left ventricular heart failure; either for temporary support, such as bridge to cardiac transplantation, (BTT), or as permanent destination therapy.	**Approved.**
17.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Thoratec Corp, 6035 Stoneridge Dr Pleasanton, CA USA 94588	Thoratec ® HeartMate 3™ Outflow Graft with Bend Relief-105581US/ [105581INT]	Implantable Component of HeartMate 3™ left ventricular	**Approved.**

		(FSC US FDA valid till 20-09-2019) (FSC US FDA valid till 24-04-2021)	Class D Shelf Life: 5 Years Fee submitted: Rs 50,000/-	assist system (LVAS).	
18.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Thoratec Corp. 6035 Stoneridge Dr Pleasanton. CA USA 94588 (FSC USA Valid 24-04-2021)	HeartMate 3 LVAS System Controller with EBB 106531US/ (106531INT) External Component Class D Shelf Life: 3 Years (Sizes & Codes as Per FSC) HeartMate 3 LVAS System Controller with EBB 106531US/ (106531INT) **Rs.50,000/-**	HeartMate 3 System Controller acts as the Central Power & Communication Hub for the HM-3 LVAS. It Passes power from the power module, Power Unit, or Li-on Batteries to the LVAD via the LVAD Driveline. The HM3 System Controller constantly monitors system performance through communication with the implanted LVAD and System Controller internal measurements, and alerts the user to any alarm conditions by activating membrane panel light	**Approved** as class A medical device instead of class D.

				emitting diodes (LEDs) and integrated audio annunciators.	
19.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Thoratec Corp, 6035 Stoneridge Dr PLEASANTON, CA USA (FSC Valid till 22-08-2022)	14 Volt Li-on Battery Set-2456 Acessories Class D Shelf Life: 3 Years **Rs.50,000/-**	Accessories used with HeartMate II Ventricular assist system	**Approved** as class A medical device instead of class D.
20.	M/s Zenith International, Room No. 104, Tahir Plaza, A/20, Block 7&8, KCHSU, Karachi (ELI-00090) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu, P.R.China (FSC China issued 09-03-2018)	PERFECT FINE Disposable Scalp Vein Set, Sterile Class-B Shelf Life: 5 Years Sizes: 19G, 21G, 22G, 23G, 25G, 26G, 27G Rs.25,000/-	Scalp Vein Set is intended to be used for insertion into a patient's vascular system as an indwelling device to administer fluids intravenously or to sample blood.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
21.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu, P.R.China (FSC issued 09-03-2018)	PERFECT FINE Disposable Infusion Set, Sterile, With Needle. Disposable Infusion Set, Sterile, with Needle, with Burette (100ml, 150ml) Class-B Shelf life: 5 Years Rs.25,000/-	Disposable Infusion Set, Sterile, with Needle, with Burette (100ml, 150ml)	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017
22.	-do-	**Legal Manufacturer:**	Perfect Fine	Chromic Catgut	**Approved** subject to

	Evaluator: **Ms. Hira Bhutto**	Huaian Angel Medical Instrument Co., Ltd. 19 East Zhuhai Road, Huaian, 223001 Jiangsu, China. (FSC Valid 08-09-2019) FSC of Germany issued on 06-05-2019	Chromic Catgut Surgical Suture with needle (USP) Class D Shelf Life: 5 Years (Codes as Per FSC) 0,1,2,2/0,3/0,4/0 **Rs.50,000/-**	surgical suture is an absorbable sterile suture composed of purified connective tissue derived from either the serosal layer of beef (bovine) or the sub mucosal fibrous layer of sheep intestines. It is used to join the edges of a soft tissue wound or incision by stitching or to ligate soft tissues. This is a single use device.	provision of codes.
23.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu, P.R.China (FSC issued 09-03-2018)	Perfect Fine Disposable Syringe, Sterile with needle (Sizes: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml) Class-B Shelf Life: 5 Years Rs.25,000/-	Disposable Syringe, Sterile with needle (Sizes: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml)	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017
24.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu,	PERFECT Disposable Insulin Syringe, Sterile (U-100) (29G, 30G, 31G) (0.5ml, 1 ml) Class B Shelf Life: 5 Years	Disposable Insulin Syringe, Sterile (U-100) (29G, 30G, 31G) (0.5ml, 1 ml)	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data.

		P.R.China (FSC China issued 09-03-2018)	Rs.25,000/-		
25.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu, P.R.China (FSC issued 09-03-2018)	PERFECT Disposable Surgical Hypodermic Needle, Sterile (Sizes: 18G, 19G, 21G, 22G, 23g, 24G, 25G, 26G, 27G) Class B Shelf Life: 5 Years Rs.25,000/-	Disposable Surgical Hypodermic Needle, Sterile (Sizes: 18G, 19G, 21G, 22G, 23g, 24G, 25G, 26G, 27G)	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
26.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu. P.R China. (FSC Valid 07-12-2019)	Perfect Fine A.D. Disposable Auto Disable Syringe, Sterile with needle Class B Shelf Life: 5 Years Codes: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml Rs.25,000/-	Disposable Auto Disable Syringe can be used in intravenous injection, hypodermic injection and drawing blood from vein.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
27.	M/s Noor International Noor House, 29-D, Block 6, PECHS, Karachi (ELI-00061) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Hoffricheter GmbH mettenheimer Str. 12/14 19601 Schwerin Germany. (FSC issuance 18-12-2018)	LAVI 40 Respiratory Therapy and Ventilation Class C Shelf Life: Not Applicable Ref:00013040 Rs.25,000/-	The LAVI Ventilator device may only be used for non-life supporting respiration. It serves as intermittent respiration support as well as to provide respiration to patients with insufficient spontaneous	**Approved** as class C medical devices subjcct to deposition of differential fee.

				breathing ability. The device is suitable for treating adults and children with a tidal volume of 100ml and bove and can be used in home health care and or in professional health care facilities. It must not be used for intensive care ventilation.	
28.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Hoffricheter GmbH mettenheimer Str. 12/14 19601 Schwerin Germany. (FSC issuance 18-12-2018)	LAVI 30 Respiratory Therapy and Ventilation Class C Shelf Life: Not Applicable. (Sizes & Codes as Per FSC) LAVI 30 Ref:00013039 Rs.25,000/-	The LAVI Ventilator device may only be used for non-life supporting respiration. It serves as intermittent respiration support as well as to provide respiration to patients with insufficient spontaneous breathing ability. The device is suitable for treating adults and children with a tidal volume of 100ml and bove and can be used in home health	**Approved** as class C medical devices subjcct to deposition of differential fee.

				care and or in professional health care facilities. It must not be used for intensive care ventilation.	
29.	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 Salvarcar Juarez, Chihuahua 32574, Mexico (FSC USFDA Valid Till (26-07-2019)	Halo ® Catheters Class D Shelf Life: 1 Years 36J14R, 36J16R Rs.50,000/-	Diagnostic Catheters	**Approved.**
30.	M/s WasimCo. KutchiGali No.1, Marriott Road Karachi. (ELI-00185) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China. (FSC Valid 24-12-2024) FSC Germany Issued on (11- 06-2019)	Classic Fine Sterile Disposable Infusion with burette (With/without Needle) Class B Shelf Life: 5 Years. Codes: 100ml, 150ml Rs.25,000/-	Infusion Sets for Single Use With needles is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.	**Approved.**

31.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China. (FSC Valid 24-12-2024) FSC Germany Issued on (11- 06-2019)	Classic Fine Disposable Syringes Sterile, With needle Class B Shelf Life: 5 Years. Codes: 1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50/60ml. Rs.25,000/-	Syringe is a sterile device consisting of a calibrated barrel (cyclinder) with plunger intended to be used for injection / Withdrawl of fluids/gas e.g. medication to /from a medical deice or the body (i.e. capable of both); a needle is not included.	**Approved.**
32.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China. (FSC Valid 24-12-2024) FSC Germany Issued on 11- 06-2019	Classic Fine Disposable Spinal Needle Sterile Class D Shelf Life: 5 Years. Sizes: 18G, 23G, 25G. Rs.25,000/-	The product Spinal Needle is made up of three parts: • Spinal Needle (Needle Tube + Needle Hub) • Stylet (Stylet Blade+ Button) • Sheath.	**Approved.**
33.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China.	Classic Fine Disposable Insulin syringe, Sterile (U-100) Class B Shelf Life: 5 Years. Codes: 0.5ml, 1ml. Rs.25,000/-	Insulin Syringe is a sterile device consisting of a calibrated barrel (Cylinder) with plunger intended to be used to administer an injection of	**Approved.**

		(FSC Valid 24-12-2024) FSC Germany Issued on 11- 06-2019		insulin to a patient subcutaneously. This is a single use device.	
34.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou city, 213115 Jiangsu, P.R. China. (FSC Valid 24-12-2024)	Classic Fine Disposable Hypodermic Needle, Sterile. Class B Shelf Life: 5 Years. Size: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, Rs.25,000/-	Sterile Hypodermic Needles for Single Use is a Sharp, hollow instrument that connects to a syringe and is commonly used to inject liquid drugs or medications directly into the skin (Under the dermis) or into a vessel or sometimes for extracting blood.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
35.	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>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Demedtitec Diagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC of Germany Issuance 13-03-2019)	**Entamoeba Histolytica IgG ELISA Echinococcus granulosus IgG.** Class B Shelf Life: 18Months (closed kit) Codes: DEENTG0140 Entamoeba Histolytica IgG DEECH01 Echinococcus granulosus IgG.	**Entamoeba Histolytica IgG** ELISA is intended for the qualitative derterminatio n of IgG Class anti-bodies against Entamoeba histolytica in human serum or plasma (citrate, heparin) **Echinococcus granulosus IgG** ELISA kit has been designed for	**Approved.**

				the detection and the quantitative determination of specific IgG antibodies against echnococuus in serum and plasma.	
36.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Demedtitec Diagnostic GmbH Lise-Meitner StraBe 2 D-24145 Kiel Germany. (FSC Germany Issuance 13-03-2019)	**Anti-Spermatozoa Antibody (ASA) TSH Receptor Ab** Class B Shelf Life: 12 Months (Unopened Kit)	Anti-Spermatozoa antibody ELISA is a reliable and quantitative test for the determination antibodies directed against human spermatozoa. This test is intended for the use with serum. TSH receptor AutoAntibody Elisa kit is intended for use by professional persons only for the quantitative determination of TRAb in human serum. Hyperthyroidism in grave's disease diagnosis and management	**Approved.**
37.	-do-	**Legal Manufacturer:**	**IDS-iSYS Multi Discipline Automated**	IDS-iSYS Multi	**Approved** subject to

	<u>Evaluator:</u> **Ms. Hira Bhutto**	M/s. Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Tyne & Wear, NE35 9PD, United Kingdom. **Manufacturing Site:** Immunodiagnostic system , 42 rue Stephane Mazeau 21320 Pouilly-En-Auxios France FSC France Issued on 07.11.2018	**System** IDS-i10 Class A Shelf Life :N/A	Discipline Automated System is an in in-Vitro diagnostic analyzer it enables immunoassays and biochemistry assays to be carried out on a single analytical platform **Immunoassays** Bone and growth Infectious disease Hypertension Autoimmunity **Biochemistry:** Substrates Enzymes Electrolytes Specific proteins	provision of valid ISO 13485 and Full Quality Assurance Certficate.
38.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Tyne & Wear, NE35 9PD, United Kingdom. FSC U.K Valid till 23.04.2024	**IDS-iSYS Insulin like Growth Factor (IGF-I) (IS-3900)** Shelf Life : 15month **IDS-iSYS Insulin like Growth Factor (IGF-I) Control Set (IS-3930)** Shelf Life 12month **IDS-iSYS Human Growth Hormone (hGH)(IS -3700)** Shelf Life : 12months **IDS-iSYS ACTH (IS-4500)** Shelf Life : 12months	The IDS – iSYS insulin like growth factor –I is an in vitro diagnostic device intended for the quantitative determination of IGF-I in human serum and plasma on the IDS-iSYS Multi – Discipline	**Deferred** till the recommendtion of committee constituted on grouping of Cluster. Stability data required FQA required

			IDS-iSYS ACTH control set (IS-4530) Shelf Life : 12months (Stability performed at 2 to 8 degrees Storage Condition) Class B Shelf Life : Mentioned above	automated system. The IDS – iSYS Human Growth Hormone is an in vitro diagnostic device intended for the quantitative determination of Human growth hormone in human serum or plasma on the IDS-iSYS Multi – Discipline automated system. The IDS – iSYS ACTH (Adrenocartic otropic hormone) is an in vitro diagnostic device intended for the quantitative determination of ACTH in human plasma on the IDS-iSYS Multi – Discipline automated system.	
39.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Immunodiagnostic Systems Limited,	**IDS-iSYS Aldosterone (IS-3300)** Shelf Life : 06months **IDS-iSYS Aldosterone Control**	Aldosterone assay is intended for the quantities determination	**Deferred** till the recommendtion of committee constituted on

		10 Didcot Way, Boldon Business Park, Tyne & Wear, NE35 9PD, United Kingdom. FSC U.K Valid till 23.04.2024	**set (IS-3330)** Shelf Life : 09months **IDS-iSYS rennin (ID-3400)** Shelf Life : 12months **IDS-iSYS Renin Control set (IS-3430)** Shelf Life : 18months (Stability performed at 2 to 8 degrees Storage Condition) Class: B Shelf Life : Mentioned above	of aldosterone in human EDTA plasma on the IDS system. The IDS – iSYS direct Renin assay is an in vitro diagnostic device intended for the quantitative determination of direct rennin in human plasma on the IDS-iSYS Multi – Discipline automated system.	grouping of Cluster. FQA required.
40.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Tyne & Wear, NE35 9PD, United Kingdom. FSC U.K Valid till 23.04.2024	**IDS-iSYS Free Testosterone (IS-5300)** Shelf Life : 12months **IDS-iSYS Free Testosterone Control set (IS-5330)** Shelf Life : 12months **IDS-iSYS Total testosterone (IS-5000)** Shelf Life : 12months **IDS-iSYS Total testosterone Control set (IS-5300)** Shelf Life : 12months **IDS-iSYS Free 17-OH Progesterone (IS-5100)** Shelf Life : 15months **IDS-iSYS Free 17-OH Progesterone Control Set (IS-5130)** Shelf Life : 15months (Stability performed at 2 to 8 degrees Storage Condition)	The IDS-iSYS free testosterone assay is an vitro diagnostic device intended for quantitative determination of free testosterone in human serum or plasma The IDS-iSYS total testosterone assay is an vitro diagnostic device intended for quantitiative determination of total testosterone	**Deferred** till the recommendtion of committee constituted on grouping of Cluster. Stability data to be reconfirmed. FQA required

			Class: B Shelf Life : Mentioned above	in human serum or plasma The IDS-iSYS 17-OH Progesterone assay is an vitro diagnostic device intended for quantitative determination 17-OH progesterone in human serum or plasma	
41.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Oxford Immunotec Ltd, 94C innovation Drive Milton Park, Abingdon, Oxfordshire OX14 4RZ. United Kingdom. (FSC Issuance 28-02-2019)	**T-SPOT.TB** T-SPOT.TB Class C Shelf Life: 18 Months Model: TB.300 T-SPOT.TB test Kit	**T-SPOT.TB** test is an in vitro diagnostic test for detection of effector T cells that respond to stimulation by Mycobacterium tuberculosis antigens and is intended for use as an aid in the diagnosis to tuberculosis TB infection. The T-SPOT. TB test is a simplified enzyme-linked immune spot (ELISPOT) Method which enumerates individual TB Specific activated	**Approved.**

				effector T Cells.	
42.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** Demeditec Diagnostic GmbH Lise-Meitner Strasse 2, D-24145 Kiel Germany. FSC Germany Issuance 13-03-2019	5HIAA ELISA, Dopamine, Metanephrine Plasma ELISA, Metaephrine Urine ELISA, Normetanephrine Plasma ELISA, Normetanephrine Urine ELISA Class B DEE1900 5HIAA ELISA Shelf Life: 30 Months DEE6300 Dopamine Shelf Life: 19 Months DEE8100Metanephrine Plasma ELISA Shelf Life: 24 Months DEE8400 Metanephrine Urine ELISA Shelf Life: 36 Months DEE8200 Normetanephrine Plasma ELISA Shelf Life: 24 Months DEE8500 Normetanephrine Urine ELISA. Shelf Life: 36 Months Rs.25,000/-	Enzyme Immunoassay for the quantitative determination.	**Deferred** till the recommenda-tions of committee constituted on grouping of Cluster
43.	M/s. Sadqain Health Care (Pvt) Ltd., Safari Villas 11, Commercial Complex, 3rd Floor, Bahria Town Phase 7, Rawalpindi. ELI-00020	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United	**Nasal Cannula** Nasal Cannula Class B Shelf Life: 5 Years	It is used to deliver oxygen into the patient's nose.	**Approved** subject to provision of Stability data.

	Evaluator: **Ms. Hira Bhutto**	Kingdom. FSC U.K Issued on 01.03.2016	Codes As per FSC Adult, nasal cannula with straight prongs and tube, 1.8m Code:1161000 Paediatric, nasal cannula with curved prongs and tube, 2.1m Code:1163000 Neonatal, nasal cannula with curved prongs and tube, 2.1m Code: 1164000		
44.	-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	**Superset (Micro Mount Catheter Mount)** **(Fixed elbow Paediatric/Neonatal Catheter mount 15m – 7.6mm port – 15f, 49mm- 100mm)** Class B Shelf Life: 5 Years Code: Uperset micro mount 15m - 15f Code:3535000	Catheter Mount connects the patient to the breathing system, providing an extension between the patient's airway and the breathing system. It provide flexibility between the airway connector and the breathing circuit, and reduce the pull on patient's airway connection.	**Approved** subject to provision of Stability data.
45.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United	**BVM (Bag-Valve-Mask) Resuscitator** Bag Valve Mask Resuscitators Class B	It is use to enable manual resuscitation of a patient whilst providing protection	**Approved** subject to provision of Stability data.

		Kingdom. FSC U.K Issued on 01.03.2016	Shelf Life : 5 Years Codes As per FSC • BVM RESUSCITATOR, INFANT, 280ML BAG WITH PRESSURE RELIEF VALVE (40CMH2O), SIZE 1 MASK Code:7150000 • BVM RESUSCITATOR, PAEDIATRIC, 550ML BAG WITH PRESSURE RELIEF VALVE (40CM H20), SIZE 3 MASK Code:7151000 • BVM RESUSCITATOR, ADULT, 1.5L BAG, SIZE 5 MASK Code: 7152000	to operator. Supplemental oxygen may also be supplied via a spigot. A pressure relief valve is provided where required, as some of the bags do not have pressure level.	
46.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 25-03-2019	**Jerican Intersorb Plus** **(**white to violet Color Change, 5L) CO_2 Absorbent Code: 2179000 Class B Shelf Life : 5 Years	It is use to reduce Carbon dioxide content in anaesthetic and respiratory gases delivered to a patient. The Intersorb plus is conventional soda lime CO2 absorbent comprised of short porous	**Approved** subject to provision of Stability data.

				3mm diameter strands.	
47.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	Superset Catheter Mount Class B 3521000: Superset double swivel; catheter mount 22F-double flip top cap with seal 22M/15F , 70mm-150mm 3514000: Superset fixed elbow catheter mount 22F-Luer port-22M/15F, 70mm-150mm Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	To provide a respiratory pathway between a breathing system and a patient's airway or facemask. Non-sterile	**Approved.**
48.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer** M/s. Intersurgical Limited, Crane House, Molly Millars Lane, Wokingham, Berkshire, United Kingdom. FSC U.K issued on 01.03.2016	Flextube Breathing System Class B 2000000-BREATHING SYSTEM 1.6M 4500000 - Breathing System, Paediatric, 1.6M Shelf Life : 05 years Fee submitted: Rs. 25,000/-	To deliver and remove respiratory gases from a patient via a system of tubing and connectors. Non-sterile	**Approved.**
49.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Manufacturer** M/s. Intersurgical Limited, Crane House, Mollymillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K (MHRA)	I-Gel Supraglottic Airways Product Codes 8201000 8202000 8203000 8204000 8205000 8215000	Use in securing and maintaining a patient airway in routine and emergency anaesthics of fasted patient during spontaneous	**Approved** subject to provision of valid ISO 13485 certificate.

		Issued on 2nd March, 2016	8225000 Class B Shelf Life : 2 years **Rs.25,000/-**	or IPP ventilation.	
50.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 25.03.2019	Intersurgical EcoLite ™adult, venture mask kit Class B Shelf Life : 03 years **Rs.25,000/-**	Venture mask kit	**Approved** subject to provision of valid ISO 13485 certificate and stability data supporting required shelf life.
51.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer** M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 02.03.20160	EcoLite ™ Oxygen Mask **Product Codes:** • 1135015 – Ecolite, Adult, Medium concentration Oxygen Mask with Tube, 2.1m • 1196015 – Ecolite, Paediatric, Medium concentration Oxygen Mask with Tube, 2.1m • 1181015 – Ecolite, Adult, High Medium concentration Oxygen Mask with Tube, 2.1m Class B Shelf Life : 03 years **Rs.25,000/-**	Oxygen Mask	**Approved** subject to provision of valid ISO 13485 certificate
52.	-do-	**Legal Manufacturer**	Anatomical Mask with hook ring	Oxygen/anesthesia Mask	**Approved** subject to

	Evaluator: **Hafiz Muhammad Asif Iqbal**	M/s. Intersurgical Limited, Crane House, MollyMillars Lane, Wokingha, Berkshire, United Kingdom. FSC U.K Issued on 02.03.2016	(Anaesthetic Face Mask) **Product Code – Product Name** 8821000 – Anatomical Face Mask, , with Hook Ring, 22F Size 1 8822000 – Anatomical Face Mask, , with Hook Ring, 22F Size 2 8823000 – Anatomical Face Mask, , , with Hook Ring, 22F Size 3 8824000 – Anatomical Face Mask, , with Hook Ring, 22F Size 4 8825000 – Anatomical Face Mask, , with Hook Ring, 22F Size 5 **Class B** **Shelf Life :** 05 years		provision of valid ISO 13485 certificate and stability data.
53.	M/s. Optisurg 17- C1, Valencia Town, Lahore. ELI-00305 **Evaluator:** **Ms. Hira Bhutto**	**Manufacturer:** Oertli Instrumente AG, Hafnerwisenstrasse 4, 9442 Berncek, Switzerland. FSC Switzerland. (FSC Valid till 14-03-2020)	OS4 Surgery System Anterior/Posterior (with Endolaser, LED and LED Plus light source without Pedal) Class C Shelf Life: Not applicable (service life is 10 years) (VC860300)	The OS4 Surgical device is used to perform surgical interventions in posterior and anterior eye Segment. In Cataaract, anterior Virectoomy Glaucoma	**Approved.**
54.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Manufacturer:** Oertli Instrumente AG, Hafnerwisenstrasse 4, 9442 Berncek, Switzerland.	OS4 Surgery System Anterior/Posterior (with LED and LED Plus light source without Pedal) Class C Shelf Life: Not	The OS4 Surgical device is used to perform surgical interventions in posterior	**Approved.**

		FSC Switzerland. (FSC Valid till 14-03-2020)	applicable (service life is 10 years) Code: (VC860200)	and anterior eye Segment. In Cataaract, anterior Virectoomy Glaucoma	
55.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Manufacturer:** Oertli Instrumente AG, Hafnerwisenstrasse 4, 9442 Berncek, Switzerland. FSC Switzerland. (FSC Valid till 14-03-2020)	CataRhex3 Phacoemulsification System (without pedal) Class C Shelf Life: N/A (service life is 10 years) Codes As per FSC (VC821100)	The CataRhex 3 is a surgery System used by opthalmologists during cataract surgery. It is designed for uses in anterior segment procedures that require simultaneous lens fragmentation, irrigation and aspiration, as well as ancillary functions such as vitreous cutting along with bipolar diathermy.	**Approved.**
56.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Manufacturer:** M/s. Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA 5095, Australia. FSC Australia. (Issued on 18-12-2018)	**Integre Pro™ LP5532** (Ophthalmic Solid-state laser system, photocoagulation) Class C Shelf Life: 7 years service life	This device is indicated for use in photocoagulation of both interior and posterior segments of eye.	**Approved** subject to provision of notarized ISO and full QA certificate.
57.	-do- **<u>Evaluator:</u>**	**Manufacturer:** Oertli Instrumente AG,	Faros Surgery- System Anterior (without dual linear	The Faros surgical platform	**Approved.**

	Ms. Hira Bhutto	Hafnerwisenstrasse 4, 9442 Berncek, Switzerland. FSC Switzerland. (FSC Valid till 14-03-2020)	pedal and without remote control) Class C Shelf life: 10 Years service life (VC840100)	enables eyes surgery of the highest level. The compact Faros is either available as a device for anterior and posterior segment surgery or as a combined system for anterior and posterior segment surgery.	
58.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Oertli Instrumente AG, Hafnerwisenstrasse 4, 9442 Berneck, Switzerland. FSC Switzerland valid till 14-03-2020)	Oertli® Faros Surgery System Anterior Posterior (VC840101) Class C Shelf life: N/A Service life: 10 years Fee submitted: Rs. 50,000/-	Device used to carry out surgical procedures in anterior and posterior segment of the eye	**Approved.**
59.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. Ellex Medical Pty Ltd., 3-4 Second Avenue, Mawson Lakes, SA 5095, Australia. FSC Australia issued on 18-12-2018)	Ultra Q Reflex™ (LQP3106-U) Class C Shelf life: N/A Service life: 7 years Fee submitted: Rs. 50,000/-	Ophthalmic microsurgical YAG laser intended to be used to perform procedures requiring the rupture of tissue in the eye	**Approved.**
60.	M/s Flowtronix Systems, Flat No. 02 A1 – Ashraf Plaza, range Road, Rawalpindi. (ELI-00217) -do-	**Legal Manufacturer:** Andocor NV-Kwikaard 104 - 2980 Zoersel-Belgium. (FSC Belgium	**ANDOCOR (**Vessel Cannulawith closed back check valve VC3B Class B	Andocor vessel cannulae are used to help check for leaks in a harvested vein that will be used in a graft	**Approved.**

	<u>Evaluator:</u> **Ms. Hira Bhutto**	issued on 28-02-2017)	Shelf Life: 5 Year	with a sterile saline solution. Additionally, the vessel cannula can be used for antegrade cardiopleagia administratio n.	
61.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Andocor NV-Kwikaard 104 - 2980 Zoersel-Belgium. (FSC issued on 28-02-2017)	**ANDOCOR** Cardiopleagia Sets Class D Shelf Life: 5 Years Codes: CSY03, CSY04, CSY05, CSY06, CSY07, CSY08, CSY09, CSY10, CSY11, CSY12, CSY13, CSY14, CSY15, CSY16, CSY17, CSY18, CSY19, CSY20, CSY21, CSY22, CSY23,M9354	Cardioplegia sets or adapters consist of flexible pc tubing wiht male/ female luer lock or 1/4 connectors. They are available in different configurations , with or without attached vessels cannulae. These devices connect to the aortic root cannulae or vessel cannulae and are intended for the delivery of cardioplegia solution or venting the heart during cardioplumon ary bypass.	**Approved** subject to provision of Stability data.
62.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Andocor NV-	**ANDOCOR** Pericardial Sump Class B	The pericardial sump is intended to	**Approved** subject to provision of Stability data.

		Kwikaard 104 - 2980 Zoersel-Belgium. (FSC Belgium issued on 28-02-2017)	Shelf Life: 5 Years Codes: PS40, PS40M, PS40MH, PS40ML, PS40MLH, PS40M1, PS40M2, PS40MLH2	use for the removal of excess fluid from the surgical field. The pericardial sump consists of a soft PVC tubing and features a weighted metal tip. Certain models feature a smooth metal tip, while others are constructed with a wire wound tip which ends in a rounded metal tip. The devices terminated in a 1/4 connector on the proximal end.	
63.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer :** M/s. Guangdon Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China. FSC China Valid until 30.12.2019 FSC Spain Issued on 04.07.2017	**ABLE** (Disposable Fistula Needles) FN-1411S, FN-1511S, FN-1611S, FN-1711S, FN-1412S, FN-15 12S, FN-1612S, FN-1712S, FN-1421S, FN-1521S, FN-1621S, FN-1721S FN-1422S, FN-1522S, FN-1622S, FN-1722S, FN-1411ZS, FN-1511ZS, FN-1611ZS, FN-1711ZS, FN-1412ZS, FN-15 12ZS, FN-1612ZS, FN-	The product is intended to puncture the mature fistula, and connect with the blood lines to establish blood circulating path outside human body in the process of haemodialysis .	**Approved** subject to provision of codes.

		(Reference Country)	1712ZS, FN-1421ZS, FN-1521ZS, FN-162 1ZS, FN-1721ZS FN-1422ZS, FN1522ZS Class B Shelf Life : 03 years		
64.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer :** M/s. Guangdon Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China. FSC Spain Issued on 04.07.2017 (Reference Country)	**ABLE** (Disposable Haemodialysers) A-40 A-60 A-80 A-200 Class C Shelf Life : 03 years	Haemodialysers is designed for the hemodialysis treatment of acute and chronic renal failure It is for single use.	**Approved** subject to provision of EPSP.
65.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer :** M/s. Guangdon Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China. FSC China Valid until 30.12.2019 (FSC of Ireland expiry date 21-04-2022)	**ABLE** (Central Venous Catheter Kit Sizes and Codes FV-1321, FV-1322, FV-1324, FV-1325, FV-1326, FV-1421, FV-1422, FV-1423, FV-1424, FV-1425, FV-1426, FV-1428, FV-1524, FV-1525, FV-1526, FV-1528, FV-1624, FV-1625, FV-1626, FV-1628 FV-2421, FV-2422, FV-2424, FV-2425, FV-2426, FV-2521, FV-2522, FV-2524, FV-2525, FV-2526, FV-2724, FV-2725, FV-2726, FV-2727,	The ABLE ® Catheter is surgically penetrated into the central vena or vena cava superior or vena cava inferior of the body via Seldinger Technique. It is possible to be inserted inside the body for less than 30 days. It may be applicable to the one of following therapy: • Continuou	**Approved** suabject to provision of Declaration of Conformity and Essential Principle of safety and performance.

			FV-2728 FV-2824, FV-2825, FV-2826, FV-2828, FV-2924, FV-2925, FV-2926, FV-2928, FV-3421, FV-3422, FV-3424, FV-3425, FV-3426, FV-3521, FV-3522, FV-3524, FV-3525, FV-3526 FV-3724, FV-3725, FV-3726, FV-3727, FV-3728, FV-4924, FV-4925, FV-4926, FV-4928 FC-2421, FC-2422, FC-2424, FC-2425, FC-2426, FC-2521, FC-2522, FC-2524, FC-2525, FC-2526, FC-2724, FC-2725, FC-2726, FC-2727, FC-2728 FC-3521, FC-3522, FC-3524, FC-3525, FC-3526, FC-3724, FC-3725, FC-3726, FC-3727, FC-3728, FC-342906 Class D Shelf Life : 03 years	s or discontinuous venous transfusion • Monitor of central venous pressure • Blood sampling	
66.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer :** M/s. Guangdon Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China. FSC China Valid until 30.12.2019	**ABLE** (Haemodialysis Catheter Kit) Product Codes: FH-1714, FH-1715, FH-1716, FH-172913-5, FH-182913-5, FH-212911, FH-212911W, FH-212913-5, FH-212913-5W, FH-211915, FH-211915W, FH-2115, FH-2115W, FH-2126, FH-2611,FH-1814, FH-1815,	Haemodialysis Catheter Kit may be applicable to the one of following therapy; • To supply the temporary blood vessel access • To monitor of central venous	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of DOC mentioning the class of medical device and Essential Principle of safety and performance.

			FH-1816, FH-2114, FH-2127, FH-2214, FH-2224, FH-222913-5, FH-222913-5W, FH-221915, FH-221915W, FH-2215, FH-2315, FH-2612, FH-2614, FH-2615, FH-2911, FH-2912, FR-2114, FR-2114W, FR-172913-5, FR-182913-5, FR-212911 FR-212911W, FR-212912, FR-212913-5, FR-212913-5W, FR-211915, FR-211915W, FR-2115, FR-2115W, FR-2126, FR-2126W, FR-2127, FR-2214, FR-2214W, FR-2224, FR-2224W, FR-222913-5,FR-222913-5W, FR-221915, FR-221915W,FR-2215, FR-2215W,FR-2225, FR-2225W,FR-2226, FR-2226W,FR-2915, FR-3224, FR-3226, FR-2611, FR-2612, FR-2615, FR-2911, FR-2912, FR-2914, FR-2915, FR-2926, FR-3214, FR-3215, FR-3225, FR-2315, FR-2315W, FR-2611W,FR-2614W, FR-252919, FR-2911W, FR-2914W, FR-3214W, FR-3225W, FR-3224W, FR-3226W,FR-2611W, FR-2612W, FR-2615W, FR-2912W	pressure; • Continuous or discontinuous venous transfusion	

			FR-2915W, FR-3215W, FR-252924W Class D Shelf Life : 03 years		
67.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Andocor NV-Kwikaard 104 - 2980 Zoersel-Belgium. (FSC issued on 28-02-2017)	**ANDOCOR** Ostial Perfusion Cannulae Class D Shelf Life: 5 Years Codes: OC1045, OC1090, OC1245, OC1290, OC1445, OC1490, OC06A, OC07A	These cannulae are used for the delivery of cardioplegia solution directly into the coronary arteries during cariopulmonary bypass. Ostial Perfusion cannulae with basket tip consist of a stainless steel shaft with a basket tip and handle terminating in a female luer lock connector on the proximal end. Ostial perfusion cannulae with balloon tip consist of PVC Tubing with a self inflating silicon balloon and terminate in a female luer lock connector on the proximal end.	**Approved** subject to provision of Stability data.
68.	-do-	**Manufacturer:** Andocor NV,	ANDOCOR Silicone Vent Catheter	Intended for use in venting	**Approved**subject to provision

	<u>Evaluator:</u> **Ms. Unum Zia Shamsi**	Kwikaard 104, B-2980, Zoersel, Belgium. (FSC Belgium valid till 28-02-2017)	Class D Codes SV16 SV20 Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	the left heart during cardiopulmonary bypass surgery up to six hours or less. Sterile	of valid Free Sale Certificate.
69.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** International Biophysics Corp. 2101 E, St. Elmo, Suite 275, Austin, TX USA 78744 (FSC US FDA valid till 18-12-2019)	IBC Aortic Punch Class B Shelf Life: 4 Years (Long) APL28 Aortic Punch, 2.8mm APL36 Aortic Punch, 3.6mm APL40 Aortic Punch, 4.0mm APL44 Aortic Punch, 4.4mm APL52 Aortic Punch, 5.2mm APL56 Aortic Punch, 5.6mm APL60 Aortic Punch, 6.0mm APL48 Aortic Punch, 4.8mm (Medium) APM28 Aortic Punch, 2.8mm APM36 Aortic Punch, 3.6mm APM40 Aortic Punch, 4.0mm APM44 Aortic Punch, 4.4mm APM48 Aortic Punch, 4.8mm APM52 Aortic Punch, 5.2mm APM56 Aortic Punch, 5.6mm APM60 Aortic Punch, 6.0mm	Single use, disposable aortic punch indicated for use in creating an opening (s) in the wall of aorta to prepare site for anastomosis	**Approved**.

			Fee submitted: Rs. 25,000/-		
70.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** Andocor NV-Kwikaard 104 - 2980 Zoersel-Belgium. (FSC Belgium Issuance 28-02-2017)	ANDOCOR Cannulation Torniquet Set Cannulation Torniquet Sets CT01, CT02, CT03, CT04, CT05, CT06, CT07, CT08, CT09 Class B Shelf Life: 5 Years Rs.25,000/-	Cannulation tourniquet sets are used as an accessory for arterial & venous cannulae during cardiopulmonary bypass.	**Approved.**
71.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer :** M/s. Guangdon Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China. FSC China Valid until 30.12.2019 FSC Spain Issued on 04-07-2017	**ABLE** (Disposable Blood Lines) Models: FB-A001V01, FB-A001V02, FB-A001V03, FB-A001V04, FB-A001V05, FB-A002V01, FB-A002V02, FB-A002V03, FB-A002V04, FB-A002V05, FB-A003V0 1, FB-A003V02, FB-A003 V03, FB-A003V04, FB-A003 V05, FB-A004V01, FB-A004V02, FB-A004V03, FB-A004V04, FB-A004V05, FB-A005V01, FB-A005V02, FB A005V03, FB-A005V04, FB-A005V05, FB-A006V01, FB-A006V02, FB-A006V03,	Disposable Blood Lines are intended to establish blood circulating path outside human body.	**Approved.**

			FB-A006V04, FB-A006V05, FB-A101V11, FB-A101V12, FB-A102V11, FB-A102V12, FB-A103V11, FB-A103V12, FB-A104V11, FB-A104V12 Class B Shelf Life : 03 years **Rs.25,000/-**		
72.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer :** M/s. Guangdon Baihe Medical Technology Co., Ltd., No. 89, Taoyuan East Road, Nanhai, Foshan 528225, Guangdong Province, China. FSC China Valid until 30.12.2019 FSC Spain Issued on 04-07-2017	**ABLE** (Disposable Pressure Transducers) Model No: FT-A001, FT-V001 Class B Shelf Life : 02 years **Rs.25,000/-**	Disposable blood pressure transducer & accessories	**Approved.**
73.	M/s Matora Digionics Pvt. Ltd. 130-C, Scotch Corner, Upper Mall, Lahore. (ELI- 00083) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal** Manufacturer: Rapid Pathogen Screening 7227 Dlainey Court Sarasota, FL USA 34240 (FSC valid 11-01-2020)	FebriDx (Differential Diagnostic testing (Fingerstick blood sample) Class B Shelf Life: 24 Months FebriDx- A viral and bacterial immune response diagnostic test.	Plastic Housing with retractable Lancet and buffer solution to be used for rapid, pint of care test for infection screening.	**Approved.**

74.	M/s. ENDOAID BIOMEDICA, 185 C, DHA EME Sector, Lahore. 2. 85 D Second Floor, Commercial Area DHA EME Sector Multan Road Lahore. ELI-00169	**Legal manufacturer** M/s. Raysen (Tianjin) Healthcare Products Co., Ltd., No.3, Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin, China. FSC China Issued on 11.03.2019	Raysen (Latex (Powder Free) Surgical Gloves) Codes as per FSC Class B Shelf Life : Not mentioned	Surgeons and clinical personnel are using this type of gloves in a sterile environment such as operating theater to perform operation.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data, Credentials of manufacturer abroad and ISO 13485.
75.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Raysen (Tianjin) Healthcare Products Co., Ltd., No.3, Huanyuxi Road, Tianyu Technology Park, Jinghai, Tianjin, China. FSC China Issued on 11.03.2019	Raysen (Latex Powdered Surgical Gloves) Codes: as per FSC Class B Shelf Life : Not mentioned	Surgeons and clinical personnel are using this type of gloves in a sterile environment such as operating theater to perform operation.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Stability data, Credentials manufacturer abroad and ISO 13485.
76.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Worldwide Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	**Vestiryl Rapid Absorbable Suture** (Codes as per FSC) Class D Shelf Life : 03 years	Vestiryl Rapid is Braid suture is stitch made to join together the open parts of wound, especially one made after a patient has been operated	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
77.	-do- **<u>Evaluator:</u>**	**Legal manufacturer** M/s. Worldwide	**Vestisilk Silk Suture (non- absorbable sutures)**	Non-Absorbable suture is a	**Approved** subject to inspection of

	Ms. Hira Bhutto	Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	(Codes as per FSC) Class C Shelf Life : 05 years	combination of surgical eyeless needle and thread of variance size and it do not cooperate any medicinal substance and/ or material of animal or human origin.	manufacturer abroad under Rule 71 of MDR, 2017
78.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Worldwide Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	**Vestiryl Plus Absorbable Suture** (Codes will be provided) Class D Shelf Life : 03 years	Absorbable suture is a combination of surgical eyeless needle and thread of variance size and it do not cooperate any medicinal substance and/ or material of animal or human origin.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017
79.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Worldwide Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	**Vestilon Nylon Suture (non-absorbable suture)** (Codes as per FSC) Class C Shelf Life : 05 years	Non-Absorbable suture is a combination of surgical eyeless needle and thread of variance size and it do not cooperate any medicinal substance and/ or matrial of animal or human origin.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017
80.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Worldwide Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai	**Vestimax Absorbable Suture (absorbable sutures)** (Codes as per FSC) Class D	Vestimax is a synthetic monofilament absorbable sterile surgical suture composed of	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017

		Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	Shelf Life : 03 years	poly (p-dioxanone) and used for suturing soft skin)	
81.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Worldwide Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	**Vestisyn (Absorbable Suture)** (Codes as per FSC) Class D Shelf Life : 03 years	Absorbable suture is a combination of surgical eyeless needle and thread of variance size and it do not cooperate any medicinal substance and/ or material of animal or human origin. Vestisyn is a short-term synthetic absorbable surgical braid suture made of polyglycolide-co-caprolactone (PGCL)	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017
82.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Worldwide Medivest Sdn.Bhd. No.2, Jalan Karyawan 4/KU7, Lorong Sungai Puloh, Taman Kapar Bestari, 42200 Kapar, Selangor, Malaysia. FSC Malaysia Valid till 25.09.2020	**Vestilene Polypropylene Suture (non absorbable)** (Codes as per FSC) Class :C Shelf Life : 05 years	Non-Absorbable suture is a combination of surgical eyeless needle and thread of variance size and it do not cooperate any medicinal substance and/ or matrial of animal or human origin.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017

83.	M/s. A & E Medical, 323-Ata Turk Block, New Garden Town, Lahore. ELI-00023 **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Authorized distributor**: M/s. Angiodynamics, Inc also DBA Navilyst Medical Inc, 26 Forest St. Marlborough,MA 01752, USA **Manufacturing site:** M/s. C.R. Bard, Inc. 289 Bay Rd, Queensbury, NY USA 12804. FSC USFDA Valid till January 17, 2020	**Navilyst Angiographic Guide Wires** (Catheter Guide Wire) Codes: 97000216 Fixed core /3mm/J/PTFE/0.69 mm (0.25in)/145cm 97000202 Fixed core /3mm/J/PTFE/0.94 mm (0.35in)/145cm 97000405 3mm/J/FC/PTFE/0.94mm (0.35in)/260cm 97000205 fixed core /3mm/J/PTFE/1.01 mm (0.38in)/145cm 97000406 3mm/J/FC/PTFE/1.01mm (0.38in)/260cm 97000401 Straight/FC/PTFE/0.94mm (0.035in)/260cm 97000101 Straight/PTFE/0.94mm (0.035in)/145cm 97000103 Straight/PTFE/1.01mm (0.38in)/145cm Class D Shelf Life : 03 years	Catheter Guide Wire	**Approved** subject to provision of FSC mentioning the nameof market authorization holder.
84.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal manufacturer** M/s. Angiodynamics, Inc also DBA Navilyst Medical Inc, 26 Forest St.	**NAMIC Angiographic Control Syringe** (Syringe, Angiographic) 70097007, 70097107,	Used in Angiography & Angioplasty Procedures.	**Approved** subject to clarification regarding linkup of legal manufacrturer and

		Marlborough,MA 01752, USA. **Manufacturer / Distributor** M/s. Angiodynamics, Inc. also DBA Navilyst Medical, Inc. 10 Glens Falls Technical Park, glens Falls, NY USA 12801. FSC USFDA Valid till May 10, 2019	70087007, 70087107 Class B Shelf Life : 03 years		distributor/manufacturing site.
85.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** M/s. Sungwon Medical Co., Ltd., 199 Taeseongtabyeon-ro, Gangnae-myeon, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea FSC Korea issued on 25-04-2019 FSC Spain issue date 16-08-2019	Accu-Sheath Introducer System (Percutaneous Catheter) Class B Codes: SWSC-4FR-10cm SWSC-4.5FR-10cm SWSC-5FR-10cm SWSC-5.5FR-10cm SWSC-6FR-10cm SWSC-7FR-10cm SWSC-8 FR-10cm SWSC-9FR-10cm SWSC-5FR-23cm SWSC-6FR-23cm SWSC-7FR-23cm SWSC-8FR-23cm SWSC-9FR-23cm Shelf Life : 03 years Fee submitted: Rs 25,000/-	Inserting catheter into an artery or vein except for central circulatory system and is intended for continuous use for not more than 30 days	**Approved.**
86.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal manufacturer:** Navilyst Medical Inc, 26 Forest St. Marlborough, MA, USA 01752 **Manufacturing site:**	NAMIC Angiographic Manifold Class B Codes: 70037202 70038202	Intended to be used in fluid management and/or invasive pressure monitoring systems	**Approved.**

		Navilyst Medical, Inc. 10 Glens Falls Technical Park, Glens Falls, NY USA 12801. FSC US FDA valid till 07-05-2021	70037303 70038303 Shelf Life : 03 years Fee submitted: Rs. 25,000/-		
87.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. SIS Medical AG, Hungerbuelstrasse 12a, 8500 Frauenfeld, CH Switzerland. FSC Switzerland Valid till 05.02.2022	**OPN NC PTCA Balloon** (Super High Pressure PTCA Balloon) **Sizes:** OPN NC Ø1.5-10 150-010-004 1.5-10 OPN NC Ø1.5-15 150-015-004 1.5-15 OPN NC Ø1.5-20 150-020-004 1.5-20 OPN NC Ø2.0-10 200-010-004 2.0-10 OPN NC Ø2.0-15 200-015-004 2.0-15 OPN NC Ø2.0-20 200-020-004 2.0-20 OPN NC Ø2.5-10 250-010-004 2.5-10 OPN NC Ø2.5-15 250-015-004 2.5-15 OPN NC Ø2.5-20 250-020-004 2.5-20 OPN NC Ø3.0-10 300-010-004 3.0-10 OPN NC Ø3.0-15 300-015-004 3.0-15 OPN NC Ø3.0-20 300-020-004 3.0-20 OPN NC Ø3.5-10 350-010-004 3.5-10 OPN NC Ø3.5-15 350-015-004 3.5-15 OPN NC Ø3.5-20 350-020-004 3.5-20 OPN NC Ø4.0-10 400-010-004 4.0-10 OPN NC Ø4.0-15 400-015-004 4.0-15 OPN NC Ø4.0-20 400-020-004 4.0-20 OPN NC Ø4.5-10 450-	Super High Pressure PTCA BalloonCatheter	**Approved** subject to provision of Manufacturing and QC processes in detail and Stability studies supporting claimed shelf life.

			010-004 4.5-10 OPN NC Ø4.5-15 450-015-004 4.5-15 OPN NC Ø4.5-20 450-020-004 4.5-20 Class D Shelf Life : 04 years		
88.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. SIS Medical Distribution AG, Hungerbuelstrasse 12a/ CH-8500 Frauenfeld, Switzerland. FSC Switzerland Valid till 05.02.2022	**TIN PTCA Balloon** (High Performance PTCA Balloon Catheter) Codes/ sizes: As per FSC #00000017 Class D Shelf Life : 03 years	High Performance PTCA Balloon Catheter	**Approved** subject to provision of Manufacturing and QC processes detail and Stability studies supporting claimed shelf life.
89.	M/s Leven Medical Care, 8-C, Ground Floor, Street No. 3 Near LGS School Shah, Jamal, Lahore. (ELI-00387) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** ALmediko saglik urunleri Turizm Gida Sanayl ve Ticaret limited Sirketi (Mimar Sinan Mah. 1420 Soak Ak No:108/203 Konak/ Izmir/ Turkiye. (FSC Issue 07-12-2017)	**Meme Thol Barrier Spray** Barrier Spray Class B Shelf Life: 24 Months Meme Thol Barrier Spray Code: 8680782940026	Meme Thol Barrier Spray is an anal barrier spray which is intended to be used to reduce and eliminate the symptomatic complaints of hemorrhoids and anal fissures. It is intended for external use Only.	**Approved** subject to inspection of manufacturer abroad under rule 71 of MDR, 2017 amd provision of Notarized credentials of manufacturer abroad.
90.	M/s. Total Technologies (Pvt) Ltd., 696, J-2, Johar Town, Lahore. ELI-00129 **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Flow-Meter S.p.A., Via del Lino 6, 24040 Levate (BG) Italy. FSC Italy Issued on 02.01.2019	**Flowmeter** (Humidifiers for medical use) CH 200 TR 200 MAK 300 MAK 500 Class B	Humidifiers use to increase the relative humidity in the treatment with medical oxygen both in hospital and at home.	**Approved.**

			Shelf Life: N/A		
91.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Flow-Meter S.p.A., Via del Lino 6, 24040 Levate (BG) Italy. FSC Italy Issued on 02.01.2019	**Flowmeter** (Venturi Suction Units) Venturi Suction Unit AV 500 Class : B Shelf Life: N/A	Venturi Suction Units	**Approved.**
92.	M/s. Surgi World 303, Muhammad Plaza, College Road, Rawalpindi. (ELI-00212) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Access System, Inc. 605 North 5600 West Salt Lake City, Utah (UT) USA. **Manufacturing Site:** M/s Bard Reynosa S.A DE. C.V Blvd Montebello No.1 Parque Industrial Colonial Reynosa ,Tamaulipas, Mexico FSC USA Valid till, November, 18,2020	HEMOSPLIT ® Long Term Hemodialysis Catheter (Long term Hemodialysis Catheter) Code: 5733150-5733690 5733730-5733270 5733310-5733350 5734420 Class D Shelf Life 2 years	The HemoSplit ® Long Term Memodialysis Cathetes are indicated for use in attaining short term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy.	**Approved** subject to provision of Stability data supporting claimed shelf life**.**
93.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 **Contract Manufacturer:** Bard Reynosa S.A.	**Bard Monopty Disposable Core Biopsy Instrument** Disposable Biopsy Instrument Class B Shelf Life: 3 Years	Bard Monopty Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes	**Approved.**

		DE. C.V. Blvd. Montebello No. 1 Paraque Industrial colonial reynosa, Tamaulipas Mexico. (FSC valid till 25-11-2020)	Codes : 121210, 121216,121410, 121416, 121610,121616, 121620, 121810, 121816, 121820, 122010, 122016, 122020, 211410, 211416, 211610, 211616, 211620, 211810, 212016, 212020,	and lengths. The acutator button is color coded according to the various gauge sizes. The core needle biopsy device is intended for use in obtaining biopsies from sof t tissues such as liver, kidney, prostrate, spleen, lymph needles and various soft tissue tumors. It is not inteded for use in bones.	
94.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 **Manufacturing Site:** Bard Reynosa S.A. DE. C.V. Blvd. Montebello No. 1 Paraque Industrial colonial reynosa, Tamaulipas Mexico. (FSC valid till 25-11-2020)	**Bard Magnum® Disposable Core Tissue Biopsy Needle** Disposable Biopsy Needle Class B Shelf Life: 3 Years Codes : MN1210, MN1213, MN1216, MN1220, MN1410, MN1413, MN1416, MN1420, MN1610, MN1613, MN1616, MN1620, MN1810, MN1813, MN1816, MN1820, MN1825, MN1830, MN2013, MN2016, MN2020,	The Bard Magnum Needle is a single Patient use core biopsy needle designed exlusively for use with Bard Magnum Resuable core Biopsy instrument fo acquisition of core biopsy tissue samples. The Magnum Biopsy System (Instrument and needles) is intended for use in obtaining	**Approved.**

				boipsies from soft tissues such a liver, kidney, prostrate, breast , spleen, lymph nodes and various soft tissues.	
95.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manugacturer:** Bard Peripheral vascular, Inc. 1625 W 3rd St Tempe, Az USA 85281 **Contract Manufacturer:** Bard Reynosa S.A. DE. C.V. Blvd. Montebello No. 1 Paraque Industrial colonial reynosa, Tamaulipas Mexico. (FSC valid till 10-07-2019)	**CONQUEST PTA Balloon Dilatation Catheter** PTA Balloon Dilatation Catheter. Class: D Shelf Life: 3 Years Codes : CQ-7552, CQ-7554, CQ-7558, CQ-7562, CQ-7564, CQ-7568, CQ-7572, CQ-7574, CQ-7576, CQ-7578, CQ-7582, CQ-7583, CQ-7584, CQ-7586, CQ-7588, CQ-7592, CQ-7594, CQ-75102, CQ- 75104, CQ-75122, CQ- 75124, CQ-12054, CQ-12062, CQ-12064, CQ-12072, CQ-12074, CQ-12082, CQ-12084, CQ-12094, CQ-120104,	CONQUEST PT Balloon Dilatation Catheter is a high performance balloon Catheter consiisting of an over the wire catheter with a balloon fixed at the distal tip. It is recommended for use in percutaneous Transluminal Angioplasty of the femoral, iliax and renal arteries and for the treatment of obstructive lesionn of native or synthetic arteriovenous dialysis fistulae. The device is also recoommende d for post dilatation of stent grafts in peripheral vasculature. This catheter is not use in	**Approved.**

				coronary arteries.	
96.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 **Contract manufacturer:** Bard Shannon Limited San Seronimo Industrial Park Lot No.1 Road No. 3 Km 79.7 Humacao, PR USA 00791. (FSC valid till 28-02-2019)	**Bard ®Sauvage® Filamentous Fabric** Surgical Fabric Class D Shelf Life: 5 Years Codes : 007942, 007943, 007944, 007828, 007829, 007940,	Bard Sauvage Filamentous Fabrics are indicated for use of cardiovascular surgical procedures requiring patch graft angioplasty such as carotid endarterctomy.These fabrics are also indicated for repair of certain intra cardiac anomalies such as septal defects. It is constructed of knitted polyster (polyethylene terephthalate. Knitted constuction is designed to resist fraying at the cut edges. Both sides of this fabris are filamentous, one considerably more htan other, the more defined filamentous surface is indicated by reference markings.	**Approved** subject to provision of Valid FSC and Stability data supporting shelf life of products.

97.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 **Contract Manufacturer:** Lavelle Machine & Tool Co., Inc. 485 Groton Rd. P.O.Box 1558 WestFord, MA USA 01886 (FSC valid till 13-02-2021)	**Bard Magnum Disposable Core Biopsy Instrument** Disposable Biopsy Instrument Class B Service Life: 10 Years. Codes : MG1522	Bard Magnum Biopsy System (Instrument and needles) is intended for use in obtaining biopsies soft tissues such as liver, kidney, prostate, spleen lymph, needles and various soft tissue tumors.	**Approved** subject to provision of Manufacturing, QC documents and FQA of manufacturing site.
98.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 **Contract Manufacturer:** C.R. Bard, Inc. 289 Bay Rd Queensbury NY USA 12804 (FSC valid till 14-12-2019)	**Rival PTA Dilatation Catheter** PTA Balloon Dilation Catheter Class D Shelf Life: 3 Years Codes As Per Fsc: RV8032, RV8034, RV8036, RV80310, RV8042, RV8044, RV80410, RV80415, RV8052, RV8054, RV8056, RV8058, RV80510, RV80515, RV8062, RV8064, RV8066, RV8068, RV80610, RV80610, RV80615, RV8072, RV8074, RV8076, RV8078, RV8082, RV8084, RV8086, RV8088, RV8092, RV8094, RV13542, RV13544, RV135410,	The Rival PTA Dilatation Catheter is inteded to dilate stenoses in the peripheral arteries, treat obstructive lesions of native or synthetic A-V Fistulae, and or re-expand endoluminal stent graft elements in the iliac arteries.	**Approved.**

			RV135415, RV13552, RV13554, RV13556, RV13558, RV135510, RV135515, RV13562, RV13564, RV13566, RV13568, RV135610, RV13572, RV13574, RV13578, RV13582, RV13584, RV13586, RV13588, RV13592, RV13594, RV135102, RV135104,		
99.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 Contract Manufacturer: C.R. Bard, Inc. 289 Bay Rd Queensbury, NY USA 12804 (FSC valid till 10-07-2020)	**Denali ® Vena Cava Filter** Vascular Grafts Class: D Shelf Life : 3 Years Codes : DL950F, DL950J	The Denali Vana Cava filter is venous intruption device designg to prevent pulmonary imbolism. It is designed to act as perminant filter when clinically indicated, the Denali filter may be percutanously removed after impnatation.	**Approved.**
100.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Bard Peripheral Vascular, Inc. 1625 W 3rd st Tempe, AZ USA 85281 **Manufacturing Site:** Bard Shannon Limited San Seronimo Industrial Park Lot No.1 Road No. 3 Km 79.7 Humacao,	**Bard PTFE Felt** Surgical Felt Class D Shelf Life : 5 Years Codes: 007975,007973,007968, 007976, 007974, 007977, 007836,007837	Bard PTFE Felt used in various applications fo general, vascular and cardiac surgery. They are commonly used as a patch , a buttress for sutures and as a material for replacement	**Approved** subject to provision of valid FSC and Stability data supporting shelf life of medical device.

		PR USA 00791. (FSC valid till 28-02-2019)		of segments of the ventricular myocardium after resection.	
101.	M/s Roche Pakistan Limited, 1st floor, 37-B, Block-6, P.E.C.H.S, Karachi (ELI-00009) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016) (FSC Germany issued on 22-02-2018)	Cobas Elecsys PAPP-A Test Kit Class C Cobas Elecsys PAPP-A Size: 100 Test Kit Code: 04854098 Shelf Life: 18 Months Cobas Elecsys PAPP-A Size: 100 Test Kit Code: 07027621190 Shelf Life: 18 Months Cobas PAPP-A Calset Size: 4 x 1 ml Code: 04854101 Shelf life: 29 Months Fee submitted: Rs. 50,000/-	Immunoassay for the in vitro quantitative determination of pregnancy-associated plasma protein A (PAPP-A) in human serum.	**Approved.**
102.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016) (FSC Germany issued on 22-02-2018)	Cobas Elecsys Anti-HAV Test Kit. Class C Cobas Elecsys Anti-HAV Size : 100 Test Code: 04854977 Shelf Life: 12 Months Cobas Elecsys Anti-HAV Size : 300 Test Code: 07026757190 Shelf Life: 12 Months Cobas PreciControl Anti-HAV	Electrochemiluminescence immunoassay for the in vitro quantitative determination of total antibodies to the hepatitis A virus in human serum and plasma. It is used as an aid to detect a past or existing hepatitis A infection, and to observe the	**Approved.**

			Size: 4x4ml Code: 04855043 Shelf Life: 12 Months Cobas Diluent Hepatitis A Size: 2 x 15 ml Code: 11361252 Shelf Life: 30 Months Fee sumitted: Rs. 50,000/-	immune response after HAV vaccination	
103.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer/** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016) (FSC Germany issued on 22-02-2018) (FSC Germany issued on 15-03-2017)	Cobas Elecsys sFlt-1 Test Kit Class C Cobas Elecsys sFlt-1 Size: 100 Test Code: 05109523 Shelf Life: 18 Months Cobas Elecsys sFlt-1 Size: 100 Test Code: 07027818190 Shelf Life: 18 Months Cobas sFlt-1 CalSet Size: 4x1ml Code: 05109531 Shelf Life: 18 Months Cobas PreciControl Multi Marker Size: 6x2 ml Code: 05341787 Shelf Life: 24 Months Fee submitted: Rs. 50,000/-	Immunoassay for the in vitro quantitative determination of soluble fms-like tyrosine kinase-1 (s-Flt-1) in human serum as an aid in the diagnosis of preeclampsia	**Approved.**
104.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany	Cobas Elecys Anti-HAV IgM Test Kit Class C Cobas Elecsys Anti-HAV IgM Size: 100 Test	Immunoassay for the in-vitro quantitative determination of IgM antibodies to the hepatitis	**Approved.**

		issued on 19-09-2016) (FSC Germany issued on 22-02-2018)	Code: 11820591 Shelf Life: 12 Months Cobas Elecsys Anti-HAV IgM Size: 300 Test Code: 07026773190 Shelf Life: 12 Months Cobas Precicontrol Anti-HAV IgM Size: 16x0.67ml Code: 11876368 Shelf Life: 12 Months	A Virus in human serum and plasma. It is used as an aid to detect an acute or recently acquired hepatitis A Virus infection.	
105.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issue date 19-09-2016)	CoaguChek® aPTT Controls (Level 1 + 2) Code: 06882692190 Size: 4 x Level 1 4 x Level 2 Class C Shelf Life: 15 Months Fee submitted: Rs. 50,000/-	Used for system checks and quality control testing of activated partial thromboplastin Time (aPTT) with the CoaguChek Pro II meter and CoaguChek aPTT Test Strips	**Approved.**
106.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issue date 19-09-2016)	CoaguChek® XS System Code: 04625412 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Used for quantitative determination of prothrombin time using capillary blood from a fingertip or untreated venous whole blood.	**Approved.**
107.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim,	CoaguChek® PT Controls (Level 1+2) Code: 06679684190	Used for system checks and quality control testing of	**Approved.**

		Germany. (FSC Germany issue date 19-09-2016)	Size: 4 x Level 1 4 x Level 2 Class C Shelf Life: 15 Months Fee submitted: Rs. 50,000/-	prothrombin time with the CoaguChek Pro II meter and Coagu Chek Pt Test Strips. Intended for professional use.	
108.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016) (FSC Germany issue date 24-10-2018)	CoaguChek® XS PT Test (Strips) Class C CoaguChek XS PT Test Size: 1 x 24 strips Code: 04625358 CoaguChek XS PT Test Size: 1 x 6 strips Code: 04625374 CoaguChek XS PT Test Size: 2 x 24 strips Code: 04625315 Shelf Life: 21 Months. Fee submitted: Rs. 50,000/-	Test Strips for the quantitative in vitro determination of prothrombin time capillary blood or from non-anticoagulated venous blood using coaguChek XS/XS Plus/XS Pro meters.	**Approved.**
109.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016)	CoaguChek® XS PT Controls Class C Codes: 04696522 Size : 4 Bottles Shelf Life: 15 Months Fee submitted: Rs. 50,000/-	Used for system checks and quality control testing of prothrombin time with the CoaguChek XS Plus or CoaguChek XS Pro meter and CoaguChek XS PT Test Strips.	**Approved.**

110.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016)	CoaguChek® aPTT Test (Strips) Class C Code: 06882382019 Size: 2 x 24 Strips Shelf Life: 21 Months Fee submitted: Rs. 50,000/-	Test Strips for determination of the activated partial thromboplastin time (aPTT) using the CoaguChek Pro II meter. Can be used with either capillary, venous, or arterial fresh whole blood.	**Approved.**
111.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016)	CoaguChek® XS PT Test PST Class C CoaguChek XS PT Test PST Code: 07671687019 Size: 24 Test Strips CoaguChek® XS PT Test PST Code:07671679190Size: 6 Test Strips Shelf Life: 21 Months Fee submitted: Rs. 50,000/-	Test Strips for determination of prothrombin time (PT) using the CoaguChek INRange/CoaguChek XS meter. The test uses fresh capillary whole blood and is intended for patient self-testing only.	**Approved.**
112.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016)	CoaguChek® PT Test (Strips) Class C Code: 06688721019 Size: 2x24 Strips Shelf Life: 21 Months Fee submitted: Rs. 50,000/-	Test Strips for determination of prothrombin time (PT) using the CoaguChek pro II meter. The test can be used with either capillary, venous, or arterial fresh	**Approved.**

				whole blood.	
113.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 24-10-2018) (FSC Germany issued on 19-9-2016)	Cobas Homocysteine Enzymatic Assay Test Kit Class C HCYS Size: 300 Test Code: 05385415 Shelf life: 14 months Homocysteine Control Kit Size: 2 x 3 ml Code: 05142423 Shelf life: 15 months Homocysteine Calibrator Kit Size: 2x3 ml Code: 05385504 Shelf life: 15 months Fee submitted: Rs. 50,000/-	In vitro test for the quantitative determination of total L-homocysteine in human serum and plasma to assist in the diagnosis of patients suspected of having hyperhomocysteinemia or homocystinuria.	**Approved.**
114.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 22-2-2018) (FSC Germany issued on 19-9-2016)	Cobas Elecsys Free bhCG IVD Test Kit Class C Free bhCG Size: 100 Tests Code: 04854071 Shelf life: 18 months Free bhCG Size: 100 Tests Code: 07027303190 Shelf life: 18 months Free bhCG Calset Size: 2 x 1 ml Code: 04854080 Shelf life: 18 months Precicontrol Maternal Care Size : 2 x 2.0 ml	Immunoassay for the in vitro quantitative determination of free bhCG (free B-subunit of human chorionic gonadotropin) in human serum.	**Approved.**

			Code: 04899881 Shelf life: 29 months Fee submitted: Rs. 50,000/-		
115.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 09-1-2019) (FSC Germany issued on 19-9-2016) (FSC Germany issued on 15-3-2017)	Cobas Cardiac C-Reactive Protein (Latex) High Sensitive (CRPHS) Test Kit Class C CRPHS Size: 2x50 Test Code: 05401607 Shelf Life: 24 Months CRPHS Size: 300 Test Code: 04628918 Shelf Life: 24 Months CRPHS Size : 600 Test Code: 08057605190 Shelf Life: 24 Months C.f.a.s. Protein (calibrator for automated system) Size: 5 x 1 ml Code: 11355279 Shelf Life: 30 Months Fee submitted: Rs. 50,000/-	In-vitro test for the quantitative determination of C-Reactive protein (CRP) in human serum and plasma for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury etc	**Approved.**
116.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016) (FSC Germany issued on 22-02-2018)	Cobas Elecsys PIGF Test Kit Class C PIGF Size: 100 Tests Code 05144671 Shelf Life: 18 Months Elecsys PIGF Size: 100 Tests Code 07027648190	Immunoassay for the in vitro quantitative determination of placental growth factor (PIGF) in human serum intended for use as an aid in the diagnosis of preeclampsia	**Approved.**

			Shelf Life: 18 Months PIGF Calset Size: 4x 1ml Tests Code 05144701 Shelf Life: 18 Months Fee submitted: Rs 50,000/-		
117.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC issuance 19-09-2016)	Cobas Tina-Quant D-Dimer Test Kit D-DI2 Tina-Quant D-Dimer Gen 2) Size: 100 Test Code: 04912551 Shelf life: 15 months D-DI2 Tina-Quant D-Dimer Gen 2) Size : 4 x 50 Test Code: 05077753 Shelf life: 15 months Cardiac D-Dimer Size: 10 Test Code: 04877802 Shelf life: 12 months D-Dimer Gen. 2 Calibrator Size: 6 x 5 ml Code: 05050901 Shelf life: 15 months D-Dimer Gen. 2 Control I/II Size: 2 x 1.0ml Code: 05050936 Shelf life: 15 months Cardiac Control D-Dimer Size: 2 x 1.0 ml Code: 04890523 Shelf life: 12 months Fee submitted: Rs. 50,000/-	In-vitro test for the quantitative immunological determination of fibrin degradation products (D-Dimer and X-oligomers) in humna plasma	**Approved.**

118.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 22-02-2018) (FSC Germany issued on 19-09-2016)	Cobas Elecsys BRAHMS PCT IVD Test Kit Class C BRAHMS PCT Size: 100 Test Code: 05056888 Shelf life: 24 months BRAHMS PCT Size: 100 Test Kit Code: 07301715190 Shelf life: 24 months Fee submitted: Rs. 50,000/-	Immunoassay for the invitro quantitative determination of PCT (Procalcitonin) in human Serum and plasma to aid in the early detection of clinically relevant bacterial infection	**Approved.**
119.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 15-03-2018)	CoaguChek® INRange System Code: 07404379018 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	Intended for the determination of prothombin time (PT) in fresh capillary blood	**Approved.**
120.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Roche Diagnostic GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany. (FSC Germany issued on 19-09-2016)	CoaguChek® Pro II (Coagulation Meter Kit) Class C Codes: 07237944190 (Without W-LAN) 07210841190 (W-LAN) Shelf Life: N/A Fee submitted: Rs. 50,000/-	Used for the determination of PT (Prothrombin time) and aPTT (activated prothromobo plastin time) by health care professionals in a point of care environment.	**Approved.**
121.	-do- **<u>Evaluator:</u>** **Mr. Shahid**	**Legal Manufacturer:** Roche Diagnostics International Ltd.	Cobas Elecsys CMV IgM Test Kit Class C	Immunoassay for the in vitro qualitative determination	**Approved.**

	Muhammad Iqbal	Forrenstrasse 2, 6343 Rotkreuz, Switzerland **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 22-2-2018 & 24-10-2018)	Shelf Life: 15 Months i) Elecsys CMV IgM Size: 100 Tests Code: 04784618190 ii) Elecsys CMV IgM Size: 300 Tests Code: 07027133190 iii) Precicontrol CMV IgM Size: 16X1 ml Code: 04784626 **Rs.50,000**	of IgM antibodies to cytomegalovirus in human serum and plasma.	
122.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Roche Diagnostics International Ltd. Forrenstrasse 2, 6343 Rotkreuz, Switzerland **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 19-09-2016 & 22-02-2018)	Elecsys HSV-1 IgG Test Kit Class C Shelf Life: 18 Months i) HSV-1 IgG Size: 100 Tests Code: 05572185 ii) Elecsys HSV-1 IgG Size: 100 Tests Code: 07027494190 iii) HSV-2 IgG Size: 100 Tests Code: 05572193 iv) Elecsys HSV-2 IgG Size: 100 Tests Code: 07027508190 v) PreciControl HSV Size: 4x3.0ml Code: 05572207 **Rs.50,000**	Immunoassay for the in vitro qualitative determination of IgG class antibodies to HSV-1 & HSC-2 in human serum and plasma. PreciControl HSV is used for quality control of the elecsys HSV-1 iGG and Elecsys HSV-2 IgG immunoassays on the Elecsys and cobas e immunoassay analyzers	**Approved.**
123.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Roche Diagnostics International Ltd. Forrenstrasse 2,	Elecsys Everolimus Test Kit Class C	Immnoassay for the in vitro quantitative determination of everlolimus	**Approved.**

		6343 Rotkreuz, Switzerland **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 19-09-2016 & 22-02-2018)	1. Everolimus Shelf life: 24 months 06633188190 2. Elecsys Everolimus Shelf life: 15 months 07027257190 3. Everolimus Calset Shelf life: 24 months 06633196190 4. PreciControl Everolimus Shelf life:15 months 07294131190 **Rs.50,000**	in human whole blood. The assay is used as an aid in the management of kidney, liver and heart transplant patient receiving everolimus Therapy.	
124.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Roche Diagnostics International Ltd. Forrenstrasse 2, 6343 Rotkreuz, Switzerland **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 19-09-2016 & 22-02-2018)	Elecsys Tacrolimus Test Kit Class C Shelf life: 1. Tacrolimus Code:05889057 Shelf life:15 Months (100 tests) 2. Elecsys Tacrolimus Code:07251254190 Shelf life: 15 Months (300 tests) 3. Tacrolimus Calset Code: 05889065 Shelf life: 36 Months 4. PreciControl ISD Code: 05889081 Shelf life: 21 Months 5. ISD Sample	In vitro quantitative determination of Tacrolimus in human whole blood. The assay is used as an aid in the management of heart, liver and kidney transplant patients receiving tacrolimus therapy.	**Approved.**

			Pretreament Code: 05889073 Shelf life: 24 Months. **Rs.50,000**		
125.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Roche Diagnostics International Ltd. Forrenstrasse 2, 6343 Rotkreuz, Switzerland **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 19-09-2016 & 22-02-2018)	Elecsys Sirolimus Test Kit Class C 1. Sirolimus Code: 06327974190 Shelf life: 15 Months 2. Sirolimus CalSet Code: 06327982190 Shelf life: 21 Months 3. Elecsys Sirolimus Code:07027834190 Shelf life: 15 Months **<u>Rs.50,000</u>**	Immunoassay for the in vitro quantitative determination of sirolimus in human whole blood. The assay is used as an aid in the management of kidney transplant patient receiving sirolimus therapy.	**Approved.**
126.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Roche Diagnostics International Ltd. Forrenstrasse 2, 6343 Rotkreuz, Switzerland **Manufacturing Site:** Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 19-09-2016 & 22-02-2018)	Elecsys Cyclosporine Test Kit Class C 1. Cyclosporine Code: 05889014 Shelf Life: 15 Months (100 tests) 2. Elecsys Cyclosporine Code: 07251246190 Shelf Life: 15 Months (300 tests) 3. Cyclosporine Calset Code: 05889022 Shelf Life: 15 Months **Rs.50,000**	Immunoassay for the in vitro quantitative determination of Cyclosporine in human whole blood.	**Approved.**
127.	-do-	**Legal**	Cobas® KRAS,	The Cobas®	**Approved.**

	<u>Evaluator:</u> **Mr. Shahid Muhammad Iqbal**	**Manufacturer:** Roche Diagnostics International Ltd. Forrenstrasse 2, 6343 Rotkreuz, Switzerland **Manufacturing Sites:** Roche Molecular System, Inc 1080 US Highway 202 South Branchburg, NJ 08876 USA. Roche Diagnostics GmbH, Sandhofer Str.116, 68305 Mannheim, Germany (FSC Germany Issue Date 15-10-2018)	Mutation Test **Cobas®4800 BRAF V600 Mutation Test (05985595190)** Class C Shelf Life: 24 Months **Rs.50,000**	KRAS Mutation Test, for use with the cobas® 4800 System, is a real time PCR test for the detection of seven somatic mutation I condons 12 and 13 of the KRAS gene in DNA Derived from formalin – fixed paraffin embedded human colorectal cancer (CRC) tumor tissue.	
128.	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi (ELI-00240) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Ningbo Yingmed Medical Instruments Co., Ltd., Room 705, Yingsheng Building, No. 456 Tai'an RD Southern Business Zone, Yinzhou District, 315199 Ningbo, China. (FSC UK MHRA issued on 9-2-2018) FSC China not provided	Yingmed Oxygen Mask Class B Adult standard Pediatric standard Adult elongated Pediatric elongated Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	Sterile, single use PVC oxygen mask	**Approved**.
129.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Ningbo Yingmed Medical Instruments Co., Ltd., Room 705, Yingsheng	Yingmed Nebulizer Mask Class-B Adult standard	Sterile, single use aerosol nebulizer mask	**Approved**.

		Building, No. 456 Tai'an RD Southern Business Zone, Yinzhou District, 315199 Ningbo, China. (FSC UK MHRA issued on 9-2-2018) FSC China not provided	Pediatric standard Adult elongated Pediatric elongated Shelf Life: 5 Years Fee submitted: Rs. 25,000/-		
130.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Ningbo Yingmed Medical Instruments Co., Ltd., Room 705, Yingsheng Building, No. 456 Tai'an RD Southern Business Zone, Yinzhou District, 315199 Ningbo, China. (FSC UK MHRA issued on 9-2-2018) FSC China not provided	Yingmed Latex Foley Class B Size: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16 Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28 Fr, 30Fr Shelf Life: 5 Years Fee submitted: Rs. 25,000/-	Sterile, single use, flexible tubes placed in the body to drain and collect urine from the bladder	**Approved**.
131.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Shenzhen Fitconn Technology Co., Ltd. 7th Floor, No. 116 Xiangshan Road, Luotian Community, Songgang Street, Bao'an, Shenzhen, Guangdong, China. (FSC China Valid till 14-3-2020)	Accumax Super (Model: CNB69009) (Compressor Nebulizer)` Class B Shelf Life: N/A Fee submitted: Rs. 25,000/-	Intended to provide clean compressed air to drive gas-powered nebulizer for delivery of medication in an aerosol form to patients through the respiratory system. Active medical device	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017**.**

132.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Manufacturer:** M/s Jiangsu Pedo-Care Medical Equipment Co., Ltd., Nanmo Industrial Park, Nanmo Town, Haian, China (FSC China Valid Till03-12-2020)	Accumax Nabulizer (Air Compressor Medical Nebulizer) Class B Shelf Life: 1153 Hours JK-40 **Rs.25,000/-**	Compressor Nebulizer Machine	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017**.**
133.	M/s PharmEvo (Pvt) Ltd.,A-29, North Western Industrial Zone, Port Qasim, Karachi (ELI-00055) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Omron Healthcare Co., Ltd. 53, Kunotsuba, Terado-cho, Muko Kyoto, 617-0002 Japan. **Manufacturing site:** Omron Dalian Co., Ltd (OMD) No. 3. Song Jiang Road Economic & Technical Development Zone, Dalian 11600, P.R. China. (FSC Netherlands Valid till 21-03-2024).	Omron ECO Temp Basic (MC-246-E) (Clinical Electronic Thermometer) Class B Shelf Life: N/A Fee submitted: Rs. 25,000/-	Digital fever thermometer for oral, axillary and rectal use	**Approved.**
134.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Omron Healthcare Co., Ltd. 53, Kunotsuba, Terado-cho, Muko, KYOTO, 617-0002 Japan. **Manufacturing site:** Omron Healthcare Manufacturing Vietnam Co, Ltd (OHV) 28 VSIP, Street 2, Vietnam-	Omron M2 Basic (HEM-7120-E) (Blood Pressure Monitor) Class B Shelf Life N/A Fee submitted: Rs. 25,000/-	Digital automatic upper arm blood pressure monitor	**Approved.**

		Singapore Industrial park II, Binh Duong Province, Vietnam (FSC Netherlands Valid till 21-03-2024)			
135.	M/s. Intek Corporation, Office No. 30, Al-Amin Plaza, The Mall, Rawalpindi. ELI-00034 **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: MicroVention, Inc. 1311 Valencia Ave Tustin, CA 92780, USA Manufacturing Sites: 1. MicroVention, Inc.35 Enterprise, Aliso Viejo, CA, USA 92656 2. MicroVention Costa Rica, S.R.L. Zona Franca coyol Alajuela, Costa Rica. 3. MicroVention, Inc. 1311 Valencia Ave Tustin, CA 92780, USA (FSC US FDA valid till 14-12-2019)	Headway Duo Microcatheter Class D Codes: MC162156S MC162167S Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Intended for general intravascular use, including peripheral and coronary vasculature for the infusion of diagnostic agents such as contrast media and therapeutic agents such as embolization materials. Also intended for neurovascular use	**Approved.**
136.	M/s. Digital Imaging Systems, 121- Habitat Apartments, Shadman II, Ghaus -ul-Azam Road, Lahore. ELI-00094 **<u>Evaluator:</u>** **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.o, Cruce Davila,	Hi-Torque Winn Guide Wire Class D Codes: 1012466 1012467 1012468 1012469 1012470 1012471 1012472 1012473	Intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal	**Approved.**

		Barceloneta, PR USA 00617 FSC US FDA valid till 18-3-2021	1012474 1012475 Shelf Life: 02 years Fee submitted: Rs. 50,000/-	angioplasty (PTA) etc	
137.	M/s Muller & Phipps Pakistan (Pvt) Ltd., Uzma Court, Main Clifton Road, Karachi (ELI-00030) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® Reader Ref: C1100 Class C Shelf Life: N/A Fee submitted: Rs. 50,000/-	A scanning fluorometer and data analyzer for the measurement of fluorescence in various RAMP® immunoassay applications.	**Approved.**
138.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® 200 Class C Ref: C2100- Control Module (CM) Ref: C3100- Test Module (TM) Shelf Life: N/A Fee submitted: Rs. 50,000/-	Fluorometric detection instrument	**Approved.**
139.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® NT-proBNP Ref: C1104 Class C Shelf Life: 24 months Fee submitted: Rs. 50,000/-	Quantitative immunochromatographic test for measurement of NTproBNP to aid in diagnosis and assesssmnet of severity in individuals suspected of having congestive heart failure etc	**Approved.**

140.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® Myoglobin Ref: C1103 Class C Shelf Life 18.7 Months Fee submitted: Rs. 50,000/-	Quantitative immunochromatographic test for measurement of myoglobin levels to aid in rapid diagnosis of acute myocardial infarction	**Approved.**
141.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® D-dimer Ref: C1106 Class C Shelf Life 24 Months Fee submitted: Rs. 50,000/-	Quantitative immunochromatographic test for quantification of the fibrin degradation product (FDP) D-dimer that is used as a diagnostic marker for DIC, VTE , DVT and PE	**Approved.**
142.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® Cardiac Controls Ref: C2003-1, C2003-2, C-2003-3 Class C Shelf Life 24 Months Fee submitted: Rs. 50,000/-	Intended for *in vitro* diagnostic use in the quality controlof cardiac markers on the RAMP platform	**Approved.**
143.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue	RAMP® Troponin I Ref: C1101 Class C Shelf Life 24 Months Fee submitted: Rs. 50,000/-	Quantitative immunochromatographic test for measurement of cardiac troponin I levels to aid in the rapid diagnosis of	**Approved.**

		date 11-12-2017)		acute myocardial infarction (AMI)	
144.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: Response Biomedical Corporation, 1781-75th Avenue W., Vancouver, British Columbia, V6P 6P2, Canada. (FSC Canada issue date 11-12-2017)	RAMP® Procalcitonin Ref: C1112 Class C Shelf Life: 25 Months Fee submitted: Rs. 50,000/-	Quantitative immunochromatographic test for measurement of prohormone procalcitonin (PCT) levels as an aid in the risk assessment of progression to severe sepsis and septic shock	**Approved.**
145.	**M/s. Seico Scientific Traders,** 1st Floor, 104, Muhammadia Plaza, Gordon College Road, Rawalpindi. ELI-00205 **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. Ortho-Clinical Diagnostics, Felindre Meadows, Pencoed Bridgend, CF 35, 5PZ United Kingdom. FSC UK valid till 03-11-2021	Vitros Immunodiagnostic Products Anti HBc Kit 1. Vitros Immunodiagnostic Products Anti HBc Reagent Kit Ref: 8496812 2. Vitros Immunodiagnostic Products Anti-HBc Calibrator Ref: 1256494 3. Vitros Immunodiagnostic Products Anti HBc Controls Ref: 6800836 Class D Shelf Life: 52 weeks Fee submitted: Rs. 50,000/-	Used to detect antibodies against hepatitis B core antigen (anti-HBc) in serum and plasma following exposure to infectious hepatitis B virus (HBV)	**Approved.**
146.	-do- **<u>Evaluator:</u>**	Manufacturer: M/s. Ortho-Clinical	Vitros Immunodiagnostic Products HBsAg Kit	For qualitative detection of	**Approved.**

	Ms. Unum Zia Shamsi	Diagnostics, Felindre Meadows, Pencoed Bridgend, CF 35, 5PZ United Kingdom. FSC UK valid till 03-11-2021	1. Vitros Immunodiagnostic Products HBsAg Reagent Kit Ref: 8435307 2. Vitros Immunodiagnostic Products HBsAg Calibrator Ref: 1421932 3. Vitros Immunodiagnostic Products HBsAg Controls Ref: 6800598 Class D Shelf Life: 52 weeks Fee submitted: Rs. 50,000/-	hepatitis B surface antigen (HBsAg) in human serum and plasma	
147.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. Ortho-Clinical Diagnostics, Felindre Meadows, Pencoed Bridgend, CF 35, 5PZ United Kingdom. FSC UK valid till 03-11-2021	Vitros Immunodiagnostic Products HBeAg Kit 1. Vitros Immunodiagnostic Products HBeAg Reagent Pack Red: 8211880 2. Vitros Immunodiagnostic Products HBeAg Calibrator Ref: 1914498 3. Vitros Immunodiagnostic Products HBe Controls Ref: 6800837 Class D Shelf Life: 52 weeks Fee submitted: Rs. 50,000/-	For qualitative detection of hepatitis B e antigen (HBeAg) in human serum	**Approved.**

148.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. Ortho-Clinical Diagnostics, Felindre Meadows, Pencoed Bridgend, CF 35, 5PZ United Kingdom. FSC UK valid till 03-11-2021	Vitros Immunodiagnostic Products Syphilis TPA Kit 1. Vitros Immunodiagnostic Products Syphilis TPA Reagent Pack Ref: 6842803 2. Vitros Immunodiagnostic Products Syphilis TPA Calibrator Ref: 6842804 3. Vitros Immunodiagnostic Products Syphilis TPA Controls Ref: 6842805 Class C Shelf Life: 52 weeks Fee submitted: Rs. 50,000/-	For the qualitative determination of total (IgG and IgM) antibodies to *treponema pallidum* (TP) specific antigen in human serum and plasma	**Approved.**
149.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. Ortho-Clinical Diagnostics, Felindre Meadows, Pencoed Bridgend, CF 35, 5PZ United Kingdom. FSC UK valid till 03-11-2021	Vitros Immunodiagnostic Products Anti-HCV kit 1. Vitros Immunodiagnostic Products Anti-HCV Reagent pack Ref: 1318450 Shelf Life: 52 weeks 2. Vitros Immunodiagnostic Products Anti-HCV Controls Ref: 6800731 Shelf Life: 52 weeks 3. Vitros Immunodiagnostic Products Anti-HCV Calibrator Ref: 1940667 Shelf Life: 25 weeks	For the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human serum and plasma	**Approved.**

			Class D Fee submitted: Rs. 50,000/-		
150.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. Ortho-Clinical Diagnostics, Felindre Meadows, Pencoed Bridgend, CF 35, 5PZ United Kingdom. FSC UK valid till 03-11-2021	Vitros Immunodiagnostic Products Anti-HIV Combo Kit 1. Vitros Immunodiagnostic Products Anti-HIV Combo Reagent Pack Ref: 6842779 Shelf Life: 52 weeks 2. Vitros Immunodiagnostic Products Anti-HIV Combo Calibrator Ref: 6842780 Shelf Life: 52 weeks 3. Vitros Immunodiagnostic Products Anti-HIV 1+ 2 controls Ref: 6800586 Shelf Life: 104 weeks Class D Fee submitted: Rs. 50,000/-	For simultaneous qualitative detection of antibodies to human immunodeficiency virus type 1 including groyp M and O and/or to anti-HIV-1 and anti-HIV-2) and HIV p24 antigen in human serum and plasma	**Approved.**
151.	M/s Anwar & Sons, Apartment No.10, Safari Villas-2, Commercial Complex, Bahria Town Phase 7, Rawalpindi (ELI-00017) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	Manufacturer: M/s. SUMI Spolka z ograniczona, odpowiedzialnoscia Sp.k. ul. Drobiarska, 35, 05-070 Sulejowek, Poland. FSC Poland issued on 05.07.2017	Tracheal Tubes Class B Types: Tracheal tube with cuff, type magil Tracheal tube with cuff type magil, siliconised Tracheal tube with low pressure cuff, type murphy Tracheal tube with low pressure cuff, type murphy, siliconised Tracheal tube with low	Tracheal tubes	**Board** refer the case to committee to give recommenda-tion on grouping of the medical device comprising Dr. Muhammad Farid Khan and Dr. Muhammad Tahir Aziz, Member of MDB

			pressure cuff, type murphy, siliconised with stylet Tracheal tube with high volume cuff, type murphy, siliconised Tracheal tube without cuff, type murphy Tracheal tube without cuff, type murphy, siliconised Tracheal tube without cuff, type murphy, siliconised with stylet Tracheal tube without cuff, type murphy, soft, siliconised Tracheal tube without cuff, type murphy, soft, siliconised with stylet Microlaryngeal tracheal tube, siliconised Microlaryngeal tracheal tube, siliconised, reinforced Tracheal tube with suction lumen, type murphy, siliconised Reinforced tracheal tube with cuff, type murphy Reinforced tracheal tube with cuff, type murphy, siliconised Reinforced tracheal tube with cuff, type murphy, siliconised with stylet Reinforced tracheal tube without cuff, type murphy Reinforced tracheal tube without cuff, type murphy, siliconised Reinforced tracheal tube without cuff, type murphy, siliconised, with stylet Preformed tracheal		

			tube with cuff, oral, type murphy Preformed tracheal tube with cuff, oral, type murphy, siliconised Preformed tracheal tube with cuff, oral-forehead, type murphy, siliconised Preformed tracheal tube with cuff, oral-forehead, type murphy, siliconised Preformed tracheal tube without cuff, oral, type murphy, Preformed tracheal tube without cuff, oral, type murphy, siliconised Preformed tracheal tube without cuff, oral-forehead, type murphy, siliconised Preformed tracheal tube without cuff, oral-forehead, type murphy, siliconised Preformed tracheal tube with cuff, nasal, type murphy Preformed tracheal tube with cuff, nasal, type murphy, siliconised Preformed tracheal tube without cuff, nasal, type murphy Preformed tracheal tube without cuff, nasal, type murphy, siliconised Codes against each type as per FSC dated 05-07-2017 Shelf Life: 05 years Fee submitted: Rs. 25,000/-		

152.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** M/s. SUMI Spolka z ograniczona, odpowiedzialnoscia Sp.k. ul. Drobiarska, 35, 05-070 Sulejowek, Poland. FSC Poland issued on 05.07.2017	Tracheostomy Tubes Class C Types: Tracheostomy tube with low pressure cuff Tracheostomy tube with low pressure cuff, siliconised Tracheostomy tube with cuff, siliconised Tracheostomy tube with double cuff, siliconised Tracheostomy tube without cuff Tracheostomy tube without cuff, siliconised Tracheostomy tube without cuff, without connector, siliconised Tracheostomy tube with suction lumen, siliconised Tracheostomy tube with cuff, with adjustable flange, siliconised Tracheostomy tube without cuff, with adjustable flange, siliconised Reinforced tracheostomy tube with cuff, with adjustable flange, siliconised Reinforced tracheostomy tube without cuff, with adjustable flange, siliconised Codes against each type as per FSC dated 06-07-2017 Shelf Life: 05 years	Tracheostomy tubes	**Board** refer the case to committee to give recommenda-tion on grouping of the medical device comprising Dr. Muhammad Farid Khan and Dr. Muhammad Tahir Aziz, Member of MDB

			Fee submitted: Rs. 50,000/-		
153.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Wuhan BBT Mini-invasive Medical Tech. Co., Ltd, 4th Floor, 2nd Building, No. 12, 2nd Caifu Road, Donghu New Technology Development Zone, Wuhan, China. (FSC China valid till 30-11-2019) (FSC UK issued on 21-06-2018)	Ultrasonic surgical system Model: BBT-UT-2200 (On UK Free Sale Certificate) Class C Shelf life: 10 years Fee submitted: Rs. 25,000/-	Indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired	**Approved.**
154.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. SUMI Spolka z ograniczona, odpoweidzialnoscia sp.k, Drobiarska 35 05-070 Sulejowek, Poland. FSC Poland Isssued on 06.06.2017	**Bronchial Tubes** Double lumen bronchial tubes, left-sided 21-2410 21-2610 21-2810 21-3210 21-3510 21-3710 21-3910 21-4110 (set without clamps) 21-2420 21-2620 21-2820 21-3220 21-3520 21-3720 21-3920 21-4120 (set with clamps) 21-2422 21-2622 21-2822 21-3222 21-3522	Bronchial tubes are used for ventilation during thoracic surgery and other medical conditions.	**Approved** subject to inspection of manufacturer abroad under Rule, 71 of MDR, 2017.

			21-3722 21-3922 21-4122 Double lumen bronchial tubes, right-sided 22-2410 22-2610 22-2810 22-3210 22-3510 22-3710 22-3910 22-4110 (set without clamps) 22-2420 22-2620 22-2820 22-3220 22-3520 22-3720 22-3920 22-4120 (set with clamps) 22-2422 22-2622 22-2822 22-3222 22-3522 22-3722 22-3922 22-4122 Double lumen bronchial tubes, left-sided with carina hook 21-3241 21-3541 21-3741 21-3941 21-4141 (set) 21-3245 21-3545 21-3745 21-3945 21-4145 Double lumen bronchial tubes, right-		

			sided with carina hook 22-3241 22-3541 22-3741 22-3941 22-4141 (set) 22-3245 22-3545 22-3745 22-3945 22-4145 Class B Shelf Life : 05 years **Rs.25,000/-**		
155.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi (ELI-00019) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** M/s Abbott Molecular Inc., 1300 East Touhy Avenue Des Plaines, IL 60018, USA (FSC USFDA Valid Till 15-05-2020)	AneuVysion DNA Probe Kit Class C i) AneuVysion DNA Probe Kit Code: 05J38-010 (10Assays) Shelf Life: 18 Months ii) AneuVysion DNA Probe Kit Code: 05J38-030 (30Assays) Shelf Life: 18 Months Fee submitted: Rs. 50,000/-	Indicated for identifying and enumerating chromosomes 13, 18, 21, X and/or Y via Fluorescence in Situ Hybridization (FISH) for Prenatal Genetic Diagnosis	**Approved** subject to provision of Full QA certificate.
156.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** Axis-Shield Diagnostics Ltd, The Technology Park, Dundee, DD2 1XA, United Kingdom. FSC UK	Alere NT-proBNP for Architect 2R10-25 (100 Test Reagent), 2R10-35 (500 Test Reagent), 2R10-01 (Calibrators) & 2R10-10 (Controls) Class C	Assay for the in vitro quantitative determination of N-terminal pro B-type natriuretic peptide in human serum and plasma on the Architect	**Approved.**

		Issuance 25-06-2018	Shelf Life: 12 Months Calibrator & Control: 11 Months **Rs.50,000/-**	iSystem	
157.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbott GmbH & Co, KG, Max-Planck-Ring 2 65205 Wiesbaden Germany. **Manufacturing Site:** Axis-Shield Diagnostics, Ltd. The Technology Park, Dundee, DD2 1XA, UK FSC Germany issuance 19-07-2018	ARCHITECT Homocysteine ARCHITECT Homocysteine Calibrators 1L71-01 Shelf Life:16 months ARCHITECTHomocysteine Controls 1L71-10 Shelf Life:20 months ARCHITECT Homocysteine Reagent Kit 1L71-25 1L71-27 Shelf Life:13 months Class C **Rs.50,000/-**	Intended for the quantitative determination of total L-homocysteine in human serum or plasma.	**Approved** subject to provision of FQA or clarification from manufacturer. Contract between Axis-shield and Abbott.
158.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbott GmbH & Co, KG, Max-Planck-Ring 2 65205 Wiesbaden Germany. **Manufacturing Site:** Denka Seiken co. Ltd., Kagamida factory 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, 959-1695 Japan FSC Germany issuance 19-07-2018	ARCHITECT ProGRP ARCHITECT ProGRP Calibrator 1P45-03 Shelf Life:10 Months ARCHITECT ProGRP Controls 1P45-12 Shelf Life:10 Months ARCHITECT ProGRP Reagent kit (1×100 Tests) 1P45-27 Shelf Life: 18 Months Class C **Rs.50,000/-**	Intended for quantitative determination of ProGRP in human serum and plasma.	**Approved** subject to clarification of product specific FQA and ISO.13485.

159.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts, USA. **Manufacturing Site:** Sekisui Medical Co. Ltd., 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan. FSC UK Issuance 11-05-2017	Coagpia APTT-N LN 02R77-20 APPT-N Reagent LN 02R78-20 $CaCl_2$ Reagent LN 02R85-10 Control Set Class C Shelf Life: 24 Months **Rs.50,000/-**	Intended for the determination of activated partial thromboplastin time in human citrated plasma.	**Approved** subject to clarification of product specific FQA.
160.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts, USA. **Manufacturing Site:** Sekisui Diagnostic (UK) Ltd, Liphook way, Allington, Maidstone, United Kingdom. FSC UK Issuance 11-05-2017	Coagpia Thrombin Time **LN 02R81-20 Thrombin Time Reagent** **LN 02R81-10 TT Normal Control** **LN 02R81-11 TT Abnormal Control** Class C Shelf Life: 24 Months **Rs.50,000/-**	Intended for the determination of thrombin time in human citrated plasma.	**Approved** subject to clarification of product specific FQA and ISO.13485.
161.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts, USA. **Manufacturing Site:**	Coagpia Fbg Reagent **Fbg Reagent** **LN 02R79-20** **Shelf Life: 18 Months** **Calibrator** **LN 02R84-01** **Shelf Life: 24 Months**	Intended for quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma.	**Approved** subject to clarification of product specific FQA.

		Sekisui Medical Co. Ltd., 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan. FSC UK issuance 11-05-2017	**Control Set LN 02R85-10 Shelf Life: 24 Months** Class C **Rs.50,000/-**		
162.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts, USA. **Manufacturing Site:** Sekisui Medical Co. Ltd., 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan. FSC UK issuance 11-05-2017	Nanopia D-Dimer **D-dimer Reagent LN 02R80-20** **D-dimer Calibrator Set LN 02R80-01** **D-dimer Control Set LN 02R80-10** Class C Shelf Life: 24 Months **Rs.50,000/-**	Intended for quantitative determination of cross-linked fibrin (D-dimers) products in human citrated plasma.	**Approved** subject to clarification of product specific FQA
163.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts, USA. **Manufacturing Site:** Sekisui Medical Co. Ltd., 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan. FSC UK issuance 11-05-2017	Nanopia FDP **FDP Reagent LN 02R83-20** **FDP Calibrator Set LN 02R83-01** **FDP Control Set LN 02R83-10** Class C Shelf Life: 24 Months **Rs.50,000/-**	Assay for the quantitative determination of fibrin/fibrinogen degradation products, in human citrated plasma.	**Approved** subject to clarification of product specific FQA
164.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts,	Caogpia PT-N **Coagpia PT-N Reagent LN 02R76-20**	Intended for determination of the prothrombin time, and in conjunction	**Approved** subject to clarification of product specific FQA.

		USA. **Manufacturing Site:** Sekisui Medical Co. Ltd., 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan. FSC UK issuance 11-05-2017	**Coagpia Calibrator LN 02R84-01** **Coagpia Control Set LN-02R85-10** Class C Shelf Life: 24 Months **Rs.50,000/-**	with the relevant deficient plasmas, for the determination of an activity of coagulation factors II, V, VII and X in human citrated plasma.	
165.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Sekisui Diagnostics LLC, 4 Hartwell Place, Lexington, Massachusetts, USA. **Manufacturing Site:** Sekisui Medical Co. Ltd., 1-3 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan. FSC UK issuance 11-05-2017	Coagpia AT Reagent **AT Reagent LN 02R82-20** **Calibrator LN 02R84-01** **Control Set LN 02R85-10** Class C Shelf Life: 24 Months **Rs.50,000/-**	Quantitative determination of antithrombin activity in human citrated plasma.	**Approved** subject to clarification of product specific FQA
166.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbott Laboratories 100 Abbott Park Road Abbott Park , Illinois, 60064 USA. **Manufacturing Site:** Biokit, S.A. Can Male , S/n 08186 Llica D Amunt Barcelona- Spain. Biokit, S.A. Av. Can Montcau 7	ARCHITECT iDigoxin ARCHITECT iDigoxin Reagent Kit 1P32-25, 1P32-27 ARCHITECT iDigoxin Calibrators 1P32-01, 1P32-02 Class C Shelf Life: 18 Months **Rs.50,000/-**	Assay for the quantitative measurement of digoxin in human serum or plasma on the ARCHITECT iSystem.	**Approved** subject to clarification of product specific FQA and provision of documents of Contract between Abbott and Biokit, Essential principle of safety and performance.

		08186 Llica d Amunt Barcelona, Spain. FSC Germany Issuance 09-04-2019			
167.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbott GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. **Manufacturing Site:** Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355, USA FSC Germany issuance 19-07-2018	ARCHITECT CA 125 II **ARCHITECT CA 125 II Calibrator 2K45-02** **Shelf Life:** **08 Months** **ARCHITECT CA 125 II Controls 2K45-11** **Shelf Life:** **08 Months** **ARCHITECT CA 125 II Reagent Kit 2K45-29** **2K45-39** **Shelf Life:** **12 Months** Class C **Rs.50,000/-**	Intended for the quantitative determination of OC 125 antigen in human serum and plasma as an aid in monitoring response to therapy for patients with epithelial ovarian cancer.	**Approved** subject to clarification of product specific FQA.
168.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbott Laboratories Diagnostics Division 100 Abbott Park Rd. Abbott Park, IL USA 60064 **Manufacturing Site:** Fisher Diagnostics. Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc. 8365 Valley Pike Middletown,	ARCHITECT STAT Myoglobin **ARCHITECT STAT Myoglobin Calibrators 2K43-01** Shelf Life: 18 Months **ARCHITECT STAT Myoglobin Controls 2K43-10** Shelf Life: 36 Months **ARCHITECT STAT Myoglobin Reagent Kit 2K43-25** Shelf Life: 18 Months	Assay For the quantitative determination of Myoglobin in human serum and plasma.	**Approved** subject to clarification of product specific FQA and provision of documents of Contract between FisherDiagnostic and Abbott, Essential principle of safety and performance. of safety

		VA USA 22645. FSC USA validity 25-04-2020	Class C **Rs.50,000/-**		
169.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbot GmbH & Co, Kg Max-Planck-Ring 2 65205 Wiesbaden Germany. **Manufacturing Site:** Fisher Diagnostics. Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc. 8365 Valley Pike Middletown, VA USA 22645. FSC Germany issuance 20-02-2017	ARCHITECT B.R.A.H.M.S PCT **ARCHITECT B.R.A.H.M.S PCT Reagent Kit (1x100) 6P22-25** **ARCHITECT B.R.A.H.M.S PCT Reagent Kit (1x500) 6P22-35** **ARCHITECT B.R.A.H.M.S PCT Calibrators 6P22-01** **ARCHITECT B.R.A.H.M.S PCT Controls 6P22-10** Class C Shelf Life: 9 Months **Rs.50,000/-**	Assay For the quantitative determination of procalcitonin (PCT) in human serum and plasma.	**Approved** subject to clarification of product specific FQA and provision of documents of Contract between Fisher Diagnostic and Abbott.
170.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Abbott Laboratories Diagnostics Division 100 Abbott Park Rd. Abbott Park, IL USA 60064 **Manufacturing Site:** Alere Medical Co., Ltd., Chiba Plant 357 Matsuhidai, Matsudo-shi, Chiba 270-2214, Japan.	AlereDetermine™ Syphilis TP **AlereDetermine™ Syphilis TP 7D2442 7D2443** Class D Shelf Life: 15 Months **Rs.50,000/-**	Qualitative determination of *Treponema Pallidum* in human serum, plasma or whole blood	**Approved** subject to linkup letter of Alere Medical Co and Abbott Laboratories and clarification of product specific FQA.

		FSC Japan issuance 31-10-2018			
171.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer &Manufacturing Site:** Alere Technologies GmbH Loebstedter Starrse 103-105, 07749 Jena, Germany. FSC Germany Issuance 25-01-2019	m-Pima™ HIV-1/2 Detect **m-Pima™ HIV-1/2 Detect 27011R050** Class D Shelf Life: m-Pima™ HIV-1/2 Detect: 280 days **Rs.50,000/-**	m-Pima Analyser, m-Pima HIV-1/2 VL, M-Pima HIV-1/2 Detect	**Approved** subject to linkup letter of Alere Medical Co and Abbott Laboratories.
172.	M/s UDL Distribution (Pvt) Limited, 1-D-13, Sector 30, Korangi Industrial Area, Karachi (ELI-00073) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** M/s Jei Daniel Biotech Corp. Jinan Facility., A201, 1st building No 69, Hua Yang Road, Jinan, Shang Dong, China (FSC China Valid Till 5-10-2020)	Happy Life Self Pregnancy Test Strip-Human Chorionic Gonadotropin (HCG) Rapid Test Kit (Colloidal Gold) Class B Shelf Life: 36 Months Fee submitted: Rs. 50,000/-	Rapid Self Pregnancy Test Strip	**Rejected.** As the same product by same manufacturer with the brand name of KLEAR has already been approved in the name of M/s Krestacorp in 12th MDB meeting.
173.	M/s Lab Link Enterprises, M-203, Block 2, PECHS Opposite Ghousiya Masjid, Karachi (ELI-00007) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	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-	Nipro Safelet Cath (IV Cannula ETFE Radiopaque catheter) Class B Shelf Life: 5 Years 14G, 16G, 18G, 20G, 22G, 24G (Sizes mentioned on FSC Indonesia. Sizes not mentioned on FSC Australia) Fee submitted: Rs. 25,000/-	Intended for introduction or withdrawal of liquids into or form the peripheral vascular system or connection with infusion set to administer the solution for a time from several hours to several days (less	**Approved.**

		2019)		than 30 days) by retaining it in vein.	
174.	M/s Novo Nordisk Pharma (Pvt) Ltd 113, Shahrah-e-Iran, Clifton, Karachi. (ELI-00264) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Novo Nordisk A/S, Novo Alle 2880 Bagsvaerd, Denmark. **Manufacturing Site:** Novo Nordisk (China) Pharmaceuticals Co. Ltd, No. 99 Nanhai Road, TEDA, 300457 Tianjin, P.R. China. (FSC Denmark valid till 28-06-2020)	NovoPen® 4 Class C Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Used for subcutaneous administration of insulin for treatment of individuals with Diabetes Mellitus	**Approved.**
175.	**M/s Johnson & Johnson** Pakistan (Pvt) Ltd., Office No.806, 8th Floor, Horizon Towers, Block 3, Scheme 5, Clifton, Karachi (ELI-00154) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Ethicon SARL, Puits-Godet 20, 2000 Neuchatel, Switzerland. (FSC Switzerland valid till 19-08-2021)	Surgicel ® (Absorbable Haemostat) Class D Sizes and codes: W1911-5x35 cm W1912-10x20 cm W1913T-5x7.5 cm W1915T-1.25x5 cm Shelf life: 5 Years Fee submitted: Rs. 50,000/-	An oxidized regenerated cellulose used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. Sterile	**Approved.**
176.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia**	**Legal Manufacturer:** DePuy Orthopaedics, Inc.	S-Rom Noiles Rotating Hinge (femoral)	Femoral component of total knee replacement	**Approved.**

	Shamsi	700 Orthopaedic Dr. Warsaw, IN USA 46582. **Manufacturing Site:** DePuy Orthopaedics, Inc. 325 Paramount Dr. Raynham , MA USA, 02767 (FSC US FDA valid till 04-06-2021)	Class D Shelf Life: 5 years 623421R: S-Rom Noiles Femoral Rotating Hinge Cemented Right Xsmall 623411R: S-Rom Noiles Femoral Rotating Hinge Cemented Right Small 623401L: S-Rom Noiles Femoral Rotating Hinge Cemented Left Medium 623401R: S-Rom Noiles Femoral Rotating Hinge Cemented Right Medium 623411L: S-Rom Noiles Femoral Rotating Hinge Cemented Left Small 623421R: S-Rom Noiles Femoral Rotating Hinge Cemented Left Xsmall Fee submitted: Rs. 50,000/-	system. Sterile.	
177.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal manufacturer:** ETHICON ENDO-SURGERY, LLC, 475 CALLE C GUAYNABO, PR USA, 00969. **Manufacturer:** ETHICON	PROXIMATE® Reloadable Linear Staplers Class D Codes: TX30B, TX30G, TX60G, TX60B Shelf Life: 5 years	Intended to be used throughout alimentary tract and in thoracic surgery for transection and resection of internal tissues. Sterile	**Approved.**

		ENDO-SURGERY S.A. DE C.V. AVENIDA DE LAS TORRES No. 7125, Colonia SALVARCAR 118, CIUDAD JUAREZ, Chihuahua MEXICO-32580 (FSC US FDA Valid till 12-02-2020)	Fee submitted: Rs. 50,000/-		
178.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal manufacturer:** ETHICON ENDO-SURGERY, LLC, 475 CALLE C GUAYNABO, PR USA, 00969. **Manufacturer:** ETHICON ENDO-SURGERY S.A. DE C.V. AVENIDA DE LAS TORRES No. 7125, Colonia SALVARCAR 118, CIUDAD JUAREZ, Chihuahua MEXICO-32580 (FSC US FDA Valid till 12-02-2020)	Echelon™ Flex Powered Articulating Endoscopic Linear Cutter Class C Codes: PCE45A PSE45A PLE45A Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Intended to be used in multiple open or minimally invasive general, gynecologic, urologic, thoracic and pediatric surgical procedures for transection, resection and the creation of anastomosis etc. Sterile	**Approved.**
179.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal manufacturer:** ETHICON ENDO-SURGERY, LLC, 475 CALLE C GUAYNABO, PR USA, 00969. **Manufacturing:** ETHICON	Proximate® Reloadable Linear Cutter with Safety Lock-Out Class D Codes: TLC55, TLC10, TLC75, TCT55, TCT10, TCT75,	Intended to be used in gastrointestinal, gynecologic, thoracic and pediatric surgery for transection, resection and the creation of	**Approved.**

		ENDO-SURGERY S.A. DE C.V. AVENIDA DE LAS TORRES No. 7125, Colonia SALVARCAR 118, CIUDAD JUAREZ, Chihuahua MEXICO-32580 (FSC US FDA Valid till 12-02-2020)	TCD75 Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	anastomosis etc. Sterile	
180.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** DePuy Orthopaedics, Inc. 700 Orthopaedic Dr. Warsaw, In USA 46582. **Manufacturing site:** DePuy Orthopaedics, Inc. 325 Paramount Dr. Raynham , MA USA 02767 (FSC US FDA valid till 04-04-2021)	Cement Restrictor Class C 546012000 - Cement Restrictor SZ2 - 10.75mm 546014000 - Cement Restrictor SZ3 - 13.25mm 546016000 - Cement Restrictor SZ4 - 15.75mm 546018000 - Cement Restrictor SZ5 - 18.25mm Shelf Life: 5 Years Fee submitted: Rs. 50,000/-	Polyethylene intramedullary canal plugs, intended for use in cemented total or hemi-hip arthoplasty to restrict the distal flow of bone cement in the femoral medullary cavity.	**Approved.**
181.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Ethicon, LLC. Highway 183 Km, 8.3 San Lorenzo, PR USA 00754. **Manufacturing Site:** Ethicon, LLC. Highway 183 Km 8.3 San Lorenzo,	Prolene™ Polypropylene Mesh Codes: PMM3 (CE-marked) PMS1 (CE-marked) PMM1(CE-marked) PMSK1(CE-marked) PML1(CE-marked) PMS3 (non-CE marked)	Used for the repair of hernia and other fascial deficiencies that requires the addition of a reinforcing or bridging material to	**Deferred** for clarification regarding codes of medical device.

<table>
<tr>
<td></td>
<td></td>
<td>PR USA 00754.

(FSC USFDA valid 03-04-2021)</td>
<td>PMH (non-CE marked)
PMII (non-CE marked)
PMLK (non-CE marked)
PMXL (non-CE marked)
PMXS (non-CE marked)

Class C

Shelf Life: 5 years

Fee submitted: Rs. 50,000/-</td>
<td>obtain the desired surgical result repair. Sterile</td>
<td></td>
</tr>
<tr>
<td>182.</td>
<td>-do-

<u>Evaluator:</u>
Ms. Unum Zia Shamsi</td>
<td>Legal Manufacturer: DePuy Orthopaedics, Inc. 700 Orthopaedic DR. Warsaw, in USA

Manufacturing site: DePuy Orthopaedics, Inc. 325 Paramount Dr. Raynham , MA USA 02767

(FSC US FDA valid till 21-05-2021)</td>
<td>LPS ™ System (Limb Preservation System)

Class D

Shelf Life: 05 to 10 Years

Sizes and Codes:
<table>
<tr><th>List of Codes</th><th>Product Description & Size</th><th>Shelf-life</th></tr>
<tr><td>19870702 5</td><td>LPS ™ SEGMENTAL COMPONENT 25MM</td><td>10 years</td></tr>
<tr><td>19870703 0</td><td>LPS ™ SEGMENTAL COMPON</td><td>10 years</td></tr>
</table>
</td>
<td>Intended for replacement of the mid shaft portion of the femur, proximal, distal and/or total femur and proximal tibia</td>
<td>Approved.</td>
</tr>
</table>

					ENT 30MM			
				19870703 5	LPS™ SEGMENTAL COMPONENT 35MM	10 years		
				19870704 0	LPS™ SEGMENTAL COMPONENT 40MM	10 years		
				19870704 5	LPS™ SEGMENTAL COMPONENT 45MM	10 years		
				19870706 5	LPS™ SEGMENTAL COMPONENT 65MM	10 years		
				19870708 5	LPS™ SEGMENTAL COMPONENT	10 years		

					85MM			
				19870710 5	LPS™ SEGMENTAL COMPONENT 105MM	10 years		
				19870712 5	LPS™ SEGMENTAL COMPONENT 125MM	10 years		
				19870805 5	LPS™ TOTAL FEMUR SEGMENTAL COMPONENT 55MM	10 years		
				19870905 5	LPS™ INTERCALARY SEGMENT 55MM	10 years		
				19871010 5	LPS™ PROXIM	10 years		

					AL FEMORAL STANDARD BODY NEUTRAL			
				19871020 5	LPS™ PROXIMAL FEMORAL TROCHANTERIC BODY NEUTRAL	10 years		
				19871110 5	LPS™ PROXIMAL FEMORAL STANDARD BODY 15 DEGREE LEFT	10 years		
				19871120 5	LPS™ PROXIMAL FEM	10 years		

					ORAL TRO CHANTERIC BODY 15 DEGREE LEFT			
				19871210 5	LPS™ PROXIMAL FEMORAL STANDARD BODY 15 DEGREE RIGHT	10 years		
				19871220 5	LPS™ PROXIMAL FEMORAL TROCHANTERIC BODY 15 DEGREE RIGHT	10 years		
				19871310 5	LPS™ DISTAL FEM	5 years		

					ORAL COMPONENT X-SMALL LEFT			
				19871311 1	LPS™ DISTAL FEMORAL COMPONENT XX-SMALL LEFT	5 years		
				19871410 5	LPS™ DISTAL FEMORAL COMPONENT X-SMALL RIGHT	5 years		
				19871411 1	LPS™ DISTAL FEMORAL COMPONENT XX-SMALL	5 years		

					RIGHT			
				198721105	LPS™ PROXIMAL TIBIAL REPLACEMENT COMPONENT X-SMALL	10 years		
				198725109	LPS™ CEMENTED STEM 9X100MM STRAIGHT	10 years		
				198725110	LPS™ CEMENTED STEM 10X100MM STRAIGHT	10 years		
				198725111	LPS™ CEMENTED STEM 11X100M	10 years		

					M STRAIGHT			
				19872511 2	LPS ™ CEMENTED STEM 12X100M M STRAIGHT	10 years		
				19872541 2	LPS ™ CEMENTED STEM 12X125M M STRAIGHT	10 years		
				19872541 3	LPS ™ CEMENTED STEM 13X125M M STRAIGHT	10 years		
				19872541 4	LPS ™ CEMENTED STEM 14X125M M STRAIGHT	10 years		

				19872702	LPS™ UNIVERSAL TIBIAL HINGE INSERT XX-SMALL 12MM	5 years		
				19872704	LPS™ UNIVERSAL TIBIAL HINGE INSERT XX-SMALL 14MM	5 years		
				19872706	LPS™ UNIVERSAL TIBIAL HINGE INSERT XX-SMALL 16MM	5 years		
				19872708	LPS™ UNIV	5 years		

					ERSAL TIBIAL HINGE INSERT XX-SMALL 18MM			
				19872702 1	LPS™ UNIVERSAL TIBIAL HINGE INSERT XX-SMALL 21MM	5 years		
				19872711 2	LPS™ UNIVERSAL TIBIAL HINGE INSERT X-SMALL 12MM	5 years		
				19872711 4	LPS™ UNIVERSAL TIBIAL	5 years		

					HINGE INSERT X-SMALL 14MM			
				19872711 6	LPS™ UNIVERSAL TIBIAL HINGE INSERT X-SMALL 16MM	5 years		
				19872711 8	LPS™ UNIVERSAL TIBIAL HINGE INSERT X-SMALL 18MM	5 years		
				19872712 1	LPS™ UNIVERSAL TIBIAL HINGE INSERT X-SMALL	5 years		

					21MM			
				19872721 2	LPS™ UNIVERSAL TIBIAL HINGE INSERT SMALL 12MM	5 years		
				19872721 4	LPS™ UNIVERSAL TIBIAL HINGE INSERT SMALL 14MM	5 years		
				19872721 6	LPS™ UNIVERSAL TIBIAL HINGE INSERT SMALL 16MM	5 years		
				19872721 8	LPS™ UNIVERS	5 years		

			AL TIBI AL HIN GE INSE RT SMA LL 18M M			
			LPS ™ UNIV ERS AL TIBI AL HIN GE INSE RT SMA LL 21M M	1987 2722 1	5 years
			Fee submitted: Rs. 50,000/-		
183.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA, 00754. **Manufacturing Site:** Ethicon, LLC. Highway 183 Km. 8.3 San Lorenzo, PR USA, 00754. (FSC US FDA valid till 03-04-2021)	PROLENE ™ Polypropylene Suture (Polypropylene, Monofilament, Sterile, Synthetic, Non-Absorbable Surgical Suture) Class D Codes: 8434H 8435H 8521H 8522H 8556H 8623H 8632G 8634G	A monofilament, synthetic, non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene. For use in general soft tissue approximation and/or ligation, including use in	**Deferred** for clarification of codes of medical device.

			8635G 8702H 8706H 8833H EP8704H W1713 W2777 W525 W527 W621 W8003T W8005T W8006T W8007T W8010T W8014T W8020T W8021T W8025T W8026T W8101 W8305 W8307 W8310 W8316 W8329 W8330 W8340 W8430 W8522 W8525 W8549 W8556 W8557		cardiovascular, ophthalmic and neurosurgical procedures.	

			W8558 W8571 W8597 W8623 W8683 W8689 W8697 W8702 W8703 W8704 W8706 W8707 W8710 W8721 W8731 W8761 W8802 W8803 W8807 W8831 W8840 W8937 W8977 8357H 8634H W8430 G W8307 G W8731 G W8761 G 8686H Shelf Life: 60 Months Fee submitted: Rs. 50,000/-		
184.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Legal Manufacturer:** Johnson and Johnson International c/o	Ethicon® Monocryl ™ Plus Antibacterial (Poliglecaprone 25) Suture	Sterile, synthetic, absorbable monofilament suture	**Deferred** for clarification of codes of medical device.

		European Logistics Centre, Leonardo Da Vincilaan 15, B E-1831 Diegem, Belgium **Manufacturing Site:** Johnson and Johnson Medical Limited, Simpson Parkway, Kirkton Campus, Livingston, Scotland, EH54 7AT, United Kingdom (FSC Belgium issued on 3-5-2019)	Class D Codes: MCP3205G MCP3650G MCP500H Shelf Life: 5 years Fee submitted: Rs. 50,000/-	prepared from a co-polymer of glycolide and e-caprolactone. Intended for use in general soft tissue approximation and/or ligation wherein an absorbable material is indicated	
185.	**M/s Zedco**, Office No. 203, Sky Mark Tower, Plot A-13, Block 7/8, K.C.H.S.U, Shahrah-e-Faisal, Karachi. (ELI-00347) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Berkshire, RG6 4UT, United Kingdom. (FSC UK valid till 07-03-2023)	ABO System Class D 1. Anti-A Monoclonal Code: 600010 Size: 10 ml Shelf life: 36 months 2. Anti-B Monoclonal Code: 610010 Size: 10 ml Shelf life: 36 months 3. Anti-A, B Monoclonal Code: 620010 Size: 10 ml Shelf life: 36 months 4. Anti-A_1 Lectin Code: 116005 Size: 5 ml Shelf life: 24 months 5. Anti-H Lectin Code: 115002 Size: 2 ml Shelf life: 24 months 6. Inert AB Serum	ABO blood grouping system	**Approved** subject to provision of EPSP.

			Code: 110010 Size: 10 ml Shelf life: 24 months Fee submitted: Rs. 50,000/-		
186.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Berkshire, RG6 4UT, United Kingdom. (FSC UK valid till 07-03-2023)	Lorne Duffy System Class D 1. Anti-Fy^{a} Monoclonal Code: 774002 Size: 2 ml Shelf life: 24 months 2. Anti-Fy^{b} Polyclonal Code:317002 Size: 2 ml Shelf life: 24 months Fee submitted: Rs. 50,000/-	Duffy blood grouping system	**Approved** subject to provision of EPSP.
187.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufacturer:** Lorne Laboratories Ltd, Unit 1, Cutbush Park Industrial Estate, Danehill, Lower Earley, Reading, Berkshire, RG6 4UT, United Kingdom. (FSC UK valid till 07-03-2023)	Lorne Kell System Class D 1. Anti-K Monoclonal Code: 760010 Size: 10 ml Shelf life: 24 months 2. Anti-k (Cellano) Monoclonal Code: 325002 Size: 2 ml Shelf life: 24 months 3. Anti-Kp^{a} Polyclonal Code:321002 Size: 2 ml Shelf life: 24 months 4. Anti-Kp^{b} Polyclonal Code: 322002 Size: 2 ml Shelf life: 24 months Fee submitted: Rs.	Kell blood grouping system	**Approved** subject to provision of EPSP.

			50,000/-		
188.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer:** Trinity Biotech, IDA Business Park, Southern Cross Road, Bray, Co Wicklow *Ireland.* (FSC Ireland Valid till 30-01-2024)	**Uni-Gold™ HIV** HIV1/HIV2 Antibody IVD kit Class D Shelf Life : 20 Months Sizes & Codes as Per FSC) Code: 1206502 Uni-Gold™ HIV Code: 1206502-100 Uni-Gold™ HIV Code: 1206502N-100 Uni-Gold™ HIV Code: 1206502-C Uni-Gold™ HIV Complete	The Kit is a single use rapid immunoassay , for the qualitative detection of antibodies to HIV in serum, plasma and whole blood .	**Approved** subject to provision of Stability study data supporting claimed shelf life.
189.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer:** Terumo BCT Ltd., Old Belfast Road, Millbrook, Larne, BT402SH, United Kingdom. **Manufacturing Sites:** Terumo BCT Vietnam Co. Ltd., Long Duc Industrial Park, Long Duc Cummune, Long Thanh District, DongNai Province, Vietnam (FSC UK issuance 16-04-2019)	**Teruflex CPDA-1 Triple Blood Bag** Blood Bag Triple with CPDA Class D Shelf Life: 36 Months (Sizes & Codes: As per FSC	Sterile Blood bag containing anti-coaggulanT(CPDA)	**Approved.**
190.	M/s Global Health Care, Office No. 41-A,	**Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-	ichroma™ CRP Class C	A fluorescence immunoassay	**Approved** subject to inspection of

	Street 15 near Foundation School, Race Course Road, Westridge, Rawalpindi. (ELI-00086) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Korea issue date 19-10-2018)	1. ichroma CRP Ref No. i-chroma CRP-25 Shelf life: 20 months 2. Boditech CRP control Shelf life: 12 months Fee submitted: Rs. 50,000/-	(FIA) for the quantitative determination of CRP in human whole blood/serum/ plasma.	manufacturer abroad under Rule 71 of MDR, 2017.
191.	-do- **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**Manufactuer:** Boditech Med Inc. 43, Geodudanj i 1-gil, Dongnae-myeon, Chuncheon-si, Gangwon-do, Korea. (FSC Korea issue date 19-10-2018)	ichroma™ D-Dimer Class C 1. ichroma D-Dimer Ref No: CFPC-25 Shelf life: 20 months 2. Boditech D-Dimer control Shelf life: 12 months Fee submitted: Rs. 50,000/-	A fluorescence immunoassay (FIA) for the quantitative determination of D-Dimer in human whole blood/ plasma.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
192.	**M/s Global Marketing Services,** 111, Hali Road Westridge 1, Rawalpindi (ELI-000109) **<u>Evaluator:</u>** **Ms. Unum Zia Shamsi**	**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, CP 32574, Mexico (FSC USFDA Valid Till 13-08-2019). Fee submitted: Rs 50,000/-	SUPER Torque® Plus Angiographic Catheter Class D Shelf Life: 3 Years Fee submitted: Rs. 50,000/-	Designed to deliver radio opaque contrast medium to selected sites in the vascular system	**Approved** subject to privison of valid FSC.

193.	M/s. Fresenius Medical Care Pakistan Pvt. Ltd., TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660 ELI-00315 **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**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	**ONLINEplus 5008** (Haemodialysis Device) **Model:** 5008 M201011 Class C Life : As per technical safety checks Rs.50,000/-	The device is used for the extracorporeal blood treatment of patients suffering from renal insufficiency.	**Approved.**
194.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. Vivonic GmbH, Kurfurst-Eppstein-Ring 4, 63877 Sailauf, Germany. FSC Germany Issued on 10th March, 2016	**AquaWTU** (Water Treatment Equipment) AquaWTU 250 6325701 AquaWTU 125 6325691 Class C Life : As per technical safety cheeks Rs.50,000/-	The water treatment system, using reverse osmosis technique, used for the production of compatible permeate for dialysis.	**Approved.**
195.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany.	**Ci-Ca® Dialysate K2** (Dialysate) **Ci-Ca® Dialysate K2** 9689201 Class C	Dialysis Solutions for CVVHD (continuous venovenous haemodialysis) treatment.	**Approved.**

		Manufacturing Site: Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. FSC Germany Issued on 2nd March, 2018	Shelf Life : 02 Years Rs.50,000/-		
196.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. Vivonic GmbH, Kurfurst-Eppstein-Ring 4, 63877 Sailauf, Germany. FSC Germany Issued on 10th March, 2016	**AquaC UNO H** (Single Station Reverse Osmosis System with integrated heat disinfection) **AquaC UNO H** F0000227 2 Class C Shelf life: N/A Rs.50,000/-	Single Station Reverse Osmosis System with integrated heat disinfection for the production of permeate for hemodialysis.	**Approved.**
197.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** i. Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8	**Hemoflow HPS** (Dialysers / Filters) **Codes\sizes** 5007041 5007051 5007061 5007071 5007081 **Class C** Shelf Life : 03 Years Rs.50,000/-	Dialysers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis).	**Approved.**

		66606 St. Wendel, Germany. ii. Fresenius Medical Care Srbija d.o.o. Beogradski put bb 26300 Vrsac Serbia. FSC Germany Issued on 6th May, 2016			
198.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** i. Fresenius Medical Care – SMAD Z.I. de la Chanade/ Savigny 69591 L'Arbresle Cedex, France. ii. Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Strabe 6-8 66606 St. Wendel, Germany. iii. Fresenius	**FX CorDiax** (Dialysers / Filters) FX CorDiax 40 – F00001588 FX CorDiax 50 – F00001589 FX CorDiax 60 – F00001590 FX CorDiax 80 – F00001591 FX CorDiax 100 – F00001592 FX CorDiax 120 – F00002384 Class C Shelf Life : 03 years Rs.50,000/-	Dialysers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis).	**Approved.**

		Medical Care(JiaNGSU) Co., Ltd. Guli Industrial park, Guli Zhen Changshu City, Jiangsu Province, China. FSC Germany Issued on 6th May, 2016			
199.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. Vivonic GmbH, Kurfurst-Eppstein-Ring 4, 63877 Sailauf, Germany. FSC Germany Issued on 10th March, 2016	**AquaBplus** (Water Treatment Equipment) AquaBplus 500 – F0000 3299 AquaBplus 1000 – F0000 3300 AquaBplus 1500 – F0000 3301 AquaBplus 2000 – F0000 3302 AquaBplus 2500 – F0000 3303 AquaBplus 3000 – F0000 3304 Class C Shelf Life : N/A Rs.50,000/-	The reverse osmosis system used for the production of permeate for hemodialysis.	**Approved.**
200.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** M/s. Fresenius	**Basic ONLINEplus 5008S** (Haemodialysis System) **Model/Code:** M201211 Class C Service Life : As per technical safty cheks	The device is used for the extracorporeal blood treatment of patients suffering from renal insufficiency.	**Approved.**

		Medical Care Deutschland GmbH, Schweinfurt Plant, Hafenstraße 9, 97424 Schweinfurt, Germany. FSC Germany Issued on 5th April, 2016	Rs.50,000/-		
201.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**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	**PlasmaFlux®** ***(Plasma filters)*** **Model/ Codes:** P1dry 5008021 P2dry 5008031 **Class:** C Shelf Life : 03 years Rs.50,000/-	Plasma filters are applied for single use for extracorporeal blood cleaning (remove basically all (or partially up to a certain molecular weight) plasma proteins from the patients' blood, leaving blood cells untouched).	**Approved.**
202.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**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.	**4008A** (Active Haemodialysis Device) **Model/Code:** M202201 Class C Service Life : As per technical safety cheeks Rs.50,000/-	The device is used for the extracorporeal blood treatment of patients suffering from renal insufficiency.	**Approved.**

		FSC Germany Issued on 2nd May, 2018			
203.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** i .Fresenius Medical Care Deutschland GmbH, St. Wendel Plant, Frankfurter Straße 6 - 8 66606 St. Wendel Germany. ii.Fresenius Medical Care Srbija d.o.o., Beogradski put bb, 26300 Vršac Serbia. FSC Germany Issued on 6th May, 2016	**Hemoflow HF** (Dialysers /Filters) **Code:** 60S 5007161 80S 5007181 Class C Shelf Life : 3 years Rs. 50,000	Dialysers are applied for single use for extracorporeal blood cleaning during renal replacement therapy (haemodialysis).	**Approved** subject to provision of Label of HF60 and Original FSc.
204.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal manufacturer** M/s. Fresenius Medical Care AG & Co. KGaA, 61346 Bad Homburg Germany. **Manufacturing Site:** Fresenius Medical Care SMAD, ZI de la Pontchonniere, Route de la Chanade / Savigny 69591 L Arbresle	**Bibag®** (Online Dry Bicarbonate Concentrate)	The bag is exclusively composed of sodium bicarbonate under a dry form. It is intended for an extemporaneous production of a liquid bicarbonate concentrate used during bicarbonate hemodialysis	**Approved.**

		Cedex, France. FSC Germany Issued on 8th March, 2016	<table><tr><td>Bibag® 5008 500g</td><td>F00008030</td></tr><tr><td>Bibag® 5008 650g</td><td>5060781</td></tr><tr><td>Bibag® 5008 900g</td><td>5060801</td></tr><tr><td>Bibag® 4008 500g</td><td>F00007965</td></tr><tr><td>Bibag® 4008 650g</td><td>5089921</td></tr><tr><td>Bibag® 4008 900g</td><td>5089911</td></tr></table> Class C Shelf Life : 03 years Rs. 50,000	sessions.	
205.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufactuer:** Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany. **Manufacturing Site:** Novamed GmbH Free Trade Zone P.O. Box 35 antalya Serbest Bölgesi Merkez Subesi, No:16, Liman Serbest Bölgesi Mahallesi, 07070 Antalya Turkey. (FSC Germany Issue Date 09-09-2016)	**AV-Set ONLINEplus BVM 5008-R** **AV-Set ONLINEplus BVM 5008-R F00000385** Class B Shelf Life: 2 Years **Rs.25,000/-**	Hemodialysis Bloodlines.	**Approved.**
206.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Fresenius Medical Care AG & Co. KGaA 61346 Bad	**AV-Set-E** Bloodlines AP16845	Bloodlines are intended for single use only for extracoporeal	**Approved**

		Homburg Germany. **Manufacturing Site:** Fresenius Medical Care (Jiangsu) Co., Ltd.Guli Industrial Park, Guli Zehn, Changshu City, Jiangsu Province. China. FSC China Valid till 09-12-2020 Listed in NANDO database	Class B Shelf Life: 3 Years **Rs.25,000/-**	blood purification.	
207.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufactuer:** Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany. **Manufacturing Site:** Novamed GmbH Free Trade Zone P.O. Box 35 antalya Serbest Bölgesi Merkez Subesi, No:16, Liman Serbest Bölgesi Mahallesi, 07070 Antalya Turkey. (FSC Germany Issue Date 09-09-2016)	**AV Set ONLINEplus-5008-R** **AV Set ONLINEplus-5008-R F00000384** Class B Shelf Life: 2 Years **Rs.25,000/-**	Hemodialysis Bloodlines is intended for single use only for extracoporeal blood Purification.	**Approved.**
208.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufactuer:** Fresenius Medical Care AG & Co. KGaA 61346 Bad	**AV Set FMC Paed/Baby R** **AV-Set-FMC Paed/Baby R F00001063**	Hemodialysis Bloodlines is intended for single use only for extracoporeal	**Approved.**

		Homburg Germany. **Manufacturing Site:** Novamed GmbH Free Trade Zone P.O. Box 35 antalya Serbest Bölgesi Merkez Subesi, No:16, Liman Serbest Bölgesi Mahallesi, 07070 Antalya Turkey. (FSC Germany Issue Date 09-09-2016)	Class B Shelf Life: 3 Years **Rs.25,000/-**	blood Purification	
209.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufactuer:** Fresenius Medical Care AG & Co. KGaA 61346 Bad Homburg Germany. **Contract Manufacturer** Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-ku Osaka 531-8510 Japan. **Manufacturing Site:** Nipro (Thailand) Corporation Ltd., 10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110 Thailand (FSC Germany Issuance 11-11-2016)	**Arterial/Venous Fistula Needles (sterilized by irradiation)** S-14GA-R25L-R 5078321 S-14GV-R25L-R 5078361 S-15GA-R25-R 5077221 S-15GV-R25-R 5077251 S-15GA-R25L-R 5078331 S-15GV-R25L-R 5078371 S-16GA-R25-R 5077231 S-16GV-R25-R 5077261 S-16GA-R25L-R 5078341 S-16GV-R25L-R 5078381 S-17GA-R25-R 5077241 S-17GV-R25-R	**Safety Fistula Needles**	**Approved.**

			5077271 S-17GA-R25L-R 5078351 S-17GV-R25L-R 5078391 Class B Shelf Life: 5 Years **Rs.25,000/-**		
210.	-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 5th July, 2016	**Swan-Neck-Catheter** (Peritoneal Dialysis Catheters) Tenckhoff-catheter 215 — 519611 Tenckhoff-catheter 180 — 5019901 Swan Neck Adult PD Catheter 416 — 5019711 Class C Shelf Life : Not mentioned	Fresenius Medical Care (FME) Catheters for Peritoneal Dialysis are applied for single use in peritoneal dialysis (CAPD or APD).	**Approved.**
211.	M/s OscarTech Pakistan Opposite Union Council, Kotla Arab Ali Khan, District, Teh, Kharian. (ELI-00020) **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer:** IMDS Operations B.V. Ceniturrban Noord 150 9301 NZ Roden The Netherlands (FSC Netherlands valid 16-09-2019)	**Nhancer Pro X** Micro Catheter Class D Shelf Life: 2 Years Codes: NHancer Pro X: NX3141325, NX61413525, NX31415560, NX61415560 **Rs. 50,000**	Rapid exchange dual lumen guide wire suooprt catheter	**Approved** subject to provision of notarized Full Quality Assurance Certificate and EPSP.
212.	-do-	**Legal**	**Guidion**	Rapid	**Approved**

	<u>Evaluator:</u> **Hafiz Muhammad Asif Iqbal**	**Manufacturer:** IMDS Operations B.V. Ceniturrban Noord 150 9301 NZ Roden The Netherlands (FSC Netherlands valid 16-09-2019)	(Guide Extension Catheter) Class D Shelf Life: 2 Years Codes: G50F25150, G60F25150, G70F25150, G80F25150 **Rs. 50,000**	exchange guide extension	subject to provision of complete Stability studies, EPSP and notarized FQA Certificate.
213.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer:** IMDS Operations B.V. Ceniturrban Noord 150 9301 NZ Roden The Netherlands (FSC Netherlands valid 16-09-2019)	**TrapIt** Trapping Balloon Class D **Shelf Life**: 2 Years **Codes:** TRP9015, TRP10015	Trapping Balloon Catheter is a single Lumen Balloon device without guide wire lumenn and is a compatible with 90 and 100 cm 6F, 7F and 8F guide catheters.	**Approved** subject to provision of notarized FQA Certificate. and EPSP
214.	M/S. COR-MED 2ND Floor 38/62 Rahman Plaza Bank Road Saddar Rawalpindi (ELI-00226) **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Entity:** DeRoyal Industries Inc. **Address:** 200 DeBask Lane Powell TN 37849 USA **Manufacturing Location :** DeRoyal Industries Inc.1703 highway 33s new tazevel,TN USA 37825 **FSC US FDA 23 MAY 2019**	***Manifolds*** CLASS B Shelf Life 3 year Codes /sizes: As per FSC	Manifolds are used during cardiac cathrterizatio n procedures for intra arterial and interavenous administratio n of contrast saline or radiographic contrast media.	**Approved** subject to provision of valid FSC.
215.	M/s. Shamco Trader Pvt Ltd, Lahore.174-A, Ahmed Block,	**Legal Manufacturer** M/s. Vital	**Renaid** Blood Tubing Set	Blood Tubing Set	**Rejected** as the same product of same

	New Garden Town, Lahore. ELI-00102 **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	Healthcare SDN BHD, Lot 3, Jalan Sultan Mohammad 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia. FSC Malaysia Valid till 16.04.2021	Codes/ Sizes: As per FSC Class B Shelf Life: 03 years **Rs.25,000/-**		manufacturer has already been approved in 13th meeting of MDB in the name of M/s Fresenius Medical Care Pakistan pvt. Ltd
216.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer** M/s. Vital Healthcare SDN BHD, Lot 3, Jalan Sultan Mohammad 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia. FSC Malaysia Valid till 16.04.2021	**Renaid** AV Fistula Needle Codes/ Sizes: As per FSC Class B Shelf Life: 03 years **Rs.25,000/-**	AV Fistula Needle	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and clarification regarding Name of medical devices.
217.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer** M/s. Vital Healthcare SDN BHD, Lot 3, Jalan Sultan Mohammad 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia. FSC Malaysia Valid till 16.04.2021	**Renaid** Hollow Fiber Dialyzers Codes/ Sizes: As per FSC Class C Shelf Life: 03 years **Rs.25,000/-**	Hollow Fiber Dialyzers	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and clarification regarding Name of medical devices and submission of differential fee Rs. 25000/-
218.	M/s. F.W. Distributores. Opposite Poonch House, Adamjee Road Saddar, Rawalpindi. ELI-00221	**Legal Manufacturer** M/s. SCW Medicath Ltd., No.4, Baolong 6th Road, Baolong Industrial Town,	Angiographic Syringes Codes: As per FSC of Belgium. Class B Shelf Life: 03 years	Angiographic syringe is intended to deliver contrast media, which is compatible	**Approved.**

	Evaluator: **Hafiz Muhammad Asif Iqbal**	Longgang, District Shenzhen, China **Applicant for Certificate:** M/s. Obelis s.a. Bd General Wahis 53, 1030 Brussels, Belgium. FSC Belgium Issued on 29.10.2018		with high-pressure injection Equipment during CT, DSA and MRI.	
219.	M/s Medichem Enterprises, 331/C, Block No.3, DMCH Society Alamgir Road, Karachi (ELI-00252) **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Manufacturer:** M/s Zhejiang Huafu Medical Equipment Co., Ltd., No.688 Xingxing 1st Road., Economic Development Zone, Pinghu, Zhejiang, China (FSC UK Issued on 21-12-2018)	Promed Disposable Infusion Set with needle with Y connector Class B Shelf Life: 3 Years Code: ISN-Va-1 **Rs.25,000/-**	Infusion Set with Y Connector	**Approved** subject to change of brand name.
220.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Manufacturer:** M/s Zhejiang Huafu Medical Equipment Co., Ltd., No.688 Xingxing 1st Road., Economic Development Zone, Pinghu, Zhejiang, China (FSC UK Issued on 21-12-2018)	Promed Disposable Syringe with Needle Class B Shelf Life: 3 Years Codes/sizes: 1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml **Rs.25,000/-**	Disposable Syringe with needle	**Approved** subject to change of brand name.
221.	M/s Uniprom Healthcare, L-151, 2nd Floor, Sehba Akhter Road, Block 13-G Gulshan-e-Iqbal, Karachi (ELI-00286) **Evaluator:**	**Manufacturer:** M/s Tristel Solutions Limited, Lynx Business Park, Fodham Road, Cambridgeshire CB8 7NY, Snailwell, UK (FSC UK Issuance	Perastel Multi Shot (medical devices/instrument disinfectant) Class C Shelf Life: Base solution 18 Months Activator 23 Months	Perestane It is a peracetic acid based high level devices/instruments disinfectant comprises base and activator.	**Approved.**

	Hafiz Muhammad Asif Iqbal	Date18-01-2017)	**Pack Sizes:** 3×4.75 Litre Base solution 3×250ml Activator solution 2×4.75 Litre Base solution 2×250ml Activator solution **Rs. 50,000**		
222.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Manufacturer:** M/s Tristel Solutions Limited, Lynx Business Park, Fodham Road, Cambridgeshire CB8 7NY, Snailwell, UK (FSC UK Issuance Date18-01-2017)	Distel High Level Medical Surface Disinfectant Class B Shelf Life: Concentrate : 3 Years Ready to use : 2 Years solution **Pack Sizes:** 3×5 Litre Concentrate 6×1 Litre Concentrate 6×500ml Ready to use **Rs. 50,000/-**	Didecyldimethylammonium Chloride + Vantocil iB based high level medical Surface disinfectant.	**Approved.**
223.	-do- **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**Manufacturer:** M/s Tristel Solutions Limited, Lynx Business Park, Fodham Road, Cambridgeshire CB8 7NY, Snailwell, UK (FSC UK Issuance Date18-01-2017)	Medistel Instrument Disinfectant Class C Shelf Life: 3 Years **Pack Sizes:** 6×1 Liter 20×250ml bottle 50ml sachet **Rs. 50,000/-**	N-Alkyl Dimethyl Benzyl Ammonium Chloride based instrument disinfectant.	**Approved.**
224.	M/s Popular International (Pvt) Ltd., House No. 141, Justice Inamullah Road, Block 7 & 8 KMCHS, Near Hill Park, Karachi	**Legal Manufacturer:** M/s Coviden LLC, 15 Hampshire Street Mansfield, MA 02048, USA **Manufacturing**	Monosof ™ Monofilament Nylon Class D Shelf Life: 5 Years **Codes/ sizes:**	Synthetic Nylon Monofilament Nonabsorbable Sutures used in general soft tissue approximatio	**Approved** subject to provision of valid FSC and QC processes detail.

	(ELI-00091) **<u>Evaluator:</u>** **Hafiz Muhammad Asif Iqbal**	**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)	As per FSC #12681-7-2017 **Rs. 50,000/-**	n and ligation including use in cardiovascular, ophthalmic, neurological surgery and microsurgery.	
225.	-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)	Ticron ™ Coated and Uncoated Braided Polyester Class D Shelf Life: 5 Years **Codes/ sizes:** As per FSC #12681-7-2017 **Rs. 50,000/-**	Synthetic Braided Polyester Non-Absorbable Sutures used in general soft tissue approximation and ligation including use in cardiovascular, ophthalmic, neurological surgery and microsurgery.	**Approved** subject to provision of valid FSC and QC processes detail.
226.	M/s 3M Pakistan (Pvt) Ltd., Islamic Chamber of Commerce Building, St No.2/A, Block 9, KDA Scheme 5, Clifton, Karachi	**Legal Manufacturer:** M/s 3M Company, 3M Health Care 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint	3M ™ Steri-Drape™ Ioban™ 2 Specialty Drape Class D Shelf Life: 2 Years	Specialty Drapes with Ioban 2 Incise film	**Approved** subject to provision of FSC of US FDA and Stability study data.

	(ELI-00259) **Evaluator:** **Hafiz Muhammad Asif Iqbal**	Paul, MN 55144, USA **FSC of US FDA not provided**	6617, 6619, 6657, 6658, 6659, 6665, 6677, 6677, 6681, 6678, 6661EZ, 6697, 6687, 6682 **Rs. 50,000/-**		
227.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer:** M/s 3M Company, 3M Health Care 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN 55144, USA **Manufacturer:** M/s 3M Company 601 22nd Ave., South Brookings, SD 57006, USA (FSC USFDA Valid Till 09-04-2019)	3M™ Tegaderm™ CHG Cholrhexidine Gluconate I.V Securement Dressing **Class D** **Shelf Life**: 2 Years **Codes/ Sizes:** 1657R, 1658R, 1659R, 1660R **Rs. 50,000/-**	Cholrhexidine Gluconate I.V Securement Dressing	**Approved** subject to provision of FSC of US FDA, Design Examination Certificate and Stability study data**.**
228.	-do- **Evaluator:** **Hafiz Muhammad Asif Iqbal**	**Legal Manufacturer:** M/s 3M Company, 3M Health Care 3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN 55144, USA **Manufacturer:** M/s 3M Company 601 22nd Ave., South Brookings, SD 57006, USA (FSC USFDA Valid Till 09-04-2019)	3M ™ Ioban™ 2 (Antimicrobial Incise Drapes) **Class D** Shelf Life: 2 Years **Codes/Sizes**: 6640, 6640EZ, 6648, 6648EZ, 6650, 6650EZ, 6651, 6651EZ , 6661EZ **Rs. 50,000/-**	Antimicrobial Incise Drapes	**Approved** subject to provision of FSC of US FDA and Stability study data.
229.	-do- **Evaluator:** **Hafiz Muhammad**	**Legal Manufacturer:** M/s 3M Company, 3M Health Care	3M ™ Bair Hugger™ Model 775 Warming Unit	The system used to prevent and treat patient	**Approved.**

	Asif Iqbal	3M Center, 2510 Conway Ave. Bldg. 275-5W-06, Saint Paul, MN 55144, USA **Manufacturer:** M/s 3M Company 10351 West, 70th Street Eden Prairie, MN 55344, USA (FSC USFDA Valid Till 27-09-2020)	Class C Shelf Life: N/A **Rs. 50,000/-**	from hypothermia.	
230.	M/s. K.M. Enterprises, 605-D-Block, M.A. Johar Town, Lahore. ELI-00054 **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Changzhou Medical Appliances General Factor Co., Ltd., HengShanQian Town, Changzhou Jiangsu China. FSC not found	**AMD I.V. Cannula (with wings and injection port)** **AMD I.V. Burette Infusion Set (with needle)** Validity until 29th March, 2021 **AMD Insulin Syringe** **AMD Auto disable Syringe (1, 2, 3, 5, 10ml)** Validity until 26th January, 2021	**AMD I.V. Cannula**	**Board regretted** the request of the firm and advised the firm to apply at the time of renewal.
231.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Changzhou Medical Appliances General Factor Co., Ltd., HengShanQian Town, Changzhou Jiangsu China. FSC China (Export Only) Valid until 12-10-2019	**AMD Disposable Syringes** **1ml, 2ml, 3ml, 5ml, 10ml, 20ml** (Syringes for single use) Class B Shelf Life : 05 years **Rs.40,000**	Disposbale Syringes	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of Full quality Assurance
232.	-do-	**Legal**	**EVE'S**	--	**Approved**

	Evaluator: **Mr. Shahid Muhammad Iqbal**	**Manufacturer:** M/s. Corporate Channels (India) Pvt., Ltd., 1590-1600, Village Paldi, Post Loyara, P.O. Badgaon, Udaipur 313001, Rajasthan, India FSC India Issued on 26.10.2017	IUCD Copper T 380A Class D Shelf Life : 05 years **Rs.50,000**		subject to provision of Full quality Assurance Certificate, Design Exam Certificate and DOC.
233.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Changzhou Medical Appliances General Factor Co., Ltd., HengShangqiao Town, Changzhou Jiangsu China. FSC not found	**AMD Disposable Infusion set with needle** (Infusion Set) Class B Shelf Life : 05 years	Infusion Set	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of original notarized ISO, FQA and credentials of manufacturer.
234.	M/s. Cardiac Care, 848-C Shadman-I, Lahore. ELI-00070 **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Medica S.p.A, Via Degli Artigiani, 7 41036, Medolla (MO), Italy. FSC Italy Issued on 05.12.2018	Hemoconcentrator **M03957 – DP03HC-EO Hemoconcentrator** **M03958 – DP07HC-EO Hemoconcentrator** **M03959 – DP09HC-EO Hemoconcentrator** Class C Shelf Life : 03 years **Rs.50,000**	Hemoconcentrators are used during cardiac bypass surgery to control hemodilution and hematocrit levels during the surgery procedure.	**Approved** subject to provision of Labels and DOC.
235.	M/s. Quality Medical Services, H-49, Gordon College Road,	**Legal Manufacturer & Manufacturing**	Ambu® SPUR® II **Ambu® SPUR® II,**	Ambu® SPUR® II, Single Patient	**Approved.**

	Rawalpindi. ELI-00123 **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Site:** M/s. Denmark Corporate Headquarter, Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup, Denmark. FSC Denmark Valid until 03 September, 2020	**Single Patient use Resuscitator (Adult, Pediatric and Infant)** Class B Shelf Life : Not available **Rs.25,000/-**	use Resuscitator (adult, Pediatric and Infant)	
236.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Denmark Corporate Headquarter, Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup, Denmark. FSC Denmark Valid until 03 September, 2020	<u>Ambu® Oval Silicone</u> **Ambu® Oval Silicone resuscitator Neonate** **Ambu® Oval Silicone resuscitator-Adult and Pediatric** Class B Shelf Life : 10 years **Rs.25,000/-**	<u>Ambu® Oval Silicone resuscitator</u>	**Approved.**
237.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Denmark Corporate Headquarter, Ambu A/S, Baltorpbakken 13, DK-2750 Ballerup, Denmark. FSC Denmark Valid until 03 September, 2020	<u>Ambu® Bag Mark IV Resuscitator</u> **Ambu® Mark IV Resuscitator** **Ambu® Mark IV Baby Resuscitator** Class B Shelf Life : Not available **Rs.25,000/-**	**Ambu® Mark IV Resuscitator**	**Approved.**
238.	M/s Muslim Trading Agencies,	**Legal Manufacturer:**	**Uryxxon® Relax**	For Strips and controls N/A	**Deferred** till the recommen-

	3 Syed Moj Darya Road, Lahore. (ELI-00359) **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	Macherey-Nagel GmbH & Co. KG Neumann-Neander str. 6-8, 52355 Düren, Germany FSC Germany Issued 22-06-2018	Medi Test Urine analysis **Medi-Test Glucose** **93001** **93024** Shelf Life: 2.5 years **Medi-Test Combi 3A** **93007** **93030** Shelf Life: 2.5 years **Medi-Test Combi 10 SGL** **93067** **93077** Shelf Life: 2 years **Medi-Test Uryxxon Stick 10** **93068** **930872** Shelf Life: 2 years Class B **Rs.25,000/-**		dation of committee constituted on grouping of Cluster.
239.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Randox Laboratories Limited, 55 Diamond Road, Country Antrim, BT29 4QY, United Kingdom FSC UK valid till 18-08-2021	**Immunoassay Premium controls** Code IA2633 Immunoassay Premium Tri-level (IA Premium 1, 2, and 3) Code IA2638 Immunoassay Premium-Level 1 (IA Premium 1) Code IA2639 Immunoassay Premium -Level 2 (IA Premium 2) Code IA2640 Immunoassay Premium -Level 3 (IA Premium 3)	This product is intended for in vitro diagnostic use, as assayed quality control material to monitor the accuracy and reproductibilit y of analytes listedin the package insert.	**Approved.**

			Class C Shelf Life: 36 Months **Rs.50,000**		
240.	M/s. Apsta International, 38-A, Johar Town, Lahore. ELI-00042 **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Laboratorium Dr. Deppe GmbH, Hooghe Weg 35, D-47906 Kempen, Germany. FSC Germany Issued on 31.10.2016	**Alpha Guard** (Surface Disinfectant & Cleaner) Class B Shelf Life : 03 years **Rs.25,000/-**	Surface Disinfectant & Cleaner 100 gm contains; 2.5 gm Polyhexamethylene Biguanide Hydrochloride 8.0 gm Didecyldimethylammonium chloride	**Approved.**
241.	M/s. Care and Cure International. 65-B, Satellite Town Rahim Yar Khan. ELI-00192 **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer & Manufacturing Site:** M/s. Yangzhou Goldenwell Medical Devices, No. 16 Tengfei Road, Dinggou Industrial Park of Jiangdu District, Yangzhou city, Jiangsu Province, P.R. China. FSC China 08-01-2021	**Cure** (Disposable Syringe) Class B Shelf Life: 05 years Disposable Syringe with needle (1, 3, 5, 10, 20, 30 and 50ml) **Rs.25,000/-**	Disposable Syringe	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017.
242.	M/s. Nipro Medical (Pvt) Ltd., Building No.24, Central Commercial Area, DHA Phase 8 (Ex Park View), Lahore. ELI-…….	**Legal Manufacturer:** M/s. Nipro Corporation, 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, Japan. **Manufacturing**	**Nipro Elisio** (Hemodialyzer) Nipro Synthetic Hemodialyzer Elisio-H Elisio-M Elisio-L	Hemodialyzer	**Approved** subject to issuance of Establishment Licence to import medical devices.

		Site: M/s. Nipro Corporation Odate Factory, 8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794, Japan. FSC Japan Issued on 11.05.2017	Class C Shelf Life: 03 years		
243.	M/s Medtronic Pakistan (Private) Limited, Office No.1301, 13th Floor Dilkusha Forum Tariq Road, Karachi (ELI-00273) **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC Switzerland validity 06-03-2021	Percepta CRT-P MRI SureScan **W1TR04** **Percepta CRT-P MRI SureScan** Class D Shelf Life: 18 months from the date of the power source connection **Rs.50,000**	MR conditional Pacemaker with cardiac resynchronization therapy. The Percepta CRT-P MRI SureScan system is indicated for patients; with ventricular dyssynchrony and with reduced ejection fraction.	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries .
244.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic CoreValve, LLC 1851 E.Deere Ave Santa Ana, CA 92705 USA **Manufacturing Sites:** Medtronic Mexico S. de R.L. de CV, Avenida Paseo Cucapah 10510 EL Lago C.P. 22210 Tijuana, Baja California, Mexico Medtronic Ireland	EnVeo™R Delivery Catheter **ENVEOR-N** **EnVeo R Delivery Catheter System.** Class D Shelf Life: 1 Year **Rs.50,000**	Delivery Catheter System.	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries and EPSP.

		Parkmore Buisness, Park West Galway, Ireland FSC Netherland validity 28-01-2020			
245.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Medtronic Vascular 37A Cherry Hill Dr Danvers, MA USA 01923 FSC USA Validity 25-01-2020	**Launcher Guiding Catheters** Class D Shelf Life: 2 Years Sizes & Codes as Per FSC **Rs.50,000**	Designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries
246.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923, USA FSC USA Validity 20-11-2018	Sherpa NX Balanced Guidewire Catheter **Sizes & Codes as Per FSC** Class D Shelf Life: 2 Years **Rs.50,000**	Guide Catheter A Sterile, Flexible tube intended to be used for the percutaneous transluminal passage and placement of diagnostic/interventional catheter or lead (e.g., pacing lead, balloon dilatation catheter) Through its lumen, within the vascular system.	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries
247.	-do- **<u>Evaluator:</u>** **Mr. Shahid**	**Legal Manufacturer:** Medtronic CoreValve,	CoreValve™Evolut™ PRO TAV **EVOLUTPRO-23**	CoreValve™ Evolut™PRO system is a recaptureable	**Approved** subject to provision of Linkup Letter

	Muhammad Iqbal	LLC,1851 E. Deere Ave. Santa Ana, CA 92705 USA. **Manufacturing Sites:** Medtronic Mexico S. de R.L. de CV, Avenida Paseo Cucapah 10510 EL Lago C.P. 22210 Tijuana, Baja California, Mexico Medtronic Ireland Parkmore Buisness, Park West Galway, Ireland FSC Netherland valid 28-01-2020	**Evolut PRO TAV, 23mm** **EVOLUTPRO-26 Evolut PRO TAV, 26mm** **EVOLUTPRO-29 Evolut PRO TAV, 29mm** Class D Shelf life: 1 Years **Rs.50,000**	transcatheter aortic valve replacement system, which includes the CoreValve™ Evolut™ PRO transcatheter aortic valve, the EnVeo™ R Delivery catheter system, and EnVeo™ R Loading System.	for Medtronic subsidiaries
248.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Sites:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 FSC USA validity 22-06-2019	Mitral/tricuspid annuloplasty Band Simulus™ adjustable Annuloplasty Band 735AC25, 735AC27, 735AC29, 735AC31, 735AC33, 735AC35, 735AC37, 735AC39 Class D Shelf Life: 5 Years **Rs.50,000/-**	Simulus™ adjustable Annuloplasty Ring &Band are indicated for use in patients undergoing surgery for diesease or damaged mitral or tricuspid valves. The Simulus™ adjustable Annuloplasty ring and band provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.	**Approved** subject to provision of Signed conclusion of stability studies, Linkup Letter for Medtronic subsidiaries, Labels and valid FSC.
249.	-do-	**Legal Manufacturer:**	Aortic Heart valve Bioprosthesis	The Freestyle bioprosthesis	**Approved** subject to

	Evaluator: **Mr. Shahid Muhammad Iqbal**	Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Sites:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA 92705. FSC USA validity 10-08-2019	**Freestyle™ Bioprosthesis, Model 995 (Aortic Root)** **FR995-19 Size 19mm** **FR995-21 Size 21mm** **FR995-23 Size 23mm** **FR995-25 Size 25mm** **FR995-27 Size 27mm** **FR995-29 Size 29mm** Class D Shelf Life : 5 Years **Rs.50,000/-**	is indicated for the replacement of pathologic or prosthetic aortic valves.	provision of Linkup Letter for Medtronic subsidiaries
250.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Sites:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 FSC USA validity 22-06-2019	Mitral/tricuspid annuloplasty Ring **Simulus™ Semi-Rigid Annuloplasty Ring, Model 800SR** **800SR24, 800SR26, 800SR28, 800SR30, 800SR32, 800SR34, 800SR36, 800SR38, 800SR40** Class D Shelf Life: 5 Years **Rs.50,000/-**	The Simulus™Semi-Rigid Annuloplasty Ring &Band are indicated for use in patients undergoing surgery for diseased for damaged mitral r tricuspid valves. Simulus™ Annuloplasty Ring &Band provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.	**Approved** subject to provision of Signed conclusion of stability studies, Linkup Letter for Medtronic subsidiaries and valid FSC.
251.	-do- **Evaluator:** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway.	Mitral/tricuspid annuloplasty Ring Class D	Tri-Ad™Adams Tricuspid Ring Is indicated	**Approved** subject to provision of Signed conclusion of

		Minneapolis, MN 55432, USA **Manufacturing Sites:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 FSC USA validity 22-06-2019	Shelf Life: 5 Years Tri-Ad™Adams Tricuspid Ring Model 900SFC 900SFC26 Size 26 mm 900SFC28 Size 28 mm 900SFC30 Size 30 mm 900SFC32 Size 32 mm 900SFC34 Size 34 mm 900SFC36 Size 36 mm **Rs.50,000/-**	for use in patients undergoing surgery for diseased or damaged tricuspid valves. The TriAd™Adams tricuspid ring provides support for and restricts expansion of the tricuspid annulus.	stability studies, Linkup Letter for Medtronic subsidiaries and valid FSC.
252.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Sites:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 FSC USA validity 22-06-2019	Mitral/ tricuspid annuloplasty ring **Simulus™ Flexibile Annuloplasty Ring, Model 700FF** **700FF23, 700FF25, 700FF27, 700FF29, 700FF31, 700FF33, 700FF35, 700FF37, 700FF39** Class D Shelf Life: 5 Years **Rs.50,000/-**	The Simulus™flexibile annuloplasty ring and band are indicated for use in patients undergoing surgery for diesease or damaged mitral or tricuspid valves. The Simulus™flexibile annuloplasty ring and band provide support for the mitral or tricupid annulus and restrict expansion of the annulus.	**Approved** subject to provision of Signed conclusion of stability studies, Linkup Letter for Medtronic subsidiaries and valid FSC
253.	-do- **<u>Evaluator:</u>**	**Legal Manufacturer:** Medtronic Inc.	Mitral/tricuspid annuloplasty Ring	The Simulus™Adjustable	**Approved** subject to provision of

	Mr. Shahid Muhammad Iqbal	710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Sites:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 FSC USA validity 22-06-2019	**Simulus™Adjustable Annuloplasty Ring, Model 735AF** **735AF25, 735AF27, 735AF29, 735AF31, 735AF33, 735AF35, 735AF37, 735AF39** Class D Shelf Life: 5 Years **Rs.50,000/-**	Annuloplasty Ring &Band are indicated for use in patients undergoing surgery for diseased for damaged mitral r tricuspid valves. Simulus™Adjustable Annuloplasty Ring &Band provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.	Signed conclusion of stability studies, Linkup Letter for Medtronic subsidiaries and valid FSC
254.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic CoreValve, LLC,1851 E. Deere Ave. Santa Ana, CA 92705 USA. **Manufacturing Sites:** Medtronic Ireland Parkmore Buisness, Park West Galway, Ireland FSC Netherland valid 28-01-2020	EnVeo™R Loading System **EnVeo R Loading System** **LS-ENVEOR-23** **LS-ENVEOR-2629** **LS-ENVEOR-34** Class D Shelf Life 1 Year **Rs.50,000/-**	EnVeo R Loading System	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries.
255.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:**	Dual –Chamber Implantable defibrillator **Cardia DR D384DRG** Class D ICD/IPG/CRT's	The Cardia DR System is intended to provide ventricular antitachycardia pacing and ventrilcular defibrillation for automated	**Approved** subject to provision of Signed conclusion of stability studies and Linkup Letter for Medtronic subsidiaries.

		Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolozhenaz, Switzerland FSC Switzerland validity 06-03-2021	devices are labeled with an 18-Months shelf life, which is 18 months form the date of the power source connection. **Rs.50,000/-**	treatment of life threatening ventricular tachyarrhyth mias.	
256.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Teleflex Medical , Annacotty Business Park, Annacotty, Co Limerick Ireland. FSC Ireland validity 08-06-2020	Micra Introducer Sheath with Hydrophilic Coating **MI2355A Micra™ Introducer Sheath with Hydrophilic Coating** Class D Shelf Life: 24 Months **Rs.50,000/-**	Vascular catheter Introduction kit, non steerable a collection of sterile, invasive devices intended to provide percutaneous vascular access to enables introduction of a catheter (not included) into the vascular system.	**Approved** subject to provision of valid FQA and Linkup Letter for Medtronic subsidiaries
257.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA 92705 **Manufacturing Site:** Epflex feinwerktechnik Gmbh IM Schwoellbogen 24 Dettingen/Erms, Baden-wurttemberg Germany 72581 FSC USA validity18-03-2020	Cardiac/peripheral vascular guidewire, single-use **Confida Brecker Guidewire GWBC30** Class D Shelf Life: 3 Years **Rs.50,000/-**	Intended for use to introduce and position catheters during diagnostic and interventional procedures within the chambers of the heart, including transcatheter aortic valve replacement.	**Approved** subject to provision of Signed conclusion and stability studies, Linkup Letter for Medtronic subsidiaries and ISO 13485.
258.	-do-	**Legal**	Cardiopulmonary	Intended use	**Approved**

	<u>Evaluator:</u> **Mr. Shahid Muhammad Iqbal**	**Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA Medplast Medical Inc. 620 Watson Sw GR. MI USA 49504 FSC USA Validity 08-03-2020	Bypass Cannula Arterial **Select 3D ® II Arterial Cannulae** **78420 Select 3D II® Art. Cannula, 20 Fr., Vented** **78422 Select 3D II® Art. Cannula, 22 Fr., Vented** **78424 Select 3D II® Art. Cannula, 24 Fr., Vented** **78520 Select 3D II® Art. Cannula, 20 Fr., Non-Vented** **78522 Select 3D II® Art. Cannula, 22 Fr., Non-Vented** **78524 Select 3D II® Art. Cannula, 24 Fr., Non-Vented** Class D Shelf Life: 3 Years **Rs.50,000/-**	in perfusion of the ascending aorta during short-term cardiopulmonary bypass. This product is intended for use up to six hour or less	subject to provision of Linkup Letter for Medtronic subsidiaries, valid ISO-13485 for Medplast site, Design Exam Certificate.
259.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA	Cardiopulmonary bypass Cannula **DLP® Pulmonary Artery vent Cannula** **12004_DLP® Vent Cannula, pulmonary artery** Class D Shelf Life: 3 Years	A Sterile, semi rigid or rigid tube intended to be used during open heart surgery where it is surgically inserted for perfusion of the ascending aorta, serving as a channel for transport of pumped ,	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries, ISO -13485 for Medplast site and Design Exam Certificate.

		Medplast Medical Inc. 620 Watson Sw GR. MI USA 49504 FSC USA Validity 08-03-2020	**Rs.50,000/-**	oxygenated, blood from a cardiopulmonary bypass system.	
260.	-do- **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Parkway. Minneapolis, MN 55432, USA **Manufacturing Site:** Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Tolochenaz, Switzerland. FSC Switzerland validity 06-03-2021	Cardiac resynchronization therapy implantable pacemaker **DTMC2D4 Compia MRI CRT-D SureScan** Class D Shelf Life: 18 months	The Compia MRI System is indicated for use in patient who is at high risk of sudden death due to ventricular tachyarrhythmias and who have heart failure with ventricular tachycardia pacing, cardioversion, and defibrillation for automated treatment of life threatening ventricular tacyarrhythmias.	**Approved** subject to provision of Linkup Letter for Medtronic subsidiaries**.**
261.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call	RF Marinr® (Steerable Electrode Catheter for intracardiac Ablation) Cardiac Radio-frequency ablation system Catheter Class D Shelf Life: 2 Years Codes: 076514, 076515, 076583, 076584,	The Medtronic RF Marinr Steerable ablation catheter is a flexible, radiopaque catheter constructed of extruded polymer over stainless steel braided. RF Marinr catheter is	**Approved.**

		Box 6001 Villalba, PR USA 00766 (FSC USFDA Valid 12-11-2020)	076585, 076586, 075302, 075312, 075402, 075405, **Rs.50,000/-**	designed for intracardiac radiofrequency ablation via the tip electrode and separate dispersive electrode, when connected to a Medtronic RF Power generator. The RF Marinr catheter may also be used for intracardiac recording or stimulation.	
262.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC USFDAValid 15-08-2020)	Select Secure MRI SureScan Endocardial Pacing Lead Class D Shelf Life: 2 Years Select Secure MRI SureScan Model: 3830 **Rs.50,000/-**	The Model 3830 lead has application where implantable artrial or ventricular, single – chamber or dual chamber pacing systems are indicated. The model 3830 lead is intended for pacing and sensing in the atrium or ventricle.	**Approved.**
263.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA	Compia MRI ™ CRT-D SureScan™ (DTMC2D4) Cardiac Resynchronization therapy implantable defibrillator (MR	Cardiac Resynchorniz ation therapy implantable defibrillator, the device is intended to provide	**Approved.**

		Manufacturing Site: M/s Medtronic Europe S.a.r.l., Route du Molliau 31, Case Postale, 1131 Totochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	conditional) Class D Shelf Life: 18 Months Compia MRI ™ CRT-D SureScan™ DTMC200 **Rs.50,000/-**	ventricular antitachycardia pacing, cardioversion, and defibrillation for automated treatment of life-threatening ventricular tachayarrhhythimias.	
264.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC Valid 12-11-2020)	Soloist® Intracardiac Electrode Catheters Cardiac Mapping Catheter, Percutaneous, single Use. Class D Shelf Life: 2 Years Codes: 44216J, 44216JF, 44516J, 441016JF, 44216U, 44516U, 441016U, 448142J, 448142CL, 44516UB. **Rs.50,000/-**	A Sterile Steerable, Flexible tube containing multiple electrodes that is introduced Percutaneously into the heart chambers in order to transmit electrical impulses for electorphysiological diagnostic examination.	**Approved** subject to provision of Stability data.
265.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacutring Site:** Medtronic, Inc, (Minneapolis, MN 55447) 3800 Annapolis Lane	Medtronic Open Pivot™ Heart Valve Model 505DM (AP 360 Mitral) Mitral Bi-leaflet Mechanical Medtronic Open Pivot™ Heart Valve Model 505DM (AP 360 Mitral) heart valve prosthesis Class D	A Sterile Artificial Susbtitute for natural Mitral heart valve intended to be implanted during open heart surgery typically to treat acquired or congenital valvular disease.	**Approved** subject to provision of Stability data.

		Minneapolis, MN USA55447 (FSC of Netherland 22-2-2020)	Shelf Life: 5 Years Codes: 16, 18, 20mm **Rs.50,000/-**		
266.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC USFDA Valid 12-11-2020)	Torqr™ (Intracardiac Electrode Catheter) Cardiac Mapping Catheter, percutaneous, Single Use Class D Shelf Life: 2 Years (Sizes & Codes as Per FSC) **Rs.50,000/-**	The Medtronic Torqr electrode catheter is a flexible, radiopaque catheter constructed of extruded polyurethane over stainless steel braided and platinum electrodes. The Medtronic torqrcatheter is intended for use in diagnostic electrophysiological procedures. The catheter is designed for recording intracadiac electrograms and temporary pacing associated with electrophysiology studies	**Approved.**
267.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA	CapSureFix Novus MRI™ SureScan™ Class D Shelf Life: 2 Years	The Model 4076 lead is designed to be usdwith a compatible implantable pulse	**Approved** subject to provision of Stability data.

		Manufacturing Site: Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC Valid 15-08-2020)	Codes: CapSureFix Novus MRI™ SureScan™ Models 4076, 5076 **Rs.50,000/-**	generator as a part of a chronic cardiac pacing.	
268.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC Valid 13-02-2020)	Attain Performa S MRI Surescan Coronary venous pacing lead Class D Shelf Life: 2 Years Codes: Model No: 4598-78, 4598-88 **Rs.50,000/-**	The Lead has application as part of a Medtronic Biventricular Pacing system.	**Approved** subject to provision of Stability data.
269.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call	RF Marinr® Unipolar Cardiac Radio-Frequency Ablation System Catheter Class D Shelf Life: 2 Years Code: RF Marinr® Unipolar 075802	A Sterile, Flexible, Steerable Catheter Intended to be used as a part of radio frequency cardiac ablation system to apply radio-frequency alternating current to	**Approved** subject to provision of ISO 13485 of Manufacturing Site.

		Box 6001 Villalba, PR USA 00766 Medtronic Mexico S.de R.L. de CV Av. Paeso Cucapah 10510 EI Lago Tijuana, Baja California Mexico C.P. 22210 (FSC Valid 12-11-2020)	**Rs.50,000/-**	ablate areas of the endocardium of beating heart in the treatment of cardiac arrhythmias	
270.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic Puerto Rico Operations Co., villalba Rd. 149, KM. 56.3 Call Box 6001 Villalba, PR USA 00766 (FSC Valid 15-08-2020)	Sprint Quattro Secure MRI SureScan Endocardial defibrillation lead Class D Shelf Life: 2 Years Model: 6947, 6947 M- **Rs.50,000/-**	The lead is intended for single, long-term use in the right ventricle. This lead has application for patients for whom implantable cardioverter defibrillator (ICDs) are indicated.	**Approved** subject to provision of Stability data of Model 6947.
271.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** Medtronic, Inc.	Percutaneous Lead Introducer Vascular Catheter Introduction Set Class D Shelf Life: 2 Years (Sizes & Codes as Per FSC)	The Medtronic® Introducer Kit is designed to provide a rapid, and relatively atraumatic, method for implanting one or more implantable, endocardial,	**Approved** subject to provision of Stability data.

		8200 Coral Sea Street NE Mounds View, MN USA 55112 (FSC Valid 15-08-2020)	**Rs.50,000/-**	pacemaker leads.	
272.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy Minneapolis, MN USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA **Contract Manufacturer:** Medplast Medical Inc. 620 Watson Sw GR. MI USA 49504 **Contract Manufacturer:** (FSC USFDA valid 08-03-2020)	DLP® Vessel Cannulae Coronary Artery perfusion Catheter Class D Shelf Life: 3 Years Codes as per FSC **Rs.50,000/-**	The vessel cannulae have soft tips and locking female luers. Several model feature on one-way valve that prevents backflow through the cannula. Some models offer a radiopaque body or band. These cannulae are intended for use up to six hours or less in conjunction with cardiopulmonary by pass surgery or In vascular surgery to perfuse a vein graft or to help check for leaks in a harvested vein which will be used for a graft.	**Approved** subject to provision of Stability data.
273.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane	DLP® Aortic Root Cannulae with Vent Line Cardioplegia Cannula	The aortic Root Cannula consists of flexible tubing permanently attached to	**Approved** subject to provision of valid FSC and Stability data.

		Minneapolis, MN USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Manufacturer:** Vention Medical Inc 620 Watson SW GR MI USA **Contract Manufacturer:** Venton Medical Costa Rica, S.A. Parque Zona Franca Metroopolitana Edificio 2c Barreal De Heredia, Heredia Costa Rica. (FSC valid 11-06-2019)	Class D Shelf Life: 3 Years **Codes:** 24009 23009 20009 20012 20012S 20014 20014L 20016 **Rs.50,000/-**	both the inlet and tip. The inlet fitting is a female luer fitting. The introducer is packaged with in the cannula body.	
274.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturing Site:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane	Medtronic Open Pivot ™ Heart Valve 500FA(Standard, Aortic) Aortic bi-leaflet mechanical heart valve prosthesis Model Sizes: 500FA19 19mm 500FA21 21mm 500FA23 23mm 500FA25 25mm	Medtronic Open Pivot ™ Heart Valve (Aortic) Is intended for use as a replacement valve in patients with diseased, damaged, or malfunctioning heart valves. This device	**Approved** subject to provision Stability data.

		Minneapolis, MN USA (FSC valid 21-11-2019)	500FA27 27mm 500FA29 29mm Class D Shelf Life: 5 Years **Rs.50,000/-**	may also be used to replace a previously implanted prosthetic heart valve.	
275.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer/Distributor:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 **Manufacturing site:** Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Contract Manucaturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 **Contract Manufacturer:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa Rica	DLP® Flexible Arch Cannulae Cardiopulmonary Bypass Cannula, Arterial. Class D Shelf Life : 3 Years Size & Codes as per FSC 70420_DLP® Art. Cannula, Flexible Arch, 3/8" Vented Conn., 20 Fr. 70422_DLP® Art. Cannula, Flexible Arch, 3/8" Vented Conn., 22 Fr. 70424_DLP® Art. Cannula, Flexible Arch, 3/8" Vented Conn., 24 Fr. 71420_DLP® Art. Cannula, Flexible Arch, 3/8" Vented Conn., 20 Fr. 71422_DLP® Art. Cannula, Flexible Arch, 3/8" Vented Conn., 22 Fr. 71424_DLP® Art. Cannula, Flexible Arch, 3/8" Vented Conn., 24 Fr.	The Cannula Consist of a curved, angled or beveled tip with or without flange that is permanently attached to a molded , clear, flexible PVC Tapered body or wirewound PVC body. The cannula body features a tip orientation line to indicate direction of the cannula tip during cannulation. **Intended Use :** These Cannulae are intended for use in perfusion of the ascending aorta during short-term Cardiopulmonary bypass. This product is intended for use up to six hours or less.	**Approved** subject to provision Stability data.

		(FSC valid 8-03-2020)	**Rs.50,000/-**		
276.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer/Distributor:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 **Manufacturing site:** Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Contract Manucaturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 **Contract Manufacturer:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa Rica (FSC USFDA valid 08-03-2020)	DLP® Single Stage Venous Cannulae Straight Tip Cardiopulmonary Bypass Cannula, Venous Class D Shelf Life : 3 Years Size & Codes as per FSC **Rs.50,000/-**	**PVC Tip:** These cannula consist of a wire wound PVC body with a clear, thin wall, multiport bullet tip. They are available in straight, right angle, or malleable tip models. **Intended use:** These cannula are intended for collection of venous blood from the right side of the heart via the superior of inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.	**Approved** subject to provision Stability data.

277.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane Minneapolis, MN USA **Manufacturing Site:** Medtronic Fabrication S.A.S. 103 Route D Anor Fourmies, Nord France **Manufacturer/ Distributor:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. (FSC valid 10-0-2021)	Streamline™ Unipolar Temporary Myocardial Pacing Wire External Pacemaker invasive Class D Shelf Life: 2 Years Model: 6494 ,6494F **Rs.50,000/-**	Unipolar Temporary Myocardial Pacing wire is intended for temporary postsurgical atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for single use only.	**Approved** subject to provision Stability data.
278.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane Minneapolis, MN USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Manufacturer:**	DLP® Coronary Artery Retraction Clips Coronary Artery exposure retractor Class D Shelf Life:3 Years Codes: DLP® Coronary Artery Retraction Clips 16130_DLP® Retraction Clip Coronary Artery, 3.0 mm 16150_DLP® Retraction Clip	The Coronary Retraction Clip is indicated for use in patients undergoing coronary artery bypass graft surgery.	**Approved** subject to provision Stability data.

		Medplast Medical Inc 620 Watson SW GR, MI USA **Manufacturer/ Distributor:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa Rica (FSC valid 08-03-2020)	Coronary Artery, 5.0 mm **Rs.50,000/-**		
279.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane Minneapolis, MN USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA Medplast Medical Inc 620 Watson SW GR, MI USA (FSC USFDA valid 08-03-2020)	DLP® Aortic Root Cannula (Cardioplegia Cannula) Class D Shelf Life: 3 Years Codes: 10009 10012 10014 10016 10018 **Rs.50,000/-**	This Cannula is intended for short term use (Six hours or less) in conjunction with cardiopulmonary bypass surgery for delivering cardioplegia solutions. The cannula may also be used to aspirate air from the aorta at the conclusion of the by pass procedure.	**Approved** subject to provision Stability data.
280.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane Minneapolis, MN USA	DLP® Coronary Artery Ostial Cannulae Coronary Sinus Cannula Class D Shelf Life: 3 Years	These Coronary Cannulae Consist of a basket-style-tip, soft (silicone) tip, or spherical tip which is	**Approved** subject to provision Stability data.

		Manufacturer: Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA **Manufacturing Facility:** Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Contractor Manufacturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 **Contract Manufacturer:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa Rica (FSC valid 08-03-2019)	Codes: 30010_DLP® Coronary Cannula, Ostial Perfusion, Basket tip, 10 Fr. 30012_DLP® Coronary Cannula, Ostial Perfusion, Basket tip, 12 Fr. 30014_DLP® Coronary Cannula, Ostial Perfusion, Basket tip, 14 Fr. 30050_DLP® Coronary Cannula, with soft, Concave tip. 30055_DLP® Coronary Cannula, with modified soft tip, Concave tip. **Rs.50,000/-**	attached to a malleable stainless steel tube, or a soft bulb beveled tip with an integral silicone body.	
281.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer/Distributor:**	DLP® Single Stage Venous Cannulae Right Angle Metal Tip Cardiopulmonary Bypass Cannula, Venous Class D Shelf Life: 3 Years	These Cannulae consist of ultrathin wall curved metal tip. The tip is bonded to a transition fitting and a flexible	**Approved** subject to provision Stability data.

		Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 **Manufacturing site:** Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Contract Manucaturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 **Contract Manufacturer:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa Rica (FSC valid 08-03-2020)	Codes: 67312_DLP® Venous Cannula, Right Angle Metal Tip, 1/4" Conn. Site12 Fr. 67314_DLP® Venous Cannula, Right Angle Metal Tip, 1/4" Conn. Site14 Fr. 67316_DLP® Venous Cannula, Right Angle Metal Tip, 1/4" Conn. Site16 Fr. 67318_DLP® Venous Cannula, Right Angle Metal Tip, 1/4" Conn. Site18 Fr. 67320_DLP® Venous Cannula, Right Angle Metal Tip, 1/4" Conn. S0ite 20 Fr **Rs.50,000/-**	wirewound PVC body terminating into a 0.64 cm (1/4 in) or 0.95 cm (3/8 in) connection site. **Indications for use:** These Cannulae are intended for collection of venous blood from the right side of the inferior vena cava during cardiopulmonary bypass surgery up to six hour or less	
282.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. 710medtronic Pkwy Minneapolis, MN USA **Manufacturer:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN	Multiple Perfusion Set Cardioplegia Solution Administration Adaptor Class D Shelf Life: 3 Years **Sizes Codes as per FSC**	The Multiple perfusion sets are intended for use in conjunction with cardiopulmonary bypass surgery for simultaneous perfusion of the aortic root	**Approved** subject to provision Stability data.

		USA **Contract Manufacturer:** Medplast Medical Inc 620 Watson SW GR, MI USA (FSC USFDA valid 08-09-2020)	**Rs.50,000/-**	and 3 or 4 veins grafts.	
283.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane Minneapolis, MN USA (FSC valid 21-11-2019)	Medtronic Open Pivot™ Aortic Heart Valve Graft Aortic bi-leaflet mechanical heart valve prosthesis/ biologic-polymer aorta graft Class D Shelf Life: 5 Years Sizes & codes as Per FSC: Medtronic Open Pivot™ Aortic Heart Valve Graft Model 502AG 502AG21 21mm 502AG23 23mm 502AG25 25mm 502AG27 27mm 502AG29 29mm **Rs.50,000/-**	The AVG is intended for use secondary to a diseased, damaged or malfunctioning aortic valve with aortic aneurysmal or occlusive disease where a replacement valve and replacement or repair of the aorta is required. This device may be used to replace a previously implanted prosthetic heart and conduit.	**Approved** subject to provision Stability data.
284.	-do- **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer:** Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane	Medtronic Open Pivot™ Heart Valve (Mitral) 500Dm Mitral bi-leaflet mechanical heart valve prosthesis Class D Shelf Life: 5 Years Codes:	Medtronic Open Pivot™ Heart Valve (Mitral) intended to use as a replacement valve in patients with diseased, damaged, or malfunctionin	**Approved** subject to provision Stability data.

		Minneapolis, MN USA (FSC valid 21-11-2019)	500DM25 25mm 500DM27 27mm 500DM29 29mm 500DM31 31mm 500DM33 33mm 500DM35 35mm **Rs.50,000/-**	g heart valves. This device may also be used to replace a previously implanted prosthetic heart valve.	
285.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer/Distributor:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 **Manufacturing site:** Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Contract Manucaturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 **Contract Manufacturer:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa	DLP® Left Hear Vent Catheter Cardiopulmonary Bypass Cannula Arterial. Class D Shelf Life: 3 Years Codes: 12008_DLP® 12101_DLP® 12110_DLP® 12113_DLP® 12115_DLP® 12116_DLP® 12118_DLP® 12001_DLP® **Rs.50,000/-**	The PVC Left Heart Vent consists of a flexible plastic tube with perforated distal segment. A small tapered silicone tip is attached to the perorated end to aid in the insertion of the proximal end of the catheter across the mitral valve. Marking rings on the tube indicate insertion depth. Intended use: the catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery.	**Approved.**

		Rica (FSC valid 08-08-2020)			
286.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer/Distributor:** Medtronic Perfusion Systems 7611 Northland Dr Minneapolis, MN USA 55428 **Manufacturing site:** Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210 **Contract Manucaturer:** Vention Medical Inc, 620 Watson SW GR, MI USA 49504 **Contract Manufacturer:** Vention Medical Costa Rica, S.A. Parque Zona Franca Metropolitana Edificio 2C Barreal De Heredia, Costa Rica (FSC USFDA valid	DLP® Single Stage Venous Cannulae Right Angle High Flow Cardiopulmonary Bypass Cannula, Venous Class D Shelf Life: 3 Years Size & Codes as per FSC **Rs.50,000/-**	PVC Tip : These cannulae consist of a wirewound PVC body with a clear, thin wall, multiport bullet tip. They are available in straight, right angle, or malleable tip models. **Indication for use:** These Cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hour or less.	**Approved** subject to provision Stability data.

		08-03-2020)			
287.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands. **Manufacturer:** Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec, H9R 5Z8 Canada (FSC of Netherlands valid 10-08-2020)	Advance Front Arctic Catheter TM 2AF283 Cardiac cryosurgical system Catheter Class D Shelf Life: 2 Years Codes: 2AF283 **Rs.50,000/-**	The Arctic Front advance cardiac CryoAblation Catheter (Artic Front Advance cryoballon) is a flexible , over-the-wire balloon catheter used to ablate cardiac tissue. **Intended Use:** The Arctic Front Advance Cardiac CryoAblation Catheter is indicated for the treatment of patients with atrial fibrillation.	**Approved** subject to provision of valid Full Quality Assurance and stability data.
288.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic, Inc. 710 Medtronic Pkwy. Minneapolis, MN USA. **Manufacturer:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. De CV Av. Paseo Cucapah 10510 EI Lago Tijuana, Baja	Aortic Punch Long Length Handle Aorta punch , single use Class D Shelf Life: 2 Years Codes: Aortic Punch, Long Length Handle Model AP525-APU525 Model AP530-APU530 Model AP535-APU535 Model AP540-	The Medtronic Aortic Punch is a disposable surgical instrument designed to produce a clean, circular opening in the aortic wall to facilitate anastomosis for revascularization.	**Approved.**

		California Mexico C.P. 22210 (FSC USFDA valid 04-03-2020)	APU540 Model AP544-APU544 Model AP548-APU548 Model AP550-APU550 Model AP552-APU552 Model AP556-APU556 Model AP560-APU560 **Rs.50,000/-**		
289.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacutring Site:** Medtronic, Inc, (Minneapolis, MN 55447) 3800 Annapolis Lane Minneapolis, MN USA55447 (FSC Valid 21-11-2019)	Medtronic Open Pivot™ Heart Valve Model 505DA (AP 360 Aortic) Class D Shelf Life: 5 Years Codes: 505DA16 16mm 505DA18 18mm 505DA20 20mm 505DA22 22mm 505DA24 24mm 505DA26 26mm **Rs.50,000/-**	A Sterile artificial Substitute for a natural aortic heart valve intended to be implanted during open heart surgery typically to treat acquired or congenital vascular disease. It consists of two flat, semicircular, pyrolytic carbon coated or polymer leafles that pivot about pyrolytic carbon or metal sturts attach to the valve housing by hinges the hinge point intersect the valve lumen resulting in a total of three openings/	**Approved** subject to provision Stability data.

				When pressurized blood hits the valve, the two halves of the circle fold away from the valve ring and allow blood to flow into the three openings before the valve flaps close again.	
290.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**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)	Ensura DR MRI SureScan Class D Shelf Life: 18 Months Code: END1DR01 **Rs.50,000/-**	Dual Chamber Implantable pacemaker, rate-responsive	**Approved** subject to provision Stability data.
291.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturing Site:** M/s Medtronic Europe S.a.r.l.,	Serena CRT-P MRI SureScan (W1TR05) Cardiac Resynchronization therapy implantable pacemaker Class D Shelf Life: 18 Months	Serena CRT-P MRI SureScan is indicated for any of the following types of heart failure patients: Patients with ventricular dyssynchrony	**Approved** subject to provision Stability data.

		Route du Molliau 31, Case Postale, 1131 Totochenaz, Switzerland (FSC Switzerland Valid Till 06-03-2021)	Code: W1TR05		
292.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Owner Operator/ Legal Manufacturer:** M/s Medtronic Inc., 710 Medtronic Parkway NE, Minneapolis MN 55432, USA **Manufacturer:** M/s Medtronic Ireland, Parkmore Business Park West, Galway, Ireland (FSC Ireland Valid Till27-01-2021)	Integrity Rapid Exchange Coronary Stent System Class D Shelf Life: 4 Years Codes as per FSC	Bare metal Cardiac Stent	**Approved** subject to provision of ISO of Manufacuring site.
293.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Medtronic Inc. 710 Medtronic Pkwy. Minneapolis, MN USA **Manufacturer/ Distributor:** Medtronic Heart Valves Division 1851 East Deere Ave. Santa Ana, CA USA. Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapha 10510 EI lago Tijuana, Baja California Mexico C.P.22210	Simulus™ Flexible Annuloplasty Band Mitral/tricuspad annuloplasty Band Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC)	The Simulus™ Flexible Annuloplasty Ring & Band are indicated for use in patients undergoing surgery for diseased for damaged mitral r tricuspid valves. Simulus™ Flexible Annuloplasty Ring & Band provide support for the mitral or tricuspid	**Approved** saubject to provision of valid FSC and Stability data.

		Medtronic, Inc. (Minneapolis, MN 55447) 3800 Annapolis lane Minneapolis, MN USA (FSC valid 22-06-2019)		annulus and restrict expansion of the annulus.	
294.	M/s HSB, Suite No C-3A, Third Floor, First City Tower, More Samanabad, Lahore. (ELI-00435) **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** M/s. Dongyang Songpu Latex (Jinzhou) Co., Ltd., 1# Industrial District, New and High-tech Development Zone, Jinzhou, Liaoning, China. FSC China Issued on 19.12.2020	**Libido** (Condom) Model: 52±2mm/ 53±2mm/55±2mm Class C Shelf Life: 05 years **Rs.50,000/-**	It will help to prevent unwanted pregnancy, transmission of HIV Infection (AIDS) and many other sexually transmitted diseases.	**Approved** subject to change of brand name and povision of EPSP and Stability studies
295.	M/s. De Khon 11-C, Old FCC, Ferozpur, Road, Gulberg (ELI-00317) **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** VSY Biotechnology BV Strawinskylaan 1143 (1077XX) Amsterdam-the Neherlands. **Manufacturing Site:** VSY Biyoteknoljive Illac Sanayi Anonim Sirketi, Istanbul Tuzla Organize Sanayi Bölgesi, 3 Cadde No:3 Tepeoren Tuzla Istambul Turkey. FSC Netherlands Validity31-01-2021	ACRIVA TRINOVA **Intraocular Lens ACRIVA TRINOVA** Class C Shelf life 3 years **Rs.50,000/-**	It is indicated in cataract due to age as well as other cataract types.	**Approved** subject to provision of ISO for manufacturing site in Turkey and Signed conclusion of stability studies.
296.	-do- **<u>Evaluator:</u>** **Mr. Shahid**	**Legal Manufacturer:** VSY Biotechnology BV Strawinskylaan	**<u>REVISCON</u>** **Intraarticular Viscosupplement**	Reviscon is indicated for the treatment of pain in	**Approved** subject to provision of FQA

	Muhammad Iqbal	1143 (1077XX) Amsterdam-the Neherlands. **Manufacturer Site:** VSY Biyoteknoljive Illac Sanayi Anonim Sirketi, Istanbul Tuzla Organize Sanayi Bölgesi, 3 Cadde No:3 Tepeoren Tuzla Istambul Turkey. FSC Netherlands Validity31-01-2021	**Medical Devices** **Reviscon 1.0%** **Reviscon Plus 1.6%** **Reviscon Mono 2.0%** Class D Shelf Life (Reviscon 1.0% And Reviscon Plus 1.6%) 3 years Reviscon Mono 2.0 %) 2 years **Rs.50,000/-**	osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservastive non pharmacologic therapy and simple analgesics (e.g acetaminophen (Paracetamol) .	Certificate for Reviscon Mono 2.0%and updated stability studies signed and supported by relevant studies.
297.	M/s Sorabjee Patel & Co., 45 Badri Building I.I Chundrigar Road, Karachi (ELI-00067) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Arcadophta Sarl (Fabricant/ Manufacturer) 11, rue Antoine Ricord-31100 Toulouse –France. (FSC of France issuance 04-12-2018)	1. Mono Blue SAfR/ Trypan blue 0.055% 0.75ml Syringe. 2. Mono Blue NafX/ trypan blue 0.25% 0.75ml Syringe. Solution of purified Trypan Blue 0.25% NafX for staining the anterior capsule of the lens & 0.055% SafR for staining the retinal membrane. Class C Shelf Life: 3 Years **Rs.50,000/-**	Mono Blue Nafx/Safr is indicated for use as an aid in ophthalmic surgery by staining the epiretinal membrane and internal lining membrane during the surgical virectomy procedure facilitating the removal of the membrane.	**Approved** as class C medical devices instead of class B.
298.	M/s S.Ejazuddin & Co., PO Box 5629, Zia Plaza, Altaf Hussain Road, Karachi (ELI-00078) **<u>Evaluator:</u>**	**Manufacturer:** M/s Genedrive Diagnostics Ltd., 48 Grafton Street, Manchester M13 9XX, United Kingdom (FSC UK Issuance Date	Genedrive® HCV ID Kit Class D Shelf Life: 375 Days Model: ID –HCV-03 **Rs.50,000/-**	Genedrive® HCV ID Kit is designed for in-vitro diagnostic use to provide qualitative detection of hepatitis C virus (HCV)in	**Approved** subject to provision of Stability data.

	Ms. Hira Bhutto	25-09-2018)		human plasma.	
299.	M/s Excel Corporation, 435 BYJ Society, Bhadurabad, Karachi. (ELI-00110) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** HangZhou Supers Industry Co., Ltd. Taifeng Village, Zhongtai Township. Yuhang District, Hanzhou City, Zhejiang Province, China. (FSC Valid 28-08-2019)	Safety-Inhale Nasal Oxygen Cannula Nasal Oxygen Cannula Class B Shelf Life: 5 Years Codes: Nasal Oxygen Cannula L, M, S, XS, 2014256172 **Rs.25,000/-**	Nasal oxygen cannula, commonly reffered to as oxygen cannulas, is medical devices used to deliver supplemental oxygen to a person that needs oxygen therapy.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of valid FSC**.**
300.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** HangZhou Supers Industry Co., Ltd. Taifeng Village, Zhongtai Township. Yuhang District, Hanzhou City, Zhejiang Province, China. (FSC Valid 28-08-2019)	Safety-Inhale Oxygen Mask Oxygen Mask Class B Shelf Life: 5 Years Codes: Oxygen Masks, Size: XL, L, M ,S 20142560303 **Rs.25,000/-**	Oxygen mask is a medical device that conveys oxygen gas to the patient connected with respiratory System. Oxygen Mask allows higher concentration and rates of flow of oxygen. It can deliver oxygen concentrations from 40 to 60 % at flow rates between 10 to 12 LPM. Intended Use: Oxygen mask is a single use device intended for delivering oxygen gas to	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of valid FSC**.**

				the patient connected with respiratory system.	
301.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** HangZhou Supers Industry Co., Ltd. Taifeng Village, Zhongtai Township. Yuhang District, Hanzhou City, Zhejiang Province, China. (FSC Valid 28-08-2019)	Safety-Inhale Nebulizer Mask Nebulizer Mask Class B Shelf Life: 5 Years (Sizes & Codes as Per FSC) Nebulizer Masks and Nebulizers XL, L, M, S Nebulizer Kit. **Rs.25,000/-**	Nebulizer Mask is the Medical device use for receiving aerosol medications. The nebulizer Mask allows the patient to breathe the aerosol mist in through the nose and mouth to treat the passageways and the lungs directly. Intended Use: Nebulizer Masks in intended for single use only for aerosol inhalation therapy.	**Approved** subject to inspection of manufacturer abroad under Rule 71 of MDR, 2017 and provision of valid FSC**.**
302.	M/s. Novatek Pakistan. P-20 Ist Floor, Chenab Market, Susan Road, Madina Town, Faisalabad. (ELI-00454) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Livetec Ingenieurburo GmbH Marie-Curie-Strabe 8, 79539, Lorrach, Germany. FSC Germany Issued on 30.04.2019	**LivePace T20** (Pace T20) a) PACE T20 + Fixing adaptor for arm and stand + patient cable + needle electrode b) PACE T20 + Fixing adaptor for arm and stand + patient cable + temporary pacing electrode Class C Shelf Life: 7 years	The PACE T20 is an external temporary dual chamber pacemaker for transvenous or myocardial pacing of the heart.	**Approved** subject to provision of Embassy attested free sale certificate**.**

			Rs.50,000/-		
303.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Livetec Ingenieurburo GmbH Marie-Curie-Strabe 8, 79539, Lorrach, Germany. FSC Germany Issued on 30.04.2019	**LivePace T10** (Pace T10) c) PACE T10 + Fixing adaptor for arm and stand + patient cable + needle electrode d) PACE T10 + Fixing adaptor for arm and stand + patient cable + temporary pacing electrode Class C Shelf Life: 7 years service life **Rs.50,000/-**	The PACE T10 is an external temporary single chamber pacemaker for transvenous or myocardial pacing of the heart.	**Approved** subject to provision of Embassy attested free sale certificate.
304.	-do- **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Michigan Instruments, 4717 Talcon Court SE, Grand Rapids, Michigan, USA. FSC USFDA Valid until 21.08.2020	**Life-Stat®** Cardiopulmonary Resuscitator Model: 1008MII Class B Shelf Life: 10 years service life **Rs.25,000/-**	Life-Stat 1008MII is designed to perform CPR on a patient that has stopped breathing in an effort to revive them. It is to be used as a life-saving device.	**Approved** subject to provision of Notarized Full quality assurance certificate, Manufacturing and quality control documents.
305.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera-KPK, Pakistan **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s Boston Scientific Corporation 300, Boston Scientific Way, Marlborough, MA 01752 USA **Manufacturer:** Boston Scientific Corporation 302	**ChoICE™ Guidewire with ICE™ Hydrophilic Coating** Catheter Guidwire Class D Shelf Life: 24Month H74912154011 08714729252467 0.014", 300cm, Straight	The Boston Scientific ChoICE Magnet, Mailman Magnet, Luge Magnet, ChoICE PT Magnet, and PT Graphix Magnet Guidewires are intended to facilitate the placement	**Approved.**

		Parkway, Global Park La Aurora, Heridia Costa Rica. **Distributer:** Boston Scientific Corp., marina Bay Cust. Fullfilment Center 500 Commander Shea Boulevard Quincy, MA USA02171 (FSC USFDA valid till 05-08-2020)	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 H74912160011 08714729252504	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 polytetrafluoroethylene (PTFE) for lubricity. The distal end of the core wire is formed (flattened) to allow for shaping. All models are available with a shapeable Straight Tip or a preformed "J"	

			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 H7491216101J2 08714729177005 0.014", 182cm, J Tip, 5 pk	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	
306.	M/s A.M.	**Legal**	Unicryl M	Unicryl M is	**Approved**

	Distributors, 4th Floor , Plot 37-C, Bukhari Commercial Area Phase VI, D.H.A, Karachi. (ELI-00248) **Evaluator:** **Ms. Hira Bhutto**	**Manufacturer:** United Medical Industires Co. Ltd., Street # 215 3rd Industrial City, Riyadh 11553 Saudi Arabia. (FSC valid 30-07-2022)	Unicryl M(Monofilament Poly (p-dioxanone) Absorbable Surgical Suture) Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC) Unicryl M Poly (p-dioxanone) Absorbable Surgical Suture **Rs.50,000/-**	indicated for use in general soft tissue approximation and/ or ligation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery but not for use in adult cardiovascular, neurological procedures or microsurgery.	subject to provision of notarized credentials of manufacturer, agency agreement, original Embassy attested FSC, EPSP. Board advised to confirm the registration status of same brand of same manufacturer given to M/s Mighty Distributor, Karachi in 2002 from PE&R Division.
307.	M/s A.M. Distributors, 4th Floor , Plot 37-C, Bukhari Commercial Area Phase VI, D.H.A, Karachi. (ELI-00248) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** United Medical Industires Co. Ltd., Street # 215 3rd Industrial City, Riyadh 11553 Saudi Arabia. (FSC Issuance 16-07-2018)	Unipro Unipro (Sterile Use Monofilament Polypropylene Synthetic Non-Absorbable Surgical Suture and Ligatures). Class D Shelf Life: 5 Years (Sizes & Codes as Per FSC) Unipro (Sterile Use Monofilament Polypropylene Synthetic Non-Absorbable Surgical Suture and Ligatures). **Rs.50,000/-**	Unipro suture is indicated for use in general soft tissue approximation and/ or ligation including use in ophthalmic, cardiovascular and neurological / neurosurgical procedures (Excluding brain, meninges and spinal cord.	**Approved** subject to provision of notarized credentials of manufacturer, agency agreement, aoriginal Embassy attested FSC, EPSP.
308.	M/s A.M. Distributors, 4th Floor , Plot 37-C,	**Legal Manufacturer:**	Unicryl Quick Unicryl Quick	Unicryl Quick is a synthetic Quick	**Approved** subject to provision of

	Bukhari Commercial Area Phase VI, D.H.A, Karachi. (ELI-00248) **Evaluator:** **Ms. Hira Bhutto**	United Medical Industires Co. Ltd., Street # 215 3rd Industrial City, Riyadh 11553 Saudi Arabia. (FSC Valid 30-07-2022)	(Braided Coated Polygylcolic acid (fast absorbing) Synthetic Absorbable Surgical Suture) Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC) Unicryl Quick (Braided Coated Polygylcolic acid (fast absorbing) Synthetic Absorbable Surgical Suture **Rs.50,000/-**	absorble surgical sterile suture composed of a homopolymer of Glycolide. The braided is coated with a mixture of olycaprolactone and calcium stearate.	notarized credentials of manufacturer, agency agreement, aoriginal Embassy attested FSC, EPSP.
309.	M/s A.M. Distributors, 4th Floor , Plot 37-C, Bukhari Commercial Area Phase VI, D.H.A, Karachi. (ELI-00248) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** United Medical Industires Co. Ltd., Street # 215 3rd Industrial City, Riyadh 11553 Saudi Arabia. (FSC Valid 30-07-2022)	Unicapron Unicapron (Monofilament Polyglecaprone absorbable Surgical Suture). Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC) Unicapron (Monofilament Polyglecaprone absorbable Surgical Suture). **Rs.50,000/-**	Unicaprone sutrures are indicatd for use in general soft tissue approximation and / or ligation whrer an absorbable material is indicated but not for use in caridvasuclar or neurological tissues, in microsurgery or opthlamic surgery.	**Approved** subject to provision of notarized credentials of manufacturer, agency agreement, aoriginal Embassy attested FSC, EPSP.
310.	M/s A.M. Distributors, 4th Floor , Plot 37-C, Bukhari Commercial Area Phase VI, D.H.A, Karachi. (ELI-00248) **Evaluator:** **Ms. Hira Bhutto**	**Legal Manufacturer:** United Medical Industires Co. Ltd., Street # 215 3rd Industrial City, Riyadh 11553 Saudi Arabia. (FSC Valid 30-07-2022)	Uniglactin Uniglactin (Braided Coated Polyglactin Absorbable Surigical Suture) Class D Shelf Life: 4 Years (Sizes & Codes as Per FSC)	Uniglactin suture is indicated for use in general soft tissue approximation and / or ligatoin including use in ophthalmic procedures, but not for	**Approved** subject to provision of notarized credentials of manufacturer, agency agreement, aoriginal Embassy attested FSC, EPSP.

			Uniglactin (Braided Coated Polyglactin Absorbable Surigical Suture) **Rs.50,000/-**	use in ophthalmic procedures, but not for use in cardiovascular or neurological tissue.	
311.	M/s. Sudais Associates, Sudais House, Street No.7, House No. 1, Khan Bahadur Colony Duran Pur Peshawer. (ELI-00031) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Doctor Japan Co., Ltd., 1-1 Kagurazaka Shinjuku-KU, Tokyo, Japan. **Manufacturing Site:** M/s. Doctor Japan Co., Ltd., Gyoda Factory, 401501, Nagano, Gyoda-City, Saitama 361-0023, Japan. FSC Japan Issued on 25.05.2017	**Dr. J Fine Core** (Disposable Semiautomatic Biopsy Needle) Class B Shelf Life: Years Codes / sizes not mentioned Rs.25,000/-	Disposable Semiautomatic Biopsy Needle	**Approved** subject to provision of ISO-13485, EPSP, FQA and Stability Data.

Item No. XVII. <u>ENLISTMENT OF MEDICAL DEVICES FOR IMPORT.</u>

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:-

Sr. No.	Name and Addresses of Establishment	Manufacture Details	Name of Medical Device with sizes/Class/Shelf Life	Brief Description	Division
1.	M/s Zenith International, Room # 104, Tahir Plaza, A/20, Block 7&8. K.C.H.S.U Karachi. (ELI-0090)	**Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009	PERFECT FINE Disposable Syringe Sterile, Without Needle (60ml) Class –A	Disposable Syringe Sterile, Without Needle (60ml)	**Approved** subject to provision of Stability data.

	Evaluator: **Ms.Hira Bhutto**	Yangzhou Jiangsu, P.R.China (FSC valid till 07-12-2019)	Shelf Life: 5 years		
2.	-do- **Evaluator:** **Ms.Hira Bhutto**	**Manufacturer:** Medicare Instument (WUXI) Ltd. 301 Xinin Road, Xibei, Xishan, Wuxi, China. (FSC China Valid 06-03-2020)	PERFECT FINE (Stethoscope) Model: (MI-3001,MI-3002) Class A Shelf life : Not Applicable	(Stethoscope)	**Approved.**
3.	-do- **Evaluator:** **Ms.Hira Bhutto**	**Manufacturer:** Yangzhou Medline Industry Co., Ltd No. 108, Jinshan Road, Economic Development Zone, 225009 Yangzhou Jiangsu, P.R.China (FSC valid till 07-12-2019)	PERFECT + Disposable Urine Bag, Sterile (2000ml) Class A Shelf Life:5 Years	Disposable Urine Bag, Sterile (2000ml)	**Approved** subject to provision of Stability data.
4.	-do- **Evaluator:** **Ms.Hira Bhutto**	**Legal Manufacturer:** Medicare Intrument (Wuxi) Ltd. No. 301 Xinxin Road, Xibei, Xishan, Wuxi, China. (FSC issuance 06-03-2020)	PERFECT FINE Aneroid Sphygmomanometer Class-A Shelf Life: Not applicable Codes: MI-1001, MI1002, KTJ-20	Aneroid Sphygmomanometer	**Approved.**
5.	M/s Pharma Supply Corporation. 49-J, Block-6, PECHS, Nursery Karachi. (ELI-00092) **Evaluator:**	**Legal Manufacturer:** Shanghai Kinmed Import & Export Co., Ltd. Suit L, 12th Floor, No. 588 Yingkou Road, Shanghai.	Kinmed Urine Bag Class-A Shelf Life: 5 Years Codes: 2000ml, 1000ml,	Kinmed Urine Bag	**Approved** subject to provision of Stability data.

	Ms.Hira Bhutto	(FSC Issuance20-09-2018)	750ml, 100ml		
6.	M/s Sultansons, 133 KutchiGali #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 Till05-02-2020)	Disposable Sterile Syringe (Included Auto-Destruct Type) Class A Shelf Life: 5 Years 60ml	Disposable Syringe without needle sterile	**Approved.**
7.	-do- **Evaluator:** **Ms.Hira Bhutto**	**Legal Manufacturer:** Honsun (Nontong) Co., Ltd. Building 1, No. 8 Tongxing Road, Economic & Technological, Development Area, 226009 Nantong City, Peoples Republic of China. (FSC Valid 06-11-2019)	Titanium Stethoscope Class A Shelf Life: Not Applicable.	Head Stethoscope is common medical device and a n essential tool for doctors. Cardiovascular, can be used to listen to heart rate, heart sounds, vascular murmurs and so on. Blood pressure also require head stethoscope.	**Approved.**
8.	-do- **Evaluator:** **Ms.Hira Bhutto**	**Legal Manufacturer:** Changzhou Zhongyou Medical Device Co., Ltd WugangZhenglu Town, Changzhou City, Jiangsu Prov., China. (FSC Valid till 09-12-2019)	Classic Disposable Urine Bag Sterile Class B Shelf Life : 05 Years Sizes (Size 100ml, 2000ml)	The Urine Bag is used to draw out and collect internal fluids.	**Approved** subject to provision of Stability data.
9.	M/s WasimCo. KutchiGali No.1, Marriott Road Karachi. (ELI-00185) **Evaluator:**	**Legal Manufacturer:** Changzhou Yuandong Medical Equipments Co., Ltd. Sanhekou Street, Chanzhou	Classic Fine Disposable Syringe Sterile Without Needle Class A Shelf Life: 5 Years	Sterile Syringes for Single Use (Without Needle) Is a device which is used to inject, E.g Fluids or medication into the human	**Approved** subject to provision of Stability data.

	Ms.Hira Bhutto	city, 213115 Jiangsu, P.R. China. (FSC Valid 24-12-2024) FSC of Germany issued on 05-06-2019	Size: 50/60 ml	body.	
10.	M/s Briogene Private Limited., 196-A, Sindhi Muslim, Cooperative Housing Society, Shahrah-e-Faisal, Jamshed Town, Karachi (ELI-00015) **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** M/s Qiagen GmbH Qiagen Str. 1, 40724 Hilden, Germany **Manufacturing Site:** M/s Qiagen Sciences LLC 19300 Germantown Road, Germantown, Maryland 20874, USA (FSC Germany Issuance Date 10-01-2019)	Digene® HC2 DNA Collection Device **Digene® HC2 DNA Collection Device 619234** Class A Shelf Life: 36 Months	The Digene HC2 DNA Collection Device is intended for the collection and transport of physician-collected cervical specimens to be tested only with the digene Hybrid Capture® 2 (HC2) HPV and CT/GC DNA Tests and self-collected vaginal specimens to be tested only with the digene HC2 High-Risk HPV DNA Test.	**Approved** subject to provision of ISO 13485 andFull quality assurance.
11.	M/s Essity Pakistan Limited., A/69, SITE Manghopir Road, Karachi (ELI-00011) **<u>Evaluator:</u>** **Mr. Shahid Muhammad Iqbal**	**Legal Manufacturer:** M/s BSN Medical Inc. 5825 Carnegie Blvd., Charlotte, NC 28209, USA **Manufacturing Facility:** M/s BSN Medical SA de CV Av. Parque SN Villa Floride Reynosa, Tamaulipas 88715, Mexico FSC USA Valid Till 09-07-2021	Dynacast Prelude Pre-Cut **Dynacast Prelude Pre-cut Single Layer Ortho Glass II** **47224-00000-03 (10cm x 30cm)** **47227-00000-03 (12.5cm x 65cm)** **47235-00000-03 (12.5cm x 76cm)** Class A Shelf Life: 3 Year	Synthetic Splint	**Approved** subject to provision of Full quality assurance.

12.	M/s Ghazali Brothers, 1st Floor, Azzainab Court Compbell Street, Karachi (ELI-00240) **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** Shenzhen Fitconn Technology Co., Ltd. 7th Floor, No. 116 Xiangshan Road, Luotian Community, Singgang Street, Bao'an, Shenzhen, Guangdong, China. (FSC Issuance 15-4-2019)	Carex Anti –Decubitus Mattress Class A Shelf Life: 1 Year Model: FU-AM001, FU-AM002	The device for the prevention and cure of the bedsore. The product includes two types according to the different bags. Spherical one and long and narrow one. The device skillfully uses the theory of dispersing the pressure of human body to actively prevent and cure the bedsores.	**Approved** subject to provision of Stability data, Manufactu-ring and quality control process and EPSP.
13.	M/s. Ahmad Medix Pvt Ltd., 129/6, Quaid-e-Azam Industrial Estate, Township, Lahore. ELI-00380 **<u>Evaluator:</u>** **Ms. Hira Bhutto**	**Legal Manufacturer:** M/s. Anji Spenq Industrial Co., Ltd., Tangpu Economic Zone, Zhejiang, China. FSC China Issued on 18.06.2019	**Spenq Alcohol Pads** (Alcohol Pads) Box of 100 pieces Class A Shelf Life: 03 years	To clean skin surface prior to injection.	**Approved** subject to provision of Fress sale certificate from China

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